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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, 423, and 478

[HHS-2016-79]

RIN 0991-AC02

Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the procedures that the Department of Health and Human Services (HHS) follows at the Administrative Law Judge (ALJ) level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage (MA) and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. In addition, this final rule revises procedures that the Department of Health and Human Services follows at the Centers for Medicare & Medicaid Services (CMS) and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting the ALJ level.

DATES: These regulations are effective on [Insert date 60 days after the date of publication in the **Federal Register**].

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SUPPLEMENTARY INFORMATION:

Abbreviations

Because we refer to a number of terms by abbreviation or a shortened form in this proposed rule, we are listing these abbreviations and shortened forms, and their corresponding terms in alphabetical order below:

AASIS—ALJ Appeal Status Information System

Act—Social Security Act

ALJ—Administrative Law Judge

APA—Administrative Procedure Act

BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
(Pub. L. 106-554)

CMS—Centers for Medicare & Medicaid Services

Council—Medicare Appeals Council

DAB—Departmental Appeals Board

DME—Durable Medical Equipment

EAJR—Expedited Access to Judicial Review

HHS—U.S. Department of Health and Human Services

IRE—Independent Review Entity

IRMAA—Income Related Monthly Adjustment Amount

MA—Medicare Advantage

MAO—Medicare Advantage Organization

MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173)

OCPM—OMHA Case Processing Manual

OIG—HHS Office of Inspector General

OMHA—Office of Medicare Hearings and Appeals

QIC—Qualified Independent Contractor

QIO—Quality Improvement Organization

SSA—Social Security Administration

VTC—Video-conferencing

Section 1557 of the Affordable Care Act

Independent of the standards in this final rule, the Department commits to complying with section 1557 of the Affordable Care Act, Pub. L. 111-148, 124 Stat. 470 (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. HHS issued a final rule to implement section 1557, *Nondiscrimination in Health Programs and Activities*, on May 18, 2016. 81 FR 31376. The final rule applies, in part, to health programs and activities administered by the Department.

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I. Background

A. Overview of the Appeals Process

In accordance with provisions of sections 1155, 1852, 1860D-4, 1869, and 1876 of the Social Security Act (Act), and associated implementing regulations, there are multiple administrative appeal processes for Medicare fee-for-service (Part A and Part B) claim, entitlement and certain premium initial determinations; MA (Part C) and other competitive health plan organization determinations; and Part D plan sponsor coverage determinations and certain premium determinations. The first, and in many instances a second, level of administrative appeal are administered by Medicare contractors, Part D plan sponsors, MA organizations or Medicare plans, or by the SSA. For example, under section 1869 of the Act, the Medicare claims appeal process involves redeterminations conducted by the Medicare Administrative Contractors (which are independent of the staff that made the initial determination) followed by reconsiderations conducted by Qualified Independent Contractors (QICs). However, all of the appeals discussed in this final rule can be appealed to the ALJs at the

Office of Medicare Hearings and Appeals (OMHA) if the amount in controversy requirement and other requirements are met after these first and/or second levels of appeal.

OMHA, a staff division within the Office of the Secretary of HHS, administers the nationwide ALJ hearing program for Medicare claim, organization and coverage determination, and entitlement and certain premium appeals. If the amount in controversy and other filing requirements are met, a hearing before an ALJ is available following a Quality Improvement Organization (QIO) reconsidered determination under section 1155 of the Act; a Social Security Administration (SSA) or QIC reconsideration, or a request for QIC reconsideration for which a decision is not issued timely and a party requests escalation of the matter under section 1869(b)(1)(A) and (d) of the Act (Part A and Part B appeals); an Independent Review Entity (IRE) reconsideration or QIO reconsidered determination under sections 1876(c)(5)(B) or 1852(g)(5) of the Act (Part C and other managed health plan appeals); or an IRE reconsideration under section 1860D-4(h) of the Act (Part D appeals). In addition, under current regulations a review by an ALJ is available following a dismissal of a request for reconsideration, if the amount in controversy and other filing requirements are met.

OMHA provides Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as applicable plans, Medicare Advantage Organizations (MAOs), and Medicaid State agencies with a fair and impartial forum to address disagreements regarding: Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors; and determinations related to Medicare beneficiary eligibility and entitlement, Part B late enrollment penalties, and income related monthly adjustment amounts (IRMAAs), which apply to Medicare Part B and Part D premiums, made by SSA. Further review of OMHA ALJ decisions, except decisions affirming a dismissal of a

request for reconsideration, is available from the Medicare Appeals Council (Council) within the DAB, a staff division within the Office of the Secretary of HHS. Judicial review is then available for Council decisions in Federal courts, if the amount in controversy and other requirements are met.

OMHA ALJs began adjudicating appeals in July 2005, based on section 931 of the MMA, which required the transfer of responsibility for the ALJ hearing level of the Medicare claim and entitlement appeals process from SSA to HHS. New rules at 42 CFR part 405, subpart I and subpart J were also established to implement statutory changes to the Medicare fee-for-service (Part A and Part B) appeals process made by BIPA in 2000 and the MMA in 2003. Among other things, these new rules addressed appeals of reconsiderations made by QICs, which were created by BIPA for the Part A and Part B programs. These rules also apply to appeals of SSA reconsiderations. The statutory changes made by BIPA included a 90-day adjudication time frame for ALJs to adjudicate appeals of QIC reconsiderations beginning on the date that a request for an ALJ hearing is timely filed. The new part 405, subpart I rules were initially proposed in the November 15, 2002 Federal Register (67 FR 69312) (2002 Proposed Rule) to implement BIPA, and were subsequently implemented in an interim final rule with comment period, which also set forth new provisions to implement the MMA, in the March 8, 2005 Federal Register (70 FR 11420) (2005 Interim Final Rule). Correcting amendments to the 2005 Interim Final Rule were published in the June 30, 2005 Federal Register (70 FR 37700) (2005 Correcting Amendment I) and in the August 26, 2005 Federal Register (70 FR 50214) (2005 Correcting Amendment II), and the final rule was published in the December 9, 2009 Federal Register (74 FR 65296) (2009 Final Rule). Subsequent revisions to part 405, subpart I to implement the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act, Pub.

L. 112-242) were published in the February 27, 2015 Federal Register (80 FR 10611) (SMART Act Final Rule).

In addition to the part 405, subpart I rules, OMHA applies the rules at 42 CFR part 478, subpart B to individuals' appeals of QIO reconsidered determinations; part 422, subpart M to appeals of IRE reconsiderations or QIO reconsidered determinations under the MA (Part C) and other competitive health plan programs; and part 423, subpart U to appeals of IRE reconsiderations under the Medicare prescription drug (Part D) program.

B. Recent Workload Challenges

In recent years, the Medicare appeals process has experienced an unprecedented and sustained increase in the number of appeals. At OMHA, for example, the number of requests for an ALJ hearing or review increased 1,222 percent, from fiscal year (FY) 2009 through FY 2014. We attribute the growth in appeals to: (1) the expanding Medicare beneficiary population¹ and utilization of services across that population; (2) enhanced monitoring of payment accuracy in the Medicare Part A and Part B (fee-for-service) programs; (3) growth in appeals from State Medicaid agencies² for beneficiaries dually enrolled in both Medicare and Medicaid; and (4) national implementation of the Medicare fee-for-service Recovery Audit program³ in 2009. The increasing number of requests has strained OMHA's available resources and resulted in delays for appellants to obtain hearings and decisions.

¹ Enrollment in fee-for-service Medicare and MA and other competitive health plans increased from roughly 49 million beneficiaries and enrollees in 2011 to 55.5 million in 2015, while enrollment in Part D prescription drug plans and MA prescription drug plans increased from roughly 29.5 million in 2011 to 39.5 million in 2015 (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>).

² In FY 2009, OMHA received 230 requests for hearing filed by Medicaid State agencies, compared to nearly 25,000 in FY 2014.

³ As of April 25, 2016, Recovery Audit-related appeals accounted for 31 percent of the pending appeals at OMHA. Based on trends in receipts at this time, we estimate that Recovery Audit related appeals currently constitute 20 percent of incoming appeals.

Despite significant gains in OMHA ALJ productivity (in FY 2014, each OMHA ALJ issued, on average, a record 1,048 decisions and an additional 456 dismissals, compared to an average of 471 decisions and 80 dismissals per ALJ in 2009), and CMS and OMHA initiatives to address the increasing number of appeals⁴, the number of requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals continue to exceed OMHA's capacity to adjudicate the requests. As of September 30, 2016, OMHA had over 650,000 pending appeals, while OMHA's adjudication capacity—based on a maximum sustainable capacity of 1,000 appeals per ALJ team—was approximately 92,000 appeals per year.

HHS has a three-prong approach to addressing the increasing number of appeals and the current backlog of claims waiting to be adjudicated at OMHA: (1) request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; (2) take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog ; and (3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals. In this final rule, HHS is pursuing the three-prong approach by implementing rules that expand the pool of available OMHA adjudicators and improve the efficiency of the appeals process by streamlining the processes so less time is spent by adjudicators and parties on repetitive issues and procedural matters. In particular, we believe the proposals we are finalizing in section II.A.2 below to provide authority for attorneys to issue decisions when a decision can be issued without an ALJ hearing, dismissals when an appellant withdraws his or her request for an ALJ hearing, remands as provided in §§405.1056 and 423.2056 as finalized in this rule or at the direction of the Council, and reviews of QIC and IRE dismissals, could redirect

⁴ CMS and OMHA initiatives include OMHA's Settlement Conference Facilitation and Statistical Sampling Initiative; and CMS's QIC formal telephone discussion demonstration and increased use of prior authorization models for areas with high payment error rates.

approximately 24,500 appeals per year to attorney adjudicators, who would be able to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload (see section VI below for more details regarding our estimate).

II. Summary of the Proposed Provisions and Responses to Comments on the July 5, 2016, Proposed Rule

In the July 5, 2016 Federal Register, we published a proposed rule that would revise the procedures that the Department of Health and Human Services would follow at the ALJ level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in MA and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. 81 FR 43790. In addition, we proposed to revise procedures that the Department of Health and Human Services would follow at the CMS and the Council levels of appeal for certain matters affecting the ALJ level. Discussed below are the comments to the July 5, 2016, proposed rule. We include a summary and explanation of each proposed regulatory provision, provide a summary of, and responses to, the comments received, and describe the changes, if any, to be made in finalizing the provision in this rulemaking.

We received 68 timely comments on the proposed rule from individuals, organizations representing providers and suppliers, beneficiary advocacy groups, law offices, health plans, CMS contractors, and others. Summaries of the public comments and our responses to those comments are set forth below.

A. General Provisions of the Proposed Regulations

1. Precedential Final Decisions of the Secretary

Council decisions are binding on the parties to that particular appeal and are the final decisions of the Secretary from which judicial review may be sought under section 205(g) of the Act, in accordance with current §§405.1130, 422.612(b), 423.2130, and 478.46(b). As explained in the 2009 Final Rule (74 FR 65307 through 65308), “binding” indicates the parties are obligated to abide by the adjudicator’s action or decision unless further recourse is available and a party exercises that right. “Final” indicates that no further administrative review of the decision is available and judicial review may be immediately sought.

In 1999, the HHS Office of Inspector General (OIG) issued a report entitled “Medicare Administrative Appeals – ALJ Hearing Process” (OEI-04-97-00160) (Sept. 1999) (<http://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf>). In that report, the OIG noted that the DAB respondents voiced strong interest in having precedent setting authority in the Medicare administrative appeals process “to clean-up inconsistencies in the appeals process.” The OIG recommended that such a case precedent system be established.

Pursuant to section 931(a) of the MMA, HHS and SSA developed a plan for the transition of the ALJ hearing function for some types of Medicare appeals from SSA to HHS, and addressed the feasibility of precedential authority of DAB decisions. See *Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals* (Mar. 2004) (https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf). HHS determined that at that time, it was not feasible or appropriate to confer precedential authority on Council decisions, but indicated that it would reevaluate the merits of granting precedential authority to some or all Council decisions after the BIPA and MMA changes to the appeals process were fully implemented.

BIPA and MMA changes to the appeals process have now been fully implemented and we stated in the proposed rule that we believed it was appropriate to propose that select Council decisions be made precedential to increase consistency in decisions at all levels of appeal for appellants. We proposed in proposed §401.109 to introduce precedential authority to the Medicare claim and entitlement appeals process under part 405, subpart I for Medicare fee-for-service (Part A and Part B) appeals; part 422, subpart M for appeals of organization determinations issued by MA and other competitive health plans (Part C appeals); part 423, subparts M and U for appeals of Part D prescription drug coverage determinations; and part 478, subpart B for appeals of certain QIO determinations. 81 FR 43790, 43792–43794. We proposed in §401.109(a) that the Chair of the DAB would have authority to designate a final decision of the Secretary issued by the Council as precedential. In the proposed rule we stated that we believed this would provide appellants with a consistent body of final decisions of the Secretary upon which they could determine whether to seek appeals. We also stated it would assist appeal adjudicators at all levels of appeal by providing clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions. Further, we stated that in the limited circumstances in which a precedential decision would apply to a factual question, the decision would be binding where the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the Council issued the precedential final decision.

We stated in the proposed rule that it is appropriate for the DAB Chair to have the role of designating select Council decisions as precedential. The DAB Chair leads the DAB, which was established in 1973. The DAB has wide jurisdiction over disputes arising under many HHS programs and components, and has issued precedential decisions for many years within several

of its areas of jurisdiction. (Examples of DAB jurisdiction may be found at 45 CFR part 16, 42 CFR part 498, 42 CFR part 426, and on the DAB's website at www.hhs.gov/dab.) The Council has been housed within the DAB as an organization since 1995 and is itself also under the leadership of the DAB Chair. Thus, we stated that the DAB Chair brings both expertise in the Medicare claims appeals over which the Council has jurisdiction and experience from the DAB's precedential cases to carrying out the role of designating Council decisions to be precedential. Moreover, we stated in the proposed rule that having the designation performed by the DAB Chair respects the continued independence of the Council as an adjudicative body by allowing the DAB to determine the effect of its own decisions. We also stated that limiting binding precedential effect to selected decisions provides the necessary discretion to designate as precedential those Council decisions in which a significant legal or factual issue was fully developed on the record and thoroughly analyzed. We further stated that designation might not be appropriate where an issue was mentioned in the decision as relevant but was not outcome determinative, and therefore may not have been as fully developed as is necessary for precedential decisions or where the issues addressed are not likely to have broad application beyond the particular case.

To help ensure appellants and other stakeholders are aware of Council decisions that are designated as precedential, we proposed in §401.109(b) that notice of precedential decisions would be published in the Federal Register, and the decisions themselves would be made available to the public, with necessary precautions taken to remove personally identifiable information that cannot be disclosed without an individual's consent. We stated that designated precedents would be posted on an accessible website maintained by HHS, and that decisions of

the Council would bind all lower-level decision-makers from the date that the decisions are posted on the HHS website.

We proposed in §401.109(c) to make these precedential decisions binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on SSA to the extent that SSA components adjudicate matters under the jurisdiction of CMS, in the same manner as CMS Rulings under current §401.108. That means the precedential decision would be binding on CMS and its contractors in making initial determinations, redeterminations, and reconsiderations, under part 405 subpart I, or equivalent determinations under parts 422 subpart M, 423 subparts M and U, and 478 subpart B; OMHA ALJs and, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 below), attorney adjudicators; the Council in its future decisions; and SSA to the extent that it adjudicates matters under the jurisdiction of CMS. Individual determinations and decisions by CMS contractors, OMHA ALJs, and the Council currently are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals. We did not propose to change the non-precedential status and non-binding effect on future initial determinations (and equivalent determinations) or claim appeals of any determinations or decisions except as to Council decisions designated as precedential by the DAB Chair.

We proposed to specify the scope of the precedential effect of a Council decision designated by the DAB Chair in §401.109(d). Specifically, we proposed that the Council's legal analysis and interpretation of an authority or provision that is binding (see, for example §§405.1060 and 405.1063) or owed substantial deference (see, for example §405.1062) would be binding in future determinations and appeals in which the same authority or provision is applied and is still in effect. However, we proposed that if CMS revises the authority or provision that is

the subject of a precedential decision, the Council's legal analysis and interpretation would not be binding on claims or other disputes to which the revised authority or provision applies. For example, if a Council decision designated as precedential by the DAB Chair interprets a CMS manual instruction, that interpretation would be binding on pending and future appeals and initial determinations to which that manual instruction applies. However, CMS would be free to follow its normal internal process to revise the manual instruction at issue. Once the revised instruction is issued through the CMS process, the revised instruction would apply to making initial determinations on all claims thereafter. We stated that this would help ensure that CMS continues to have the ultimate authority to administer the Medicare program and promulgate regulations, and issue sub-regulatory guidance and policies on Medicare coverage and payment.

If the decision is designated as precedential by the DAB Chair, we proposed in §401.109(d) that the Council's findings of fact would be binding in future determinations and appeals that involve the same parties and evidence. For example, we stated in the proposed rule that if a precedential Council decision made findings of fact related to the issue of whether an item qualified as durable medical equipment (DME) and the same issue was in dispute in another appeal filed by the same party, and that party submitted the same evidence to support its assertion, the findings of fact in the precedential Council decision would be binding. However, we noted that many claim appeals turn on evidence of a beneficiary's condition or care at the time discrete items or services are furnished, and that therefore §401.109, as proposed, is unlikely to apply to findings of fact in these appeals.

In addition, consistent with §401.109, we proposed at §405.968(b)(1) to add precedential decisions designated by the Chair of the Departmental Appeals Board (DAB) as an authority that is binding on the QIC. We also proposed at §§405.1063 and 423.2063, which currently cover the

applicability of laws, regulations, and CMS Rulings, to add new paragraph (c) to the sections to provide that precedential decisions designated by the DAB Chair in accordance with §401.109 are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and (in §405.1063(c)) on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. Finally, we proposed to add precedential decisions to the titles of §§405.1063 and 423.2063 to reflect the additional topic covered by proposed paragraph (c).

We received forty-eight comments on this proposal. In two instances, the same commenter submitted the same comment twice, so there were forty-six distinct comments. Among those offering comments were providers and suppliers and organizations representing them, beneficiary advocacy groups, health plan providers and administrators, and individuals. Overall, the majority of commenters supported the proposal to designate certain Council cases as precedent, but some of them made requests for clarification or modification, which we address below. Twelve commenters either opposed the proposal or suggested that it be tabled for further review. Some commenters did not take a clear position in favor of or against adoption of the proposal but offered various comments which we address below. Provided below are summaries of the specific comments received and responses to these comments:

Comment: Numerous commenters raised concerns regarding the lack of specific standards or criteria for selecting precedential decisions. One commenter suggested that the Council should adopt the standards currently used by federal circuit courts for designating precedential decisions. Two commenters requested clarity on the precedential effect of factual findings. One further opined that factual statements should never be given precedential effect because the Council is not a fact finding institution and because facts change over time. One

commenter suggested that only decisions fully favorable to beneficiaries should be designated as precedential. Two commenters suggested that all Council decisions involving legal analysis or interpretations of authority should have precedential force, and others suggested that in addition to granting precedential authority to the Council, the rule should require MACs and QICs to treat prior ALJ decisions as precedential.

Response: We appreciate the commenters' concern about additional clarity as to how decisions will be selected to have precedential effect. As explained above, the purpose of §401.109 is to increase predictability and consistency in decision-making throughout the appeals process, and to provide clear direction on repetitive legal and policy questions. We believe that designating certain decisions as precedential, and therefore binding on all lower levels of review, will help ensure that appellants and other stakeholders are provided a more predictable outcome at all stages of review. In addition, selecting certain decisions as precedential helps to ensure that similar cases receive consistent results.

We understand commenters' concern that stakeholders understand the considerations that will guide designation of precedential Council decisions. However, given that the variety of issues that may arise in the interpretation and application of Medicare law and policy is broad and changes rapidly, it is not practicable to articulate a comprehensive set of criteria that the DAB Chair must follow to determine which decisions are appropriate for such designation. We can, however, identify some factors that the DAB Chair may consider when determining whether to designate a decision as precedential. The primary goal is to identify Council decisions involving issues of wide applicability where designation as precedent is likely to materially contribute to improving predictability and consistency in decisions prospectively. For example, decisions that address recurring legal issues, or interpret or clarify an existing law, CMS rule or

policy, may be appropriately designated as precedential. In addition, the DAB Chair may also consider whether a decision has general application to a broad number of cases. Another factor the DAB Chair may consider is whether a decision analyzes or interprets a legal issue of general public interest. Before designating a decision as precedential, the DAB Chair may also take into consideration the state of the record developed at the lower levels of review. Records where the facts are fully developed and analyzed, or where legal arguments have been fully raised and argued are better candidates for precedential designation.

In response to the commenter's suggestion that the Council should adopt standards currently used by federal circuit courts for designating precedential decisions, we do not believe federal court standards provide the best model for criteria transferable to this internal agency administrative adjudication process. As a threshold matter, each federal circuit court establishes its own standards for designating precedent, so there is no uniform circuit court rule the Council can simply adopt. Moreover, there are substantial differences between the Medicare appeals system and the federal court system, and many factors considered by federal circuit courts in designating precedential decisions have no application in the Medicare appeals context. For example, many federal circuit courts will designate a decision as precedential if it establishes a rule of law within the circuit or creates a conflict with another circuit. Such criteria would not be applicable or helpful for the Council to consider because the Medicare appeals process is not divided into circuits. It is worth noting, however, that the factors identified in the preceding paragraph are similar to some of the factors federal circuit courts typically consider in designating precedent.

In regards to the effect of factual findings in precedential decisions, the Council's legal analysis and interpretation in a decision is applied in a specific factual context, as is also true

with court decisions. That analysis and interpretation in a decision designated as precedential must be applied by decision-makers at lower levels in future cases in which the same authority or provision applies and is still in effect. If the same authority or provision would not apply in a future case because the relevant facts are not the same, the precedential decision also would not be applicable in the future case. Moreover, if CMS issues new regulatory provisions or revised policies, a precedential decision analyzing and interpreting the prior regulations or policies may not apply on review of a coverage decision made under the new regulation or policy if the relevant content of the new regulation or policy is different from that interpreted in the precedential decision.

We understand the commenters may be concerned that proposed §401.109(d)(2) authorizes the establishment of generally applicable “factual precedent.” That proposed section, however, provides that factual findings in precedential decisions are binding only in future determinations and appeals involving the same parties, facts, and circumstances. The purpose of this provision is to discourage parties to a precedential decision from subsequently filing repetitive appeals involving the same facts in an effort to get a “second bite at the apple.” It does not mean factual findings in a precedential decision would be binding in future claims involving different facts, parties, or circumstances.

We also disagree with the assertion that the Council is not a fact-finding institution. The Council’s review is de novo and based on review of the entire administrative record as compiled through the OMHA level of appeal, including review of the hearing if one was conducted, as well as all additional admissible evidence and briefings submitted to the Council. Accordingly, Council decisions properly include factual findings and, as stated above, adjudicators will take into consideration relevant factual changes when determining whether a precedential decision

should apply. We disagree with the suggestion that the DAB Chair should limit the pool of precedential decisions to only those that are favorable to the beneficiary. We do not believe the DAB should take into consideration to which party the decision was favorable when designating a decision as precedential. To do so would insert bias into the selection process, which goes against the DAB's mission to provide impartial and independent review. We also disagree with the suggestion that all Council decisions involving legal analysis or interpretations of authority should have precedential effect. We understand the commenter's suggestion in this regard is to ensure consistency in the types of decisions that are designated as precedential. However, many Council decisions turn on the resolution of specific disputes of fact or on issues too unusual to have applicability or usefulness in other cases. As such, in those instances, the legal analyses or interpretations will not have widespread applicability or usefulness. We also decline to require MACs and QICs to treat prior ALJ decisions as precedential. Although there are limited circumstances where an ALJ decision may become a final decision, it is the role of the Council to issue final decisions on behalf of the Secretary. Those decisions of the Council designated as precedent will be binding on cases to which they are applicable at all lower levels of the agency adjudication process nationwide. We do not believe it would be appropriate for the decision of a single ALJ to establish precedent affecting parties nationwide without having been subject to review by the Council. Moreover, because ALJs would not be bound by each other's decisions, the decision of a MAC or QIC issued in compliance with one ALJ's decision might be reversed by a different ALJ. Therefore, making individual ALJ decisions precedential and binding on MACs and QICs would not necessarily serve the goal of increasing predictability and consistency.

Based on comments received and for the reasons we set forth, we are adding the following language to the final regulation at §401.109(a) to include general criteria the DAB Chair may consider when selecting a Council decision as precedential, “In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.”

Comment: Several commenters questioned the provision granting the DAB Chair sole authority to designate decisions as precedential, or suggested that the designation process should include input from other sources, including providers, contractors, stakeholders, CMS, and OMHA. One commenter expressed concern that the DAB Chair as an agency employee may be biased against appellants. Other commenters felt the rule should provide a mechanism for appellants, advocates, and stakeholders to request that specific decisions be deemed precedential. In a similar vein, some commenters felt that the rule should include procedures for challenging and overturning precedent. Some commenters suggested that these procedures should include granting appellants the right to seek judicial review after a decision is deemed precedential. A few commenters expressed concern that the rule contains no time frames for designating and applying precedential decisions.

Response: We disagree that it is inappropriate for the DAB Chair to have the sole authority to designate certain Council decisions as precedential. The Council is an adjudicatory and deliberative body comprised of the DAB Chair, Administrative Appeals Judges and Appeals Officers and is independent of the agency’s operating divisions. To involve others, whether components of the agency or outside parties, in the designation process would undermine the independence of the Council. Any influence on the Council’s legal interpretation or analysis

outside the record and arguments developed within the scope of a case is inappropriate. Moreover, the DAB Chair, as a member of the Council, has the expertise and experience to determine which decisions should be designated as precedential because they will provide improved predictability and consistency across future cases. We also note here the designation of a decision as precedential does not create a new law or policy. By designating decisions as precedential, the DAB Chair is merely providing for consistent legal interpretation and analysis of CMS's existing laws, rule and policies. The contention that the DAB Chair as an "agency employee" may create a body of law that is more favorable to HHS is unsupported. The mission of the DAB is to provide impartial, independent review of disputed decisions in a wide range of HHS programs under more than 60 statutory provisions. The DAB Chair will continue to advance that mission when designating precedential Council decisions.

To the extent that appellants or CMS or its contractors believe that a case may result in a decision that should be considered precedential, then the parties are free to argue so in their appeal requests or own motion referrals. In addition, the Council routinely permits parties to file briefs and other written statements pursuant to 42 CFR §405.1120, which constitutes an appropriate mechanism by which parties could argue the potential precedential status of a decision. Filing a brief in a case would also aid in the fuller development and analysis of legal issues, which may make the resulting decision a better candidate for precedential designation.

The regulations provide recourse to those appellants who do not agree with a Council's decision—judicial review. Appellants who disagree with the Council's legal interpretation or analysis in a decision may appeal the decision to federal district court in accordance with §405.1136, regardless of whether the decision is designated as precedential. CMS also has recourse if it disagrees with a precedential decision. If CMS disagrees with the Council's legal

interpretation and analysis of CMS's policy or rule, then CMS may change the policy or rule, or issue a later clarification or ruling. Given these existing mechanisms by which parties may challenge decisions on the merits or by which CMS may prospectively change policies, we do not believe it is necessary to include appeal rights or other procedures specific to challenging the designation of particular decisions as precedential.

We also decline to specify a timeframe in which the DAB Chair must designate a decision as precedential because resource and procedural constraints may limit how quickly the designation process may be completed. We do anticipate, however, that the DAB Chair will generally make the designation within a reasonable amount of time after the issuance of the decision, though as noted below, the DAB Chair may choose to wait to designate certain decisions as precedent until the time to file a request for judicial review expires. We also expect publication of the decision in the Federal Register to be done around the same time as a precedential decision is identified on the HHS website in order to provide public notice.

Comment: We received several comments requesting clarification on the effects of Council decisions designated as precedential. Two commenters sought clarification as to how findings made in precedential decisions should be used in the context of Medicare Part C and D appeals, and asked whether MAOs and Part D plan sponsors will be held accountable to these findings from an oversight perspective. One commenter sought clarification as to whether the Council will designate as precedential decisions relating to pre-service and copayment issues. Other commenters requested clarification on the effect of federal district court decisions that reverse Council decisions designated as precedential. One commenter further opined that because of the possibility of precedential decisions being overturned on judicial review, it is inappropriate to make Council decisions precedential. A few commenters also suggested that the

rule should include procedures for reversing claim denials resulting from subsequently overturned precedent. One commenter requested clarification as to whether a party whose appeal is denied based on a precedential decision must proceed through the full appeals process prior to seeking judicial review of the denial.

Response: We understand the desire for clarification on the effects of precedential decisions. To the extent the commenters are seeking clarification as to whether Part C and D plans will be required to determine the applicability of precedential decisions when adjudicating future cases, we clarify that §401.109, as finalized, applies to all Medicare parts. As previously stated, the legal analysis and interpretation of a Medicare authority or provision in a decision designated as precedential must be applied by decision-makers at lower levels in future cases in which the same authority or provision applies and is still in effect. If the commenters seek clarification on whether Part C and D plans will be subject to additional oversight by CMS related to the application of precedential decisions, after the rule is finalized CMS will evaluate the extent to which the application of precedential decisions will require modification to existing plan oversight processes. In regards to whether Council decisions related to pre-service and copayment issues will be designated as precedential, we have outlined the factors the DAB Chair may consider when designating a precedential decision in the final regulation at §401.109(a). With regard to the effect of a federal court decision that reverses a particular Council decision designated as precedential, the individual case would no longer be binding on the parties and would no longer serve as precedent. In order to ensure that this situation rarely arises, however, the DAB Chair may choose to wait to designate certain decisions as precedent until the time for appeal expires or until a federal court renders a final, unreviewable, decision on judicial review. Although we recognize the possibility that a Council decision designated as precedential may

later be reversed, we do not agree that it is therefore inappropriate to designate certain decisions as precedential. The proposed structure is similar to the federal court system, where a federal circuit court's decision may be given precedential effect even though it ultimately may be reversed by the United States Supreme Court.

We also recognize the possibility that an appellant may seek judicial review of a later case applying the precedential decision. If a federal court reverses a later case applying a precedential Council decision, then the effect of the court's ruling on the original precedential decision will depend on many factors, including the court's basis for reversal, whether the court remands to the Council, whether the court's decision itself is non-precedential or non-published, and whether other federal courts have issued conflicting decisions. For example, a finding by the court that the precedent was misapplied to the later case might have a different impact than a finding that the rationale underlying the precedent was erroneous. Due to the many different possibilities, we do not believe we can address in advance the possible effects of federal court decisions on later cases applying precedential Council decisions.

For the same reasons, we also do not find it appropriate to create new procedures for reversing claim denials resulting from subsequently overturned precedent. We do note, however, that the existing appeals process permits some of the relief sought. If a party believes that a denial is based on overturned precedent, then it is free to appeal the denial and make that argument before the adjudicator.

If a party believes that its claim has been inappropriately denied because of the application of a precedential decision, the party must still exhaust the administrative appeals process as statutorily required under sections 1869 and 205 of the Act. We are without authority in this rulemaking to waive statutory requirements.

Comment: Some commenters expressed concerns that the proposal undermines ALJ independence and one commenter expressed concern that granting precedential authority to the Council will impose greater limits on the scope of ALJ reviews than currently exist.

Response: We disagree that the proposed rule impedes ALJ independence. ALJs, as well as the Council, are required to apply the laws and regulations pertaining to the Medicare and Medicaid programs as well as CMS rulings published under the authority of the CMS Administrator, regardless of whether a decision is designated as precedential (see §405.1063). Council decisions do not create new laws or policies, but instead interpret CMS's existing laws, regulations and rulings and determine how they apply to specified circumstances. An ALJ remains free to determine whether and how the relevant authority as interpreted by the Council applies in the context of a specific case.

Comment: Many commenters voiced general support for the proposal, but indicated contractors, providers, and suppliers need to be adequately trained and educated regarding the proper application of precedential decisions. A few commenters suggested that MACs and QICs should be provided with summaries of each precedential decision explaining how the decision may be applied to future claims. A few commenters sought clarification as to whether precedential decisions will be treated as supplemental to CMS manuals and guidelines. A few commenters also requested that all OMHA and Council decisions be made publicly available, even if non-precedential. One commenter suggested that precedential decisions should be posted on the Council's website and should only apply to claims decided after the posting date.

Response: We thank the commenters for their support. As we stated in the proposed rule, in addition to publishing decisions designated as precedential in the Federal Register, precedential decisions will be posted on an accessible HHS website and a precedential decision

would be binding from the date posted. As regards the request that all OMHA and Council decisions be made publicly available (even if not precedential), we note that implementing this suggestion to publish the high volume of decisions issued at both the OMHA and Council levels would require extensive additional resources.

We agree that it is important for CMS, its contractors, providers, beneficiaries and other stakeholders to be educated on the existence of precedential decisions and their effects on pending appeals. In order to promote consistency, CMS, OMHA and the Council have participated in joint training sessions for the past several years. We anticipate including training sessions on precedential decisions as an effective means of educating all levels of adjudicators. In addition, education sessions may also be appropriate during forums where the public participates, such as the OMHA Appellant Forum. We find it inadvisable, however, to require the Council to provide to MACs and QICs summaries of each precedential decision discussing the precedential effect of a decision and how it should be applied to future cases. The precedent arises from the Council decision itself, and creating separate summaries risks possible ambiguity or misunderstanding. While lower levels of review are bound by a legal interpretation or analysis, or certain factual findings, stated in a Council decision that has been designated as precedential, it is outside the Council's jurisdiction to instruct the review of lower-level adjudicators in cases not before the Council.

As we have noted, Council precedents do not create new law or policy and therefore do not "supplement" manuals or guidelines but may analyze, interpret, and apply them.

Comment: One commenter felt the proposal will not effectively reduce the backlog because it will take a significant amount of time to establish a meaningful body of precedential decisions.

Response: We acknowledge that it will take time to establish a body of precedential decisions addressing enough issues to meaningfully impact the backlog. Nevertheless, we believe that establishing precedential decisions will allow for more predictable and consistent outcomes at all levels of administrative review. Moreover, we anticipate that designating certain Council decisions as precedential will help parties better determine the likelihood of success on appeal and assist parties in making decisions regarding whether to pursue administrative appeal of their cases.

After review and consideration of the comments received, and for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.968, 405.1063, and 423.2063 as proposed without modification, and are finalizing §401.109 with the following modification. As discussed above, we are adding the following language to §401.109(a) to include the general factors the DAB Chair may consider when selecting a Council decision as precedential: “In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.”

2. Attorney Adjudicators

As described below, we proposed changes to provide authority for attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, to remand appeals as provided in §§405.1056 and 423.2056 or at the direction of the Council, and to conduct reviews of QIC and IRE dismissals. 81 FR 43790, 43794–43795. Sections 1155, 1852(g)(5), 1860D-4(h), 1869(b)(1)(A), and 1876(c)(5)(B) of the Act provide a

right to a hearing to the same extent as provided in section 205(b) by the HHS Secretary for certain appealable decisions by Medicare contractors or SSA, when the amount in controversy and other filing requirements are met. Hearings under these statutory provisions are conducted by OMHA ALJs with delegated authority from the HHS Secretary, in accordance with these sections and the APA.

Under current §§405.1038 and 423.2038, OMHA ALJs are also responsible for a portion of the appeals workload that does not require a hearing because a request for an ALJ hearing may also be addressed without conducting a hearing. For example, under §§405.1038 and 423.2038, if the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue, or if all parties agree in writing that they do not wish to appear before the ALJ at a hearing, the ALJ may issue a decision on the record without holding a hearing. Under current §§405.1052(a)(1) and 423.2052(a)(1), OMHA ALJs must also address a large number of requests to withdraw requests for ALJ hearings, which appellants often file pursuant to litigation settlements, law enforcement actions, and administrative agreements in which they agree to withdraw appeals and not seek further appeals of resolved claims. In addition, pursuant to §§405.1004 and 423.2004, OMHA ALJs review whether a QIC or IRE dismissal was in error. Under these sections, the ALJ reviews the dismissal, but no hearing is required. In FY 2015, OMHA ALJs addressed approximately 370 requests to review whether a QIC or IRE dismissal was in error. Also adding to the ALJs' workload are remands to Medicare contractors for information that can only be provided by CMS or its contractors under current §§405.1034(a) and 423.2034(a), and for further case development or information at the direction of the Council. Staff may identify the basis for these remands before an appeal is assigned to an ALJ and a

remand order is prepared, but an ALJ must review the appeal and issue the remand order, taking the ALJ's time and attention away from hearings and making decisions on the merits of appeals.

Under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC under subsection (c). Subsection (c) of section 1869 of the Act involves the conduct of reconsiderations by QICs. We stated in the proposed rule that we believe the statute does not require the action to be taken by an ALJ in cases where there is no QIC reconsideration (for example, where the QIC has issued a dismissal), or in cases of a remand or a withdrawal of a request for an ALJ hearing, and therefore the findings of fact and conclusions of law need not be rendered. As we stated in the proposed rule, ALJ hearings are ideally suited to obtain testimony and other evidence, and hear arguments related to the merits of a claim or other determination on appeal. ALJs are highly qualified to conduct those hearings and make findings of fact and conclusions of law to render a decision in the more complex records presented with a mix of documentary and testimonial evidence. However, we stated in the proposed rule that well-trained attorneys can perform a review of the administrative record and more efficiently draft the appropriate order for certain actions, such as issuing dismissals based on an appellant's withdrawal of a request for an ALJ hearing, remanding appeals for information or at the direction of the Council, and conducting reviews of QIC and IRE dismissals.

In addition, current §§405.1038 and 423.2038 provide mechanisms for deciding cases without an oral hearing, based on the written record. Cases may be decided without an oral hearing when the record supports a finding in favor of the appellant(s) on every issue; all of the parties have waived the oral hearing in writing; or the appellant lives outside of the United States and did not inform the ALJ that he or she wishes to appear, and there are no other parties who wish to appear. We stated in the proposed rule that, in these circumstances, the need for an

experienced adjudicator knowledgeable in Medicare coverage and payment law continues, and well-trained attorneys can review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision in the appealed matter.

To enable OMHA to manage requests for ALJ hearings and requests for reviews of QIC and IRE dismissals in a more timely manner and increase service to appellants, while preserving access to a hearing before an ALJ in accordance with the statutes, we proposed to revise rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B, to provide authority that would allow attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, to dismiss appeals when an appellant withdraws his or her request for an ALJ hearing, and to remand appeals for information that can only be provided by CMS or its contractors or at the direction of the Council, as well as to conduct reviews of QIC and IRE dismissals. We also proposed to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. As we stated in the proposed rule, allowing attorney adjudicators to issue decisions, dismissals, and remands as described above, and to conduct reviews of QIC and IRE dismissals would expand the pool of OMHA adjudicators and allow ALJs to focus on cases going to a hearing, while still providing appellants with quality reviews and decisions, dismissals, and remands. In addition, we proposed that the rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council.

In addition, we noted that even if an attorney adjudicator was assigned to adjudicate a request for an ALJ hearing, that hearing request still could be reassigned to an ALJ for an oral hearing if the attorney adjudicator determined that a hearing could be necessary to render a decision. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with current §§405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal regardless of the waivers, pursuant to current §§405.1036(b)(3) or 423.2036(b)(3). We also noted that parties to a decision that is issued without an ALJ conducting an oral hearing pursuant to current §§405.1038(a) or 423.2038(a) (that is, the decision is favorable to the appellant on every issue and therefore may be issued based on the record alone) continue to have a right to a hearing and a right to examine the evidence on which the decision is based and may pursue that right by requesting a review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.

To implement this proposal, we proposed to revise provisions throughout part 405 subpart I, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections and in section III of the proposed rule. In addition, we proposed to define an attorney adjudicator in §405.902, which provides definitions that apply to part 405 subpart I, as a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance. We also proposed to indicate in §405.902 that the attorney adjudicator is authorized to take the actions provided for in subpart I on requests for ALJ hearing and requests for reviews of QIC dismissals. We stated that these revisions to

§405.902 would provide the public with an understanding of the attorney adjudicator's qualifications and scope of authority, and we also noted that attorney adjudicators would receive the same training as OMHA ALJs, which we note would focus on substantive areas of Medicare coverage and payment policy, as well as administrative procedures unrelated to the hearing components for which ALJs are exclusively responsible.

Provided below are summaries of the specific comments received and responses to these comments:

We received forty-seven comments on this proposal. A majority of the comments came from providers and suppliers, organizations representing providers and suppliers, beneficiary advocacy organizations, representatives, health plan providers, CMS contractors, and individuals. Twenty-nine of the commenters, mostly from the appellant community, generally supported or raised no objection to the proposal, but had requests for clarification, suggestions for modifications, and concerns or questions. Three commenters fully supported the proposal. Five commenters were equivocal. Three commenters generally supported the proposal, but opposed allowing attorney adjudicators to conduct reviews of QIC and IRE dismissals. Seven commenters opposed the proposal, including two comments from professional associations for ALJs.

Comment: A majority of commenters, mostly from organizations representing the appellant community, voiced broad support for the proposal, but a few commenters questioned whether the use of attorney adjudicators would significantly alleviate the backlog. One commenter questioned the utility of using attorney adjudicators given that all attorney adjudicators would be afforded the same training as ALJs. The commenter suggested it seemed logical to simply hire more ALJs instead.

Response: We thank the commenters for their support. Requests for a hearing before an ALJ have increased dramatically in recent years and appeals pending at OMHA continue to exceed OMHA's capacity to adjudicate appeals within the time frames set forth in the statute and rules. The introduction of attorney adjudicators is one action that would help OMHA process cases more efficiently. Attorney adjudicators would allow OMHA to identify and adjudicate appeals that do not require a hearing as early in the administrative process as possible. The use of attorney adjudicators to adjudicate these appeals would reduce the wait time for appellants to receive decisions in cases in which no hearing is required or conducted. It would also help to address the volume of appeals OMHA continues to receive by channeling some of those appeals through a less costly adjudicator, which will allow OMHA to hire more adjudicators than the same resources would allow if allocated to hiring ALJs and support staff, while reserving ALJs and their support staff for appeals that require a hearing. We estimated in the proposed rule that, based on FY 2015 data, the proposal to expand the pool of adjudicators at OMHA could redirect approximately 23,650 appeals per year to attorney adjudicators, to process these appeals at a lower cost to the government than would be required if only ALJs were used to address the same workload. (Basing the estimates on FY 2016 data, we now estimate the impact to be approximately 24,500 appeals per year.) Thus, we believe the use of attorney adjudicators will help OMHA manage high receipt levels, and help alleviate the backlog by allowing OMHA to increase its overall adjudication capacity. OMHA has added as many ALJs and support staff as its current space and budget allow it to sustain. Additional ALJs and support staff will be hired to meet the need for adjudicators, as resources become available. However, the proposal would allow for OMHA to adjudicate more appeals using existing resources by providing for adjudication by attorney adjudicators of appeals that do not require a hearing before an ALJ.

Comment: Two commenters asked if attorney adjudicators would be doing the work that paralegals are already currently performing under the direction of an ALJ.

Response: Some OMHA paralegals do currently draft remands, dismissals, and decisions that will be made on the record under the direction of an ALJ. However, we do not believe that is comparable to the work that will be performed by attorney adjudicators. Attorney adjudicators would be licensed attorneys and would have full responsibility for reviewing the record, assessing the pertinent facts in the record and identifying the relevant authorities, conducting the necessary analysis, and drafting and issuing the decision, remand, or dismissal under the attorney adjudicator's signature.

Comment: A few commenters believed that attorney adjudicators would not resolve the backlog because providers are unlikely to waive their right to a hearing if doing so would require them to forego the ability to present clinical information to either an ALJ or an attorney adjudicator.

Response: As discussed above and in the proposed rule, we believe attorney adjudicators will be an important new resource to help address the volume of appeals by increasing OMHA's adjudications capacity, which may help alleviate the backlog of pending appeals at OMHA. However, we have not suggested that the attorney adjudicator proposal will resolve the backlog; it is one of a number of administrative actions that we are undertaking to address the appeals workload and resulting backlog, and is in concert with other actions, such as requesting additional funding for the program. Further, we do not believe the proposal would require providers or other appellants to forego the ability to present clinical information to either an ALJ or attorney adjudicator. Although waiving the right to a hearing under current §§405.1038(b) and 423.2038(b) means an appellant and the other parties forego the ability to present clinical

information to an ALJ at a hearing, that does not preclude the appellant and other parties from presenting written information, including clinical information, for the ALJ to consider in issuing a decision based on the record alone, in accordance with current §§405.1018 and 423.2018. The same would be true under the regulations as finalized in this rule, except that an attorney adjudicator instead of an ALJ would issue the decision. The decision to waive the right to appear at a hearing before an ALJ is solely at the discretion of the appellant and, as finalized in this rule, the other parties who would be sent a notice of hearing if a hearing were to be scheduled. By waiving the right to appear at a hearing, the party would be requesting that the ALJ or attorney adjudicator issue a decision based on the written evidence in the record. In addition, we note that parties also have the option to withdraw a waiver of the right to appear at the hearing any time before a notice of decision has been issued under §§405.1036(b)(2) and 423.2036(b)(2).

Comment: Many of the commenters who generally supported the proposal believed that OMHA should establish clear and specific guidelines for both the qualifications and the hiring of attorney adjudicators. Commenters suggested that attorney adjudicators should have at least one to three years of experience in Medicare coverage, payment, and appeals, obtained through work with a provider, OMHA, or CMS or its contractors. A few commenters recommended that OMHA hire its existing attorney advisors working under the direction of ALJs as attorney adjudicators.

Response: We thank the commenters for their support. We believe the definition we proposed in §405.902 is sufficient to identify the requirement that attorney adjudicators be licensed attorneys, the knowledge that attorney adjudicators will possess, and their scope of authority. OMHA will identify desirable qualifications, including the specific knowledge, skills, and abilities necessary for an attorney adjudicator to be successful in the position, and human

resource professionals will determine the specific guidelines for the qualifications and hiring for the position of attorney adjudicator in accordance with the Office of Personnel Management and HHS Departmental standards, after the effective date of the rule. The position description for the attorney adjudicator position and the job announcements will reflect these assessments and determinations. Further, although we may consider hiring existing OMHA attorney advisors as attorney adjudicators, we do not believe it would be appropriate to detail this type of information in the regulations at this time, or to make statements about what the qualifications may be before those delegated with authority to take human resource actions, such as the classification of positions and the determination of qualification standards, are consulted.

Comment: Most commenters emphasized the importance of training to help ensure attorney adjudicator decisions are consistent with Medicare law and guidance. One commenter from a professional association for ALJs indicated “with no definition of well trained or review criteria, an attorney adjudicator with little or no Medicare adjudicatory training or experience is more likely to issue a legally or factually incorrect decision than a well-seasoned ALJ.” By contrast, several of the commenters who generally supported the proposal appreciated that, as discussed above and in section II.B of the proposed rule, attorney adjudicators would receive the same training as ALJs.

Response: We thank the commenters for their support, and disagree with the commenter who opined that in the absence of clearly defined training or review criteria, an attorney adjudicator with little or no Medicare adjudicatory training/experience would be more likely to issue a legally or factually incorrect decision than an ALJ. Section 405.902, as finalized in this rule, defines an attorney adjudicator as a licensed attorney employed by OMHA “with knowledge of Medicare coverage and payment laws and guidance.” As noted above (and

discussed in section II.B of the proposed rule), attorney adjudicators would undergo the same training as new OMHA ALJs to help ensure that their decisions are consistent with Medicare law and guidance. In addition to hiring qualified adjudicators, OMHA ALJs and other legal staff, which would include attorney adjudicators, are required to attend continuing education and training programs to maintain familiarity with the most current Medicare law and guidance.

Comment: One commenter, on behalf of an association for ALJs, asked “what does guidance mean with respect to the Medicare Program, and if the attorney adjudicator receives guidance as to how to proceed with the claim from a supervisor at OMHA, an attorney adjudicator is not an independent decision-maker.”

Response: We believe this commenter misinterpreted the term “guidance” as set forth in the definition of attorney adjudicator in §405.902. CMS and its contractors issue guidance that describe criteria for coverage and payment of items and services in the form local coverage determinations (LCDs), and CMS program memoranda and manual instructions. This is the guidance that is referenced in the definition of attorney adjudicator in §405.902. Current §405.1062(a) provides that ALJs are not bound by LCDs or CMS program guidance but must give substantial deference to these policies if they are applicable to a particular case. Section 405.1062(a), as finalized in this rule, extends the provision to require that attorney adjudicators, like ALJs, give the same substantial deference to these policies.

Comment: To guarantee an impartial and fair adjudication process, some commenters suggested OMHA should require attorney adjudicators to file a financial disclosure report to ensure no financial conflicts of interest exist. Other commenters believed that the fact that attorney adjudicators would be rated and eligible for awards could create a conflict of interest

because attorney adjudicators would have no protection from agency interference and may be assigned cases outside of rotation.

Response: As executive branch employees, all OMHA employees are subject to the Federal criminal conflict of interest statute at 18 U.S.C. 208, which prohibits a federal employee from participating in matters in which the employee, certain family members, or certain business associates have a financial interest, and to the Federal Employee Standards of Conduct at 5 CFR 2635, which provide general principles of ethical conduct and administer requirements regulating appearances of conflicts of interests, gifts, financial interests, impartiality in official duties, outside employment, and misuse of position. The regulations at 5 CFR 2634, implementing Federal statutes and administered by the Office of Government Ethics, set the guidelines for which employees are required to file financial disclosure reports subject to certification by an ethics official, in accordance with applicable statutes. HHS ethics officials, in consultation with the Office of Government Ethics, will determine which employees will be required to submit financial disclosures in accordance with the ethics regulations at 5 CFR 2634, which determines the content of such disclosures.

In addition, §§405.1026 and 423.2026, as finalized in this rule, serve as important safeguards in the administrative appeals process, and provide that an ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision. This rule as finalized also provides a process that would allow a party to object to an assigned ALJ or attorney adjudicator. The objecting party would also have the opportunity to have the Council review the objections in cases where an adjudicator does not withdraw pursuant to §§405.1026 and 423.2026.

Under 5 U.S.C. 43 and 5 CFR 430.101, attorney adjudicators, as Federal employees, would be subject to the Performance Management Appraisal Program (PMAP), which provides for an annual performance appraisal of HHS Federal employees. ALJs are exempt from annual performance appraisals pursuant to 5 U.S.C. 4301(2)(D) and 5 CFR 430.202(b). However, the statutes governing PMAPs do not provide an exclusion that would exempt attorney adjudicators from annual performance reviews. Annual performance reviews are an important tool for holding employees accountable and we believe that as stewards of taxpayer dollars, we are responsible for holding adjudicators accountable for minimal production levels and levels of quality in their work, through annual performance reviews or otherwise. However, in managing its obligation to administer PMAPs for all OMHA employees except ALJs, OMHA will take precautions to avoid performance criteria that would interfere with an attorney adjudicator's ability to independently make findings of fact based on the record, identify the applicable authorities, and issue a decision in accordance with those authorities, so as to afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs. Further, OMHA's business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. Based on the foregoing, we believe there will be protections in place to guarantee an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

Comment: Some commenters felt that attorney adjudicator decisions should be subject to oversight or a quality review process.

Response: We thank the commenters for their suggestion. In addition to reviews by the Council pursuant to a party's request for review or a referral by CMS as a check on individual

decisions issued by ALJs and as proposed, attorney adjudicators, OMHA has a quality assurance program (QAP). The OMHA QAP involves a retrospective review of ALJ decisions and assists OMHA in identifying opportunities for training and policy development to increase decisional quality. The OMHA QAP will include attorney adjudicator decisions after the rule is implemented.

Comment: One commenter suggested OMHA should compile a yearly report to assess the impact attorney adjudicators have on the backlog, including the types of decisions issued and the percentage of dispositions that were in favor of the government.

Response: We thank the commenter for its suggestion. The OMHA website (www.hhs.gov/omha) currently contains summary tables that list overall disposition data and dispositions by ALJ. The data, which is organized by fiscal year, includes the number of dispositions that were fully favorable, unfavorable, partially favorable, and dismissed. The disposition data will be expanded to include data for attorney adjudicators as they begin to decide appeals. We believe this data would assist OMHA and the public with assessing the impact of attorney adjudicators on the appeals workload.

Comment: One commenter indicated the proposed rule does not specify who would assign the cases to the ALJs and attorney adjudicators. Several commenters asked how cases will be assigned to attorney adjudicators and suggested OMHA must establish a well-defined process for assignment of cases to attorney adjudicators.

Response: OMHA's business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. More information on the appeal assignment process is available in the OMHA Case Processing Manual (OCPM), which is accessible to the public at the OMHA

website (www.hhs.gov/omha). If an appeal is initially assigned to an ALJ and the ALJ later determines it can be adjudicated by an attorney adjudicator, the appeal would be reassigned to an attorney adjudicator in the same manner as a new appeal assignment to an attorney adjudicator. Similarly, if an appeal is initially assigned to an attorney adjudicator and the attorney adjudicator later determines that only an ALJ can adjudicate the appeal, the appeal would be reassigned to an ALJ in the same manner as a new appeal assignment to an ALJ.

Comment: Several commenters supported the proposal to allow requests for hearings initially assigned to an attorney adjudicator to be reassigned to an ALJ for oral hearing if necessary in order to render a decision. However, commenters suggested OMHA establish clearer guidance and thresholds for reassignment and a timeline for an attorney adjudicator to reassign an appeal to an ALJ. One commenter indicated the proposal does not provide the regulatory text or authority for an attorney adjudicator to refer an appeal to an ALJ for hearing when the attorney adjudicator determines a hearing is required. A few commenters also indicated the proposal does not specify the procedure for reassignment of cases from an ALJ to an attorney adjudicator, where the ALJ has determined the disposition could be fully favorable, nor does the proposal require the ALJ to make a record of such a determination.

Response: We believe the threshold requirement of whether a hearing is necessary for a decision is clear in the statute and regulations. In addition, we decline to establish a time frame in the regulations for an attorney adjudicator to reassign a case to an ALJ, as this would be an internal process, and to do so would limit our flexibility to establish and change business processes through OMHA operational policies, which the Administrative Procedure Act (APA) permits OMHA to adopt without notice and comment rulemaking. We also do not believe that regulation text or authority is necessary for an attorney adjudicator to refer an appeal to an ALJ,

as an attorney adjudicator would be referring the appeal to an ALJ because the attorney adjudicator believes that he or she does not have the authority to issue a decision in the appeal, for example, because the attorney adjudicator believes a hearing is necessary to decide the appeal.

Further, the procedure for reassignment of cases from an ALJ to an attorney adjudicator, for example, where the ALJ has determined the disposition could be fully favorable to the appellants on every issue based on the record and no other party is liable for the claims at issue, will also be established by OMHA operational policies, including the OCPM. However, we note that in the scenario presented in the comment, the ALJ would also have the authority to retain assignment of the appeal and issue a decision without conducting a hearing. In the event that an ALJ determines the disposition could be fully favorable to the appellants on every issue based on the record and no other party is liable for the claims at issue and the case is reassigned to an attorney adjudicator, the ALJ will not make a record of the determination because the attorney adjudicator will make an independent assessment and will not be bound by the ALJ's determination.

Comment: Several commenters asked whether OMHA would inform the parties to an appeal when the appeal is assigned to an attorney adjudicator.

Response: OMHA would continue its current practice of issuing a Notice of Assignment to appellants when a request is assigned, which includes the assigned adjudicator. Appellants and other parties can also obtain and track the status of a pending appeal, including its assigned adjudicator, by visiting OMHA's ALJ Appeal Status Information System (AASIS) page at: <http://aasis.omha.hhs.gov>.

Comment: Several commenters asked whether a party waiving the right to attend the hearing could choose a decision by either an attorney adjudicator or an ALJ, and whether parties could object to the assignment. One commenter suggested modeling the attorney adjudicator process on existing Federal court process for the assignment of magistrates, where all parties would be given the option for their case to be assigned to an attorney adjudicator.

Response: Sections 405.1038 and 423.2038, as finalized in this rule, specifically indicate an ALJ or attorney adjudicator may decide a case on the record when an appeal can be decided without a hearing before an ALJ. These regulations, as finalized, serve as notice that waiving the right to appear at a hearing allows an attorney adjudicator to issue a decision, if a hearing is not necessary to decide the appeal (we note that a hearing may still be conducted by an ALJ if it is necessary to decide the appeal, even if one or more of the parties has waived their right to appear at the hearing). We believe that allowing the parties to choose whether an ALJ or attorney adjudicator will issue the decision when the right to appear at the hearing is waived, or to object if the appeal is assigned to an attorney adjudicator would negate some of the anticipated efficiencies of the proposal and provide the parties with undue influence over the adjudicator assigned to the appeal. However, we note that under §§405.1036(b)(2) and 423.2036(b)(2), as finalized in this rule, appellants and other parties may withdraw a waiver of the right to appear at the hearing at any time before a notice of decision has been issued. In addition, if an appellant has concerns about the individual assigned to the appeal having a conflict or bias, §§405.1026 and 423.2026, as finalized in this rule, can be used to request that the adjudicator withdraw from the appeal. We appreciate the suggestion to consider having an option for the parties to have their case assigned to an attorney adjudicator, similar to the Federal court process for some magistrate assignments. However, we do not believe that such an option would be appropriate

for the administrative appeals addressed in this rule, because attorney adjudicators may only adjudicate appeals that do not require a hearing. A hearing may be necessary in some cases to decide the appeal, and in these cases, under section 1869 of the Act and the regulations finalized in this rule, only an ALJ may conduct a hearing.

Comment: Two commenters from professional associations for ALJs indicated that appellants, including self-represented appellants, may not know the difference between a decision by an independent ALJ as compared to a decision issued by an attorney adjudicator. In the commenters' opinion, the record must clearly demonstrate a valid and informed waiver of the right to have a claim heard by an ALJ.

Response: We do not believe there will be a qualitative distinction in decisions issued by ALJs and attorney adjudicators, and both adjudicators will share a similar qualified decisional independence with respect to the decisions that they issue, as discussed further below. However, parties to Medicare claims and appeals are presumed to have knowledge of the published Medicare rules and guidance, regardless of whether they have representation. Therefore, we believe this final rule would serve as sufficient notice that by waiving the right to appear at a hearing, parties would be aware that the decision may be issued by either an ALJ or an attorney adjudicator, if no hearing is required to decide the appeal. However, we will review and revise appeal instructions, and online and other guidance available to appellants to highlight that if an oral hearing is waived, an attorney adjudicator may issue the decision. We will also review and revise current Form HHS-723 (Waiver of Right to an Administrative Law Judge (ALJ) Hearing) to clearly convey that a decision may be issued by an attorney adjudicator.

With regard to unrepresented beneficiaries and enrollees, we believe they represent the most vulnerable segment of the appellant population. However, it is rare that an unrepresented

beneficiary waives the right to appear at the hearing. In practice, in the few instances when this does occur, OMHA reviews the stated reason for waiving the right to appear at the hearing and may contact the unrepresented beneficiary or enrollee to confirm that the waiver is knowingly made. We believe this process will help ensure that an unrepresented beneficiary or enrollee understands the implications of waiving his or her right to appear at the hearing and the record demonstrates that understanding. In addition, we are reviewing the current form for waiving the right to appear at a hearing (form HHS-723), to determine if revisions may be necessary so users will understand that by waiving the right to appear at the hearing, the waiving party would be aware that the decision may be issued by either an ALJ or an attorney adjudicator, if no hearing is required to decide the appeal.

Comment: Several commenters asked whether a party could appeal an unfavorable decision by an attorney adjudicator to an ALJ. Several commenters believed OMHA should allow parties who disagree with the attorney adjudicator's decision to request an ALJ review the attorney adjudicator's decision and allow the ALJ to reissue an amended decision should the ALJ find the attorney adjudicator's decision to be deficient.

Response: A party would not have the right to appeal an unfavorable decision by an attorney adjudicator to an ALJ. All parties to an appeal would receive a written notice of decision issued by an attorney adjudicator. The notice of decision would provide instructions for requesting a review of the decision by the Council if a party disagrees with the decision. The rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council (see §§405.1102 and 405.1106, as finalized in this rule). Parties to a decision issued without an ALJ conducting an oral hearing pursuant to

§§405.1038(a) or 423.2038(a) continue to have a right to a hearing and a right to examine the evidence on which the decision is based, and may pursue that right by requesting review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.

Comment: One commenter noted that the proposed rule is silent on the requirements for a timely request for ALJ hearing when a party to an appeal wishes to appeal a fully favorable on the record decision issued by an attorney adjudicator.

Response: As discussed above, parties to a decision issued without an ALJ conducting an oral hearing pursuant to §§405.1038(a) or 423.2038(a) continue to have a right to an ALJ hearing, and may pursue that right by appealing to the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. Sections 405.1102(a)(1) and 423.2102(a)(1), as finalized in this rule, provide that a party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a review of the decision by the Council by filing a written request for review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal. We believe §§405.1102(a)(1) and 423.2102, as finalized in this rule, provide the requirements for filing a timely request to appeal a decision issued by an attorney adjudicator, including a fully favorable decision issued by an attorney adjudicator. In addition, we note that the notice of decision sent with an attorney adjudicator's decision will include instructions for filing a request for review with the Council, including the time frame in which the request for review must be filed.

Comment: One commenter stated "in any waiver to allow a decision by an attorney adjudicator, it must be clearly explained that by accepting such a decision, the beneficiary may

be waiving his or her right to appeal the decision to the Federal district court as it will not have completed all administrative proceedings below.”

Response: We disagree with the commenter’s interpretation that a beneficiary would be waiving their right to appeal to Federal district court by waiving the right to an ALJ hearing. Section 405.904(a)(2), as finalized in this rule, states “If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.”

Comment: A few commenters, on behalf of Medicare contractors, asked whether attorney adjudicators could render summary decisions in favor of CMS Recovery Auditors or other interested contractors, or only in favor of the appellant. These commenters suggested summary decisions should be permitted to extend in both directions.

Response: We interpret the commenter’s use of the term “summary decisions” to mean decisions that are issued on the record without a hearing before an ALJ, and we assume the commenters are asking whether attorney adjudicators could issue decisions on the record that are favorable to CMS and its contractors (or to CMS, the IRE, and/or the plan sponsor) pursuant to §§405.1038(a) and 423.2038(a). Sections 405.1038(a) and 423.2038(a), as finalized in this rule, clearly limit the ALJ’s or attorney adjudicator’s ability to issue decisions on the record to situations where the administrative record supports a finding fully in favor of the *appellant(s)* on every issue and no other party to the appeal is liable for claims at issue. Decisions that are

favorable to CMS and its contractors (or to CMS, the IRE, and/or the plan sponsor), are not fully favorable to the appellant(s) (because CMS and its contractors (or CMS, the IRE and/or the plan sponsor) are not appellants in a request for an ALJ hearing), and therefore, such a decision could not be issued on the record under §§405.1038(a) and 423.2038(a.), as finalized in this rule.

Comment: Many commenters suggested that OMHA establish a bright line rule and clear scope of an attorney adjudicator's authority. One commenter indicated "the number of cases that fall within [attorney adjudicators'] scope of authority is so limited, that their use will have no more than negligible impact on the processing of appeals."

Response: We believe the rule as finalized, clearly establishes the scope of an attorney adjudicator's authority. The scope and authority of an attorney adjudicator to issue decisions under the rule as finalized, is set forth in §405.902, which states an "attorney adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals." Other rules in the subpart then describe when an attorney adjudicator may issue a decision, dismissal, or remand. As finalized in this rule, an attorney adjudicator may issue: (1) decisions that can be issued without an ALJ conducting a hearing in accordance with §§405.1038 and 423.2038; (2) dismissals when an appellant withdraws his or her request for an ALJ hearing in accordance with §§405.1052 and 423.2052; (3) remands to the QIC, IRE, or other contractor, or the Part D plan sponsor, in accordance with §§405.1056 and 423.2056; and (4) reviews of QIC and IRE dismissals in accordance with §§405.1004 and 423.2004.

Comment: Some commenters supported allowing attorney adjudicators to issue dismissals when an appellant withdraws a request for hearing, remands for information that can

only be supplied by CMS or contractors and, in certain instances, issue decisions that are fully favorable to the appellant, but the commenters opposed allowing attorney adjudicators to review a QIC or IRE dismissal, stating neither §405.1004 nor §423.2004 preclude a hearing being held for review of a QIC or IRE dismissal, respectively. These commenters suggested that the review of QIC and IRE dismissals “may sometimes require a hearing to determine findings of fact or conclusions of law.”

Response: We recognize that current §§405.1004 and 423.2004 do not preclude conducting a hearing on a review or a QIC or IRE dismissal, and acknowledge review of QIC and IRE dismissals may sometimes require a hearing to determine findings of fact or conclusions of law. As discussed previously regarding the reassignment of cases from an attorney adjudicator to an ALJ, an attorney adjudicator may refer an appeal to an ALJ because the attorney adjudicator believes that he or she does not have the authority to issue a decision in the appeal, for example, because the attorney adjudicator believes a hearing is necessary to determine findings of fact or conclusions of law. These appeals will be reassigned to an ALJ to conduct a hearing. However, as discussed above and in section II.B of the proposed rule, although under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC, we believe that the statute does not require that the same action be taken by an ALJ in cases where there is no QIC reconsideration, for example, where the QIC has dismissed the request for reconsideration. In addition, we believe the determination whether a QIC or IRE dismissal was issued in error generally can be conducted on the record, given the limited scope of review, in the same manner as QICs review MAC dismissals of redetermination requests, and the Council reviews ALJ dismissals of requests for hearing. Moreover, we believe attorney adjudicators will

be capable of reviewing the administrative record, identifying the issues related to the dismissal, and determining whether the QIC and IRE dismissal was issued in error.

Comment: One commenter requested that for cases where an attorney adjudicator finds the QIC or IRE dismissed an appeal in error, the appeal should be remanded to the QIC or IRE with the attorney adjudicator's reasoning for the decision and with instructions on how to proceed.

Response: Sections 405.1004(b) and 423.2004(b), as finalized in this rule, state if the ALJ or attorney adjudicator determines that the QIC's or IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC or IRE for a reconsideration in accordance with §§405.1056 and 423.2056. We expect that an ALJ's or attorney adjudicator's notice of remand will explain the ALJ's or attorney adjudicator's basis for vacating the QIC's or IRE's dismissal, and §§405.1056(d) and 423.2056(d)), as finalized in this rule, state that the ALJ or attorney adjudicator will remand the case to the QIC or IRE for a reconsideration, which we believe is the only required instruction.

Comment: A few commenters, including two professional associations for ALJs, opposed the attorney adjudicator proposal on the basis that the proposal is inconsistent with the APA or the Act and improperly delegates decision-making authority to individuals who are not appointed as ALJs. The commenters also argued provisions of the APA and the Act give ALJs judicial independence to render decisions, and attorney adjudicators do not have judicial independence to the same extent as ALJs.

Response: We disagree with the commenters and believe the proposal is fully consistent the APA and the Act. As a preliminary matter, we note that in interpreting the APA, courts have held that ALJs have "qualified decisional independence" in carrying out their adjudicative

functions, rather than full “judicial independence.” According to the case law, the intent of the APA is that ALJs should decide each case based on the record evidence, free from any pressure from their employing agencies to reach a particular result in a particular case. This decisional independence is designed to help ensure impartial decision-making and to maintain public confidence in the essential fairness of the process. This decisional independence is, however, “qualified” because ALJs are still bound to follow the regulations and policies of their employing agency, and are also subject to direction designed to ensure efficient operation and service to the public. See *Butz v. Economou*, 438 U.S. 478, 513 (1978); *Abrams v. Social Security Administration*, 703 F. 3d 538, 545 (Fed. Cir. 2012); *Nash v. Bowen*, 869 F. 2d 675, 680 (2nd Cir. 1989), cert. denied, 493 U.S. 812 (1989); *Nash v. Califano*, 613 F. 2d 10, 15 (2nd Cir. 1980). In implementing this final rule, OMHA will afford attorney adjudicators the same level of qualified decisional independence. As discussed above, OMHA will take precautions to avoid performance criteria that would interfere with an attorney adjudicator’s ability to independently make findings of fact based on the record, identify the applicable authorities, and issue a decision in accordance with those authorities, so as to afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs. Further, OMHA’s business process is to assign appeals to ALJs in rotation so far as practicable, as required under 5 U.S.C. 3105, and OMHA would assign appeals to attorney adjudicators in the same manner. This qualified decisional independence helps ensure an impartial and fair adjudication process for all parties to an appeal before an OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

Sections 554 and 556 of the APA apply only to adjudications that are required by statute to be determined on the record after an opportunity for an agency hearing. In accordance with

sections 1155, 1852(g)(5), 1860D–4(h), 1869(b)(1)(A), and 1876(c)(5)(B) of the Act and their implementing regulations (at 42 CFR part 405 subpart I, part 478 subpart B, part 422 subpart M, and part 423 subpart U), individuals dissatisfied with certain lower level appeal determinations are entitled to a hearing, subject to timely filing and amount in controversy limitations, to the same extent as is provided under section 205(b) of the Act. Reading these sections together, the Act directs the Secretary of Health and Human Services to provide an opportunity for a hearing regarding the right to Medicare benefits, which the Secretary has delegated to OMHA ALJs to conduct and render a decision. The rule, as finalized, is not inconsistent with the APA or the Act, but instead would augment this process by authorizing attorney adjudicators to make decisions in appeals when there is no requirement for a hearing, or in cases where parties waive the right to appear at a hearing before an ALJ and the hearing is not necessary to make a decision. The Act requires only that parties be given an opportunity for a hearing; no provision of the Act requires the Secretary to utilize an ALJ to issue a decision that does not require a hearing, for example, because the parties have waived their right to one or because no reconsideration has been issued.

Parties will continue to have an opportunity for a hearing where a reconsideration has been issued, the hearing request has been timely filed, and the amount remaining in controversy has been met. In that respect, the proposal, as finalized in this rule, does not change the process or the rights of the parties. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with §§405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal regardless of the waivers, pursuant to §§405.1036(b)(3) or

423.2036(b)(3). In addition, parties to a decision issued without an ALJ conducting an oral hearing pursuant to §§405.1038(a) or 423.2038(a) continue to have a right to a hearing and a right to examine the evidence on which the decision is based, and may pursue that right by requesting review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. Under the rule we are finalizing, either an attorney adjudicator or an ALJ may issue a decision when no hearing is required before an ALJ, but if a hearing is to be held, the ALJ will conduct that hearing and issue the decision. We believe this process is fully in accord with the APA and the Act.

Comment: One commenter suggested that “it is a violation of statute to assign attorney adjudicators to render decisions that are less than fully favorable to a beneficiary because it deprives the beneficiary of an impartial ALJ, appointed and protected under the provisions of the APA.”

Response: We disagree with the commenter. In accordance with section 1869(b)(1)(A) of the Act, any individuals dissatisfied with an initial determination and reconsideration are entitled to a hearing, subject to timely filing and amount in controversy limitations, and (d)(1)(A) states that an ALJ “shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) and render a decision *on such hearing*” (emphasis added). However, the rule we are finalizing, provides for a decision by another adjudicator (an attorney adjudicator) if such a hearing is waived under §405.1038(b) or not required under §405.1038(c), as finalized in this rule. As discussed above, no provision of the Act requires the Secretary to utilize an ALJ to issue a decision that does not require a hearing. OMHA will afford attorney adjudicators with a similar level of qualified decisional independence that is afforded to ALJs, to help ensure an impartial and fair adjudication process for all parties to an appeal before an

OMHA adjudicator, regardless of whether the case is assigned to an ALJ or to an attorney adjudicator.

Comment: One commenter referred to the language in section II.B of the proposed rule where we stated that we believed well-trained attorneys could review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision in the appealed matter. 81 FR 43790, 43794. The commenter indicated “well-trained attorney” is not defined in the proposed regulation and asked whether a “well trained” attorney is required to be a member in good standing of a bar in the United States.

Response: Section §405.902, as finalized in this rule, states an “Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.” A licensed attorney would be a member in good standing of a bar in the United States.

Comment: One commenter argued that proposed §405.1006(e)(1)(ii), (e)(1)(iii) and (e)(2)(iii) may overcomplicate the process of aggregating claims because an attorney adjudicator could determine that the minimum amount in controversy was met, but would be required to refer the appeal to an ALJ if it appeared that the claims were not properly aggregated or if the appeal did not meet the required amount in controversy, in order for an ALJ to dismiss the request for hearing. The commenter also believed ALJs might simply adopt the attorney adjudicator’s preliminary determination, which could result in improperly denied requests for hearing.

Response: We appreciate the commenter's perspective but believe these procedures are necessary to help ensure that a request for a hearing before an ALJ is reviewed by an ALJ before being dismissed for not meeting the amount in controversy required for an ALJ hearing. A referral to an ALJ would only be necessary when the attorney adjudicator believes the appealed claims do not meet the amount in controversy requirement and the aggregation request may not be valid, because the request for hearing would be subject to a possible dismissal for not meeting the amount in controversy requirement. Section 405.1006(e)(1) and (2), as finalized in this rule, provide that only an ALJ may determine that the claims were not properly aggregated and therefore do not meet the minimum amount in controversy required for an ALJ hearing. Thus, the ALJ is required to make this determination, and would not be permitted to simply adopt the attorney adjudicator's preliminary determination without conducting an independent review. If an ALJ dismisses a request for hearing after determining that an aggregation request was not valid, and therefore the minimum amount in controversy was not met, and the appellant does not agree with the dismissal, the appellant may request a review of the dismissal by the Council. Instructions for requesting a review by the Council will be included in the notice of dismissal sent to the appellant with the ALJ's dismissal order.

After review and consideration of the comments received, and for the reasons discussed above and in the proposed rule, we are finalizing our proposals as discussed above without modification to provide authority for attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, dismissals when an appellant withdraws his or her request for an ALJ hearing, remands as provided in §§405.1056 and 423.2056 or at the direction of the Council, and reviews of QIC and IRE dismissals. Also,

we are finalizing the definition of attorney adjudicator in §405.902 as proposed without modification.

In addition, we are making a conforming technical revision to §423.558(b) to replace “ALJ hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions” for consistency with the revised title of part 423, subpart U, and the revisions discussed above providing for attorney adjudicator reviews.

3. Application of 405 Rules to Other Parts

Current §422.562(d) states that unless subpart M regarding grievances, organization determinations and appeals under the MA program provides otherwise, the regulations found in part 405 apply under subpart M to the extent appropriate. In addition, current §422.608, which is a section within subpart M, provides that the regulations under part 405 regarding Council review apply to the subpart to the extent that they are appropriate. Pursuant to §417.600, these rules governing MA organization determinations are also applicable to beneficiary appeals and grievances when the beneficiary is enrolled in a competitive medical plan or HMO (also known as “cost plan”) under section 1876 of the Act; therefore our discussion of MA proceedings applies also to cost plan appeals and grievances initiated under §417.600.

Similar to current §422.562(d), §478.40(c) indicates that the part 405 regulations apply to hearings and appeals under subpart B of part 478 regarding QIO reconsiderations and appeals, unless they are inconsistent with specific provisions in subpart B. Thus, the part 405 rules are used, to the extent appropriate, for administrative review and hearing procedures in the absence of specific provisions related to administrative reviews and hearing procedures in part 422, subpart M; and part 478, subpart B, respectively. These general references to part 405 are often helpful in filling in gaps in procedural rules when there is no rule on point in the respective part.

However, as we stated in the proposed rule, there has been confusion on the application of part 405 rules when a part 405 rule implements a specific statutory provision that is not in the authorizing statute for the referring subpart and HHS has not adopted a similar policy for the referring subpart in its discretion to administer the MA, QIO, and cost plan appeals programs (81 FR 43795). For example, certain procedures and provisions of section 1869 of the Act (governing certain determinations and appeals under Medicare Part A and Part B) that are implemented in part 405, subpart I are different than or not addressed in sections 1155 (providing for reconsiderations and appeals of QIO determinations), 1852(g) (providing for appeals of MA organization determinations), and 1876 (providing for appeals of organization determinations made by section 1876 health maintenance organizations (HMOs) and competitive medical plans (CMPs)). Section 1869 of the Act provides for, among other things, redeterminations of certain initial determinations, QIC reconsiderations following redeterminations or expedited determinations; ALJ hearings and decisions following a QIC reconsideration; DAB review following ALJ decisions; specific time frames in which to conduct the respective adjudications; and, at certain appeal levels, the option to escalate appeals to the next level of appeal if the adjudication time frames are not met. In addition, section 1869(b)(3) of the Act does not permit providers and suppliers to introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration.

In contrast, sections 1852(g)(5) of the Act and 1876(c)(5)(B) of the Act incorporate some, but not all, of the provisions of section 1869 of the Act, and add certain requirements, such as making the MAO, HMO, or CMP a party to an ALJ hearing. For example, sections 1852(g)(5) and 1876(c)(5)(B) of the Act specifically incorporate section 1869(b)(1)(E)(iii) of the Act to

align the amount in controversy requirements for an ALJ hearing and judicial review among the three sections. However, sections 1852(g) and 1876(c)(5)(B) do not incorporate adjudication time frames and escalation provisions, or the limitation on new evidence provision of section 1869(b)(3) of the Act.

Additionally, section 1155 of the Act provides for an individual's right to appeal certain QIO reconsidered determinations made under section 1154 of the Act directly to an ALJ for hearing. However, section 1155 of the Act does not reference section 1869 of the Act or otherwise establish an adjudication time frame, and provides for a different amount in controversy requirement for an ALJ hearing.

Despite these statutory distinctions, HHS has established similar procedures by regulation to the extent practicable, when not addressed by statute. For example, section 1860D-4(h) of the Act, which addresses appeals of coverage determinations under Medicare Part D, incorporates paragraphs (4) and (5) of section 1852(g) of the Act. As discussed above, section 1852(g) does not incorporate adjudication time frames from section 1869 of the Act or otherwise establish such time frames. However, through rulemaking for Part D coverage determination appeals, HHS has adopted a 90-day adjudication time frame for standard requests for an ALJ hearing and requests for Council review of an ALJ decision, as well as a 10-day adjudication time frame when the criteria for an expedited hearing or review are met.

To clarify the application of the part 405 rules, we proposed revisions to parts 422 and 478. Specifically, we proposed in §§422.562(d) and 422.608 that the part 405 rules would not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1852 of the Act (81 FR 43796, 43876–43877). Similarly, we proposed in §478.40(c) that the part 405 rules would not apply when the part 405 rule implements a statutory provision that

is not also applicable to section 1155 of the Act (81 FR 43890–43891). In addition, we proposed in §478.40(c) to remove language that equates an initial determination and reconsidered determination made by a QIO to contractor initial determinations and reconsidered determinations under part 405 because that language has caused confusion with provisions that are specific to part 405 and QIC reconsiderations, and it is not necessary to apply the remaining part 405, subpart I procedural rules in part 478, subpart B proceedings. We stated in the proposed rule that, in addition to clarifying the application of part 405 rules to other parts, these revisions would help ensure that statutory provisions that are specific to certain Medicare appeals are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals (81 FR 43796). In our discussion of these proposals, we identified the statutory differences in sections 1155 and 1852(g) of the Act compared to section 1869 discussed above.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received three comments on proposed §§422.562(d), 422.608, and 478.40(c), expressing concern that the added language is too general and does not address the specific changes that are intended by the proposals. The commenters indicated that the general language will create more confusion rather than clarifying existing ambiguity about which part 405 rules apply to MA program appeals under part 422, subpart M and to appeals of QIO reconsidered determinations under part 478, subpart B, and may have the unintended consequence of stripping away protections for unrepresented beneficiaries. Two of the commenters stated that the proposals will take away important safeguards that currently provide consistency in application of beneficiary rights across the appeals spectrum and provide answers

in the absence of specific applicable provisions. The same commenters argued that under proposed §§422.562(d) and 422.608, part 405 rules apply to administrative reviews, hearing processes, and representation of parties “to the extent that they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act” but the only provisions of section 1869 of the Act that are referenced in section 1852(g)(5) of the Act relate to amounts in controversy. The commenters argued that the language of the proposals would mean that all sections of part 405, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. The same commenters used the part 405 rule in §405.1018, which requires a good cause determination for the submission of new evidence by providers, suppliers, and beneficiaries represented by a provider or supplier, if such evidence was not submitted prior to the issuance of the QIC’s reconsideration determination, as an example of where the proposals may have an unintended consequence of taking away a beneficiary safeguard. The commenters suggested that if current §405.1018(d), which states that the requirements of §405.1018 do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, was not available in part 422, subpart M proceedings, then an enrollee in the MA program may not be able to invoke the protections in §405.1018(d). All commenters requested that after the agency provides further details on which part 405 rules do not apply, it should provide the public with an opportunity to review the specific changes and allow them to make more meaningful comments on the proposal.

Response: We do not agree with the comment that the proposal would mean that all sections of part 405, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. The proposal related to part 405, subpart I provisions that

implement requirements in section 1869 of the Act that are not also contained in section 1852(g). Section 1852(g)(5) of the Act, which is implemented in part 422, subpart M, does, as the commenter highlights, reference portions of section 1869 of the Act related to the amount in controversy threshold. However, section 1852(g)(5) of the Act also entitles an MA enrollee to “a hearing before the Secretary to the same extent as is provided in section 205(b) [of the Act],” which is also referenced in section 1869 of the Act. Thus, section 1852(g) of the Act includes certain provisions, in addition to the amount in controversy provisions, that are also in section 1869 of the Act. The provisions of part 405, subpart I that implement these provisions would continue to apply to part 422, subpart M appeals to the extent they are appropriate, and therefore the proposal would not mean that all sections of part 405, subpart I, other than those relating to amounts in controversy, are unavailable to fill the gaps in part 422, subpart M. Rather, as we explained in the preamble to the proposed rule, the proposal would serve to clarify that the provisions of part 405, subpart I that implement provisions of section 1869 of the Act that are not also addressed in sections 1852 and 1155 of the Act, are not appropriate to apply in appeals initiated under part 422, subpart M, and part 478, subpart B. Using the commenter’s example of §405.1018, only paragraphs (c) and (d)(2) specifically relate to a provision of section 1869 of the Act; specifically, as we explained in the proposed rule, section 1869(b)(3) of the Act does not permit providers and suppliers to introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration. The other subsections of §405.1018 do not effectuate a specific provision of section 1869 of the Act, but rather relate to the hearing before the Secretary, which is also required under section 1852(g) of the Act, and therefore applying the

other subsections of §405.1018 to part 422, subpart M would continue to be appropriate under the proposal.

Proposed §§422.562(d), 422.608, and 478.40(c) were intended to clarify the application of part 405 rules to appeals and hearings initiated under other parts and to help ensure that statutory provisions that are specific to appeals under section 1869 of the Act are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals. In explaining the proposal, we also provided examples of specific provisions in section 1869 of the Act that are not also in sections 1852 and 1155 of the Act, and therefore the proposal would impact the part 405, subpart I provisions that implement those specific provisions of section 1869 of the Act that we discussed in explaining the proposal. While we believe our proposals provided sufficient information and notice regarding the part 405, subpart I provisions that would not apply in MA program appeals under part 422, subpart M and in appeals of QIO reconsidered determinations under part 478, subpart B, commenters raised concerns that the proposal and proposed regulation text were not sufficiently detailed. In response to the commenters' concerns we are finalizing §§422.562(d), 422.608, and 478.40(c) with modifications to specify in greater detail those part 405 provisions that implement provisions of section 1869 of the Act that are not also applicable to sections 1852 or 1155 of the Act, and that we do not believe apply to part 422, subpart M and part 478, subpart B adjudications. We specifically discussed three such provisions in section II.C of the proposed rule. The three specific topics covered by part 405, subpart I that implement provisions of section 1869 of the Act and that we believe do not apply to part 422, subpart M and part 478, subpart B adjudications are: (1) specific time frames to conduct adjudications at each level of administrative appeal (sections 1869(a)(3)(C)(ii), (c)(3)(C)(i),

(d)(1), and (d)(2) of the Act); (2) the option to request escalation of appeals when a QIC, OMHA, or the Council does not render a decision within an applicable adjudication time frame (sections 1869(c)(3)(C)(ii) and (d)(3) of the Act); and (3) the requirement that a provider or supplier, or beneficiary represented by a provider or supplier, must establish good cause to introduce evidence that was not presented at the reconsideration by the QIC (section 1869(b)(3) of the Act). Because these provisions of section 1869 of the Act were discussed in the proposed rule as examples of provisions that are not also included in sections 1852 and 1155 of the Act, and that we do not believe apply to appeals and hearings under part 422, subpart M and part 478, subpart B, and because these three areas have historically been the subject of the greatest confusion for appellants and OMHA staff regarding application of part 405 rules to other parts, we are finalizing the proposal with respect to those three areas. We will conduct additional notice and comment rulemaking if we identify additional provisions in the part 405, subpart I rules that implement provisions of section 1869 of the Act that are not also included in sections 1852(g) and 1155 of the Act, and we believe those provisions should not apply to part 422, subpart M and part 478, subpart B adjudications. Furthermore, we believe that listing the specific sections of part 405, subpart I that do not apply in MA program appeals under part 422, subpart M, and in appeals of QIO reconsidered determinations under part 478, subpart B addresses commenters' concerns regarding confusion or ambiguity.

Section 1869(d)(1)(A) of the Act provides that unless the appellant waives the statutory adjudication time frame, the ALJ conducts and concludes a hearing on a decision of the QIC and renders a decision no later than the end of the 90-day period beginning on the date a request for hearing is timely filed. In addition, section 1869(d)(2) of the Act provides that the DAB conducts and concludes a review of the decision on a hearing and renders a decision no later than the end

of the 90-day period beginning on the date a request for review is timely filed. Sections 1852(g)(5) and 1155 of the Act do not contain similar adjudication time frames for an ALJ and DAB to render a decision. Therefore, we are specifying in §§422.562(d) and 478.40(c), and in §422.608 through reference to §422.562(d)(2), that the adjudication time frames at the OMHA level and the Council in part 405 do not apply in proceedings under either part 422, subpart M or part 478, subpart B. Similarly, because the part 405 escalation provisions originate in section 1869(c)(3)(C)(ii) and (d)(3) of the Act and are not incorporated into sections 1852(g) or 1155 of the Act, and the part 405 rules for adjudication time frames for an ALJ or the Council do not apply, we are specifying that the options to request escalation of an appeal in part 405 do not apply in proceedings under either part 422, subpart M or part 478, subpart B. In addition, we do not think it would be appropriate to apply the part 405, subpart I rules to time frames for adjudications below the OMHA level for Part C and QIO appeals because those parts already contain regulations regarding time frames and expediting appeals that are different from the part 405, subpart I provisions. For example, under §422.572(f) and §422.590(g), if an MAO fails to provide the enrollee with timely notice of an expedited organization determination or expedited reconsideration, the failure constitutes an adverse determination; the adverse decision then, respectively, is subject to appeal or must be forwarded to the IRE. With respect to OMHA-level adjudication time frames and the option to escalate an appeal from the OMHA level to the Council, we note that §405.1016, as finalized in this rule, applies only to requests for a hearing filed after a QIC has issued a reconsideration. In the final rule establishing the MA program, CMS stated that part 405 regulatory provisions that are dependent upon QICs would not apply to part 422, subpart M adjudications because an IRE—not a QIC—conducts reconsiderations for MA appeals (70 FR 4588, 4676). We believe the same rationale extends to reconsiderations

conducted by a QIO under part 478, subpart B. We also believe it is unwise to extend the adjudication time frames to additional cases or to create an option for escalation of an appeal where such provisions are not required by statute given the current volume of pending appeals at OMHA and the Council. However, we note that the vast majority of MA and QIO appeals are filed by beneficiaries and enrollees, and current OMHA and Council policy provides for the prioritization of appeals filed by beneficiaries or enrollees. Thus, we anticipate that there will be little change in adjudicatory processing times for most appellants in MA program appeals and appeals of QIO reconsidered determinations. Accordingly, we do not believe that the policies we are finalizing above will take away current protections or safeguards for beneficiaries.

In addition, section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC reconsideration unless there is good cause that precluded the introduction of such evidence at or before that reconsideration. Several provisions in part 405 implement this limitation on the submission of new evidence by providers and suppliers, as well as beneficiaries represented by providers and suppliers, and further implement rules for the review of whether good cause exists for late submissions. Neither section 1852(g)(5) nor section 1155 of the Act contains a similar limitation on the submission of new evidence by providers and suppliers if such evidence was not presented at an earlier stage in the appeal proceedings. Furthermore, the requirement to show good cause for the introduction of new evidence applies to evidence that was not presented at the QIC reconsideration and, as noted above, part 405 provisions that are dependent upon QICs do not apply to adjudications under part 422, subpart M, and we believe the same rationale extends to reconsiderations conducted by QIOs under part 478, subpart B. Therefore, we are specifying in §§422.562(d) and 478.40(c), and in §422.608 through reference to §422.562(d)(2), that the good cause limitations on new

evidence submitted by providers, suppliers, and beneficiaries represented by a provider or supplier, outlined in part 405, subpart I do not apply in proceedings under part 422, subpart M or part 478, subpart B. Although two commenters expressed concern that the proposals could mean that an enrollee in the MA program would not be able to invoke the protection of current §405.1018(d), these finalized rules specifically identify §§405.1018(c), 405.1028(a), and 405.1122(c) as part 405 sections that do not apply in part 422, subpart M, and therefore the protections afforded to unrepresented beneficiaries in current §405.1018(d) are unnecessary in part 422, subpart M appeals because there is no need for any appellant in a Part C appeal to show good cause for the introduction of new evidence for the first time at the OMHA level. As we stated above, we do not believe that the policies we are finalizing will take away current protections or safeguards for beneficiaries appealing an MA organization determination (or cost plan determination) or appealing from a QIO determination.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the following changes to §§422.562(d), 422.608, and 478.40(c). We are specifying in §§422.562(d) and 478.40(c), and in 422.608 through reference to §422.562(d)(2), those specific provisions of part 405, subpart I discussed in the proposed rule that are not applicable to MA program appeals under part 422, subpart M or appeals of QIO reconsidered determinations under part 478, subpart B, as discussed above. The provisions we are specifying are: (1) §405.950 (time frames for making a redetermination); (2) §405.970 (time frame for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level); (3) §405.1016 (time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council); (4) The option to request that an

appeal be escalated from the OMHA level to the Council as provided in §405.1100(b) and the time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in §405.1100(c) and (d); (5) §405.1132 (request for escalation to Federal court); and (6) §§405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c) and any other references to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

4. OMHA References

When the 2005 Interim Final Rule was published in March 2005, implementing the part 405, subpart I rules, OMHA was not yet in operation. Further, processes and procedures were being established under the part 405 subpart I rules, with new CMS contractors and the newly transitioned ALJ hearing function. Since that time, OMHA and CMS and its contractors have developed operating arrangements to help ensure appeals flow between CMS contractors and OMHA, and that appeal instructions for appellants provide clear direction on how and where to file requests for hearings and reviews. However, many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule, and OMHA is not mentioned in the regulation text.

To provide clarity to the public on the role of OMHA in administering the ALJ hearing program, and to clearly identify where requests and other filings should be directed, we proposed to define OMHA in §405.902 as the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act. We also proposed to amend rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B

to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. To implement these changes, we proposed to revise provisions throughout part 405 subparts I and J, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections in section III of the proposed rule.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received three comments on this proposal. One commenter supported the proposal as necessary to update regulatory language to clearly reflect the role of OMHA in administering ALJ appeals. Two commenters opposed the proposal. One commenter argued that each change from “ALJ” to “OMHA” takes a specific power granted directly to an ALJ adjudicating a case and transfers it to OMHA administrators. Another commenter interpreted the proposal as a transfer of control over ALJs’ workloads from ALJs to OMHA.

Response: We disagree with the commenters’ interpretation of the proposal as a transfer of authority from ALJs to OMHA administrators. Rather, the proposal provides clarity to the public on the role of OMHA in administering the ALJ hearing program and clearly identifies where requests and other filings should be directed to ease appellant confusion and more efficiently process appeals by helping to ensure filings are properly routed. As discussed above (and in section II.D of the proposed rule), many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule. OMHA was not yet in operation or mentioned in the regulation text at the time the Interim Final Rule was published in March 2005. We believe that reference to OMHA or an

OMHA office in place of current references to an unspecified entity, ALJs, and ALJ hearing offices would provide a clearer explanation of a topic in certain regulations and would clarify areas of the regulations that may have confused appellants in the past. For example, current §405.970(e)(2)(ii) states that, for cases that have been escalated from the reconsideration level of appeal to the OMHA level of appeal, the QIC forwards the case file “to the ALJ hearing office.” The concept of an ALJ hearing office is most analogous to OMHA’s individual field offices. In practice, however, the QIC sends case files for escalated cases to a centralized location, not to individual field offices. Thus, we believe reference to OMHA would be more appropriate here. Similarly, as another example, current §405.1104 states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be “pending before the ALJ” at the end of an applicable adjudication time period under §405.1016 may request to escalate the appeal to the Council level of review. However, appeals that are eligible to be escalated may be unassigned and not yet before an ALJ. Thus, we believe that it would be appropriate to state “pending with OMHA” in this regulation (see §405.1016(f)(1), as finalized).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals without modification to define OMHA and replace certain references to ALJs, ALJ hearing offices, and unspecified entities with a reference to OMHA or an OMHA office.

5. Medicare Appeals Council References

The Council is currently referred to as the “MAC” throughout current part 405, subpart I; part 422, subpart M; and part 423, subparts M and U. This reference has caused confusion in recent years with the transition from Fiscal Intermediaries and Carriers, to Medicare administrative contractors—for which the acronym “MAC” is also commonly used—to process

claims and make initial determinations and redeterminations in the Medicare Part A and Part B programs. In addition, current §§422.618 and 422.619 reference the Medicare Appeals Council but use “Board” as the shortened reference, and part 478, subpart B, references the DAB as the reviewing entity for appeals of ALJ decisions and dismissals but the Council is the entity that conducts reviews of ALJ decisions and dismissals, and issues final decisions of the Secretary for Medicare appeals under part 478, subpart B.

To address potential confusion with references to Medicare administrative contractors and align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals throughout part 405, subpart I; part 422, subpart M; and part 423, subparts M and U, we proposed to amend the following rules to replace “MAC” or “Board” with “Council”:

§§405.902, 405.904, 405.906, 405.908, 405.910, 405.926, 405.980, 405.982, 405.984, 405.990, 405.1026, 405.1036, 405.1037, 405.1042, 405.1046, 405.1048, 405.1050, 405.1052, 405.1054, 405.1060, 405.1062, 405.1063, 405.1100, 405.1102, 405.1104 (as re-designated and revised as proposed §405.1016(e)–(f)), 405.1106, 405.1108, 405.1110, 405.1112, 405.1114, 405.1116, 405.1118, 405.1120, 405.1122, 405.1124, 405.1126, 405.1128, 405.1130, 405.1132, 405.1134, 405.1136, 405.1138, 405.1140, 422.561, 422.562, 422.608, 422.612, 422.616, 422.618, 422.619, 422.622, 422.626, 423.560, 423.562, 423.1968, 423.1974, 423.1976, 423.1978, 423.1980, 423.1982, 423.1984, 423.1990, 423.2026, 423.2036, 423.2042, 423.2046, 423.2048, 423.2050, 423.2052, 423.2054, 423.2062, 423.2063, 423.2100, 423.2102, 423.2106, 423.2108, 423.2110, 423.2112, 423.2114, 423.2116, 423.2118, 423.2120, 423.2122, 423.2124, 423.2126, 423.2128, 423.2130, 423.2134, 423.2136, 423.2138, and 423.2140.

In addition, to align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals in part 478, subpart B, we proposed to amend §§478.46 and 478.48 to

replace “Departmental Appeals Board” and “DAB,” with “Medicare Appeals Council” and “Council”.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received two comments on this proposal—one of which was a collective comment submitted by the four then-current CMS DME Medicare Administrative Contractors (MACs). Both comments supported the proposal to replace references to “MAC” with “Council” as necessary to reduce confusion between the Council and CMS Medicare Administrative Contractors.

Response: We thank the commenters for their support and agree that the proposed revisions will reduce confusion.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals without modification to replace references to “MAC” and “Board,” with “Council” in the sections listed above, and to replace references to “Departmental Appeals Board” and “DAB” with “Medicare Appeals Council” and “Council” in §§478.46 and 478.48. In addition to the sections listed above, we are also making a conforming technical revision to §423.558(b) to replace the reference to “MAC” in §423.558(b) with “Council.”

B. Specific provisions of part 405, subpart I and Part 423, subparts M and U

1. Overview

Part 405, subpart I and part 423, subpart U contain detailed procedures for requesting and adjudicating a request for an ALJ hearing, and a request for a review of a QIC or IRE dismissal. Part 423, subpart U provisions were proposed in the March 17, 2008 Federal Register (73 FR

14342) and made final in the December 9, 2009 Federal Register (74 FR 65340), and generally follow the part 405, subpart I procedures. In this final rule, we generally discuss provisions of the proposed rule related to part 405, subpart I, and then whether any aligning revisions to part 423, subpart U, were proposed, unless a provision is specific to part 405 and there is no corresponding part 423 provision. We then discuss the policies we are finalizing in this final rule related to parts 405 and 423.

2. General provisions, reconsiderations, reopenings, and expedited access to judicial review

a. Part 423, subpart M general provisions (§423.562)

Current §423.562(b)(4) lists the appeal rights of a Part D plan enrollee, if the enrollee is dissatisfied with any part of a coverage determination. Specifically, paragraph (b)(4)(v) describes the right to request Council review of the ALJ's hearing decision if the ALJ affirms the IRE's adverse coverage determination in whole or in part, and paragraph (b)(4)(vi) describes the right to judicial review of the hearing decision if the Council affirms the ALJ's adverse coverage determination in whole or in part, and the amount in controversy requirements are met. We proposed revisions to paragraphs (b)(4)(v) and (vi) to account for the possibility that an appeal at the OMHA level could be decided by an attorney adjudicator or by an ALJ without conducting a hearing. 81 FR 43790, 43797. We proposed to revise paragraph (b)(4)(v) to insert "or attorney adjudicator" after each instance of "the ALJ." We stated in the proposed rule that this proposal was necessary to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), by stating the right to request Council review of an attorney adjudicator decision that affirms the IRE's adverse coverage determination. We also proposed to remove "hearing" before "decision" in paragraph (b)(4)(v) to reflect that an attorney adjudicator

issues decisions without conducting a hearing, and an ALJ may issue a decision without conducting a hearing.

In paragraph (b)(4)(vi), we proposed to remove “ALJ’s” and insert “ALJ’s or attorney adjudicator’s” in its place to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), by including an attorney adjudicator’s decision as a decision that may be affirmed by the Council. We also proposed to remove “hearing” before “decision” in paragraph (b)(4)(vi) because while the Council may conduct a hearing, Council decisions are generally issued without conducting a hearing, and the decision of the Council is subject to judicial review.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §423.562 as proposed without modification.

b. Part 423, subpart U title and scope (§423.1968)

The current heading of part 423, subpart U references ALJ hearings but does not reference decisions. We proposed to revise the heading by replacing “ALJ Hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions” to reflect that subpart U covers decisions by ALJs and attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43797.

Current §423.1968 explains the scope of the requirements in subpart U. We proposed in §423.1968 to expand the scope of subpart U to include actions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43797. Specifically, we proposed at §423.1968(a) to add that subpart U sets forth requirements relating to attorney adjudicators with respect to reopenings; at §423.1968(b) to add that subpart U sets forth requirements relating to ALJ decisions and decisions of attorney adjudicators if no hearing is conducted; and at §423.1968(d) to add that subpart U sets forth the requirements relating to Part D enrollees' rights with respect to ALJ hearings and ALJ or attorney adjudicator reviews. We stated that these changes are necessary to accurately describe the scope of the revised provisions of subpart U to implement the attorney adjudicator proposal discussed in section II.B of the proposed rule and II.A.2 of this final rule above.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §423.1968 as proposed without modification.

c. Medicare initial determinations, redeterminations and appeals: General description (§405.904)

Section 405.904(a) provides a general overview of the entitlement and claim appeals process to which part 405, subpart I applies. Current paragraphs (a)(1) and (a)(2) provide that if a beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, the beneficiary may request that the Council review the case. To provide for the possibility that a

decision may be issued without conducting a hearing by an ALJ, as permitted under current rules, or an attorney adjudicator, as proposed in II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), we proposed to add language in paragraphs (a)(1) and (a)(2) to provide that if the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator when no hearing is conducted, the beneficiary may request that the Council review the case. We stated in the proposed rule that this would provide a comprehensive overview of the entitlement and claim appeals process, with information on the potential for and right to appeal decisions by ALJs when no hearing is conducted, and the right to appeal decisions by attorney adjudicators. 81 FR 43790, 43797.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on this proposal. The commenter supported our proposal as necessary to ensure that beneficiaries' concerns were given appropriate consideration by clearly stating that there is a right to request that the Council review a case when no hearing is conducted and a decision is issued by an ALJ or attorney adjudicator.

Response: We thank the commenter for its support. We believe the changes will help beneficiaries (and others appellants pursuant to §405.904(b)) understand that they have the same right to appeal decisions by ALJs when no hearing is conducted, or decisions by attorney adjudicators, as they currently have to appeal decisions by an ALJ when a hearing is conducted.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.904 as proposed, with the following modifications. We are removing "Administrative Law Judge (ALJ)" and "Medicare Appeals Council (Council)" from paragraph (a)(1) and adding "ALJ" and "Council" in their

places, respectively, for consistency with the rest of part 405, subpart I and because the term “ALJ” is already defined in §405.902.

d. Parties to the initial determinations, redeterminations, reconsiderations proceedings on a request for hearing, and Council review (§405.906)

Section 405.906 discusses parties to the appeals process and subsection (b) addresses parties to the redetermination, reconsideration, hearing and MAC. We proposed in the paragraph heading and introductory text to subsection (b) to replace the phrases “hearing and MAC” and “hearing, and MAC review,” respectively, with “proceedings on a request for hearing, and Council review” because, absent an assignment of appeal rights, the parties are parties to all of the proceedings on a request for hearing, including the hearing if one is conducted, and they are parties to the Council’s review. 81 FR 43790, 43797.

We received no comments on this proposal, other than comments in support of our general proposals to replace references to “MAC” and “Board,” with “Council,” and to replace references to “Departmental Appeals Board” and “DAB” with “Medicare Appeals Council” and “Council,” as discussed in section II.A.5 above. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.906 as proposed without modification.

e. Medicaid State agencies (§405.908)

Section 405.908 discusses the role of Medicaid State agencies in the appeals process and states that if a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC and judicial review levels. We proposed to replace “ALJ” with “OMHA” to provide that the State agency has party status regardless of the adjudicator assigned to the State agency’s request for an ALJ hearing or request for review of a QIC dismissal at the OMHA level

of review, as attorney adjudicators may issue decisions on requests for hearing and adjudicate requests for reviews of QIC dismissals, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43797–43798.

Provided below is a summary of the specific comment received and response to the comment:

Comment: We received one comment on this proposal. The commenter supported the proposal to clarify that Medicaid State agencies that file a request for redetermination have the right to retain party status at the OMHA level regardless of whether a case is assigned to an ALJ or to an attorney adjudicator. However, the commenter asked that the term “OMHA level of review” be replaced with “and attorney adjudicator or ALJ review,” or, alternatively, that the term “OMHA level of review” be defined as the level of review that entails review by an ALJ or attorney adjudicator, and used consistently throughout the regulations. The commenter expressed concern that the term “OMHA level of review” could be confusing because the term is not currently in common use.

Response: We thank the commenter for the recommendation. As a preliminary matter, we note that the changes proposed in §405.908 to which the commenter is referring would revise the last sentence to read, “If a State agency files a request for redetermination, it may retain party status at the QIC, OMHA, Council, and judicial review levels.” The word “review” in this sentence is part of the term “judicial review” as described in §405.1136, rather than a general descriptor of all levels of appeal. Therefore, we believe the term to which the commenter objects can more accurately be described as the “OMHA level.” We believe the term “OMHA level” provides a convenient shorthand for referring to the adjudication level that entails an ALJ hearing, or an on-the-record review by an ALJ or attorney adjudicator, and we note that the term

is also used in proposed §§405.910, 405.956, 405.976, 405.1028, 405.1032, 405.1046, 405.1100, 405.1108, 405.1110, 405.1122, 423.2032, 423.2110, and 423.2122. We do not share the commenter's concern that the term as used in proposed §405.908 or elsewhere in part 405, subpart I or part 423, subparts M and U is confusing, especially in light of the proposed addition of "OMHA" and "attorney adjudicator" to the definitions being finalized in §405.902, which collectively define OMHA as administering the ALJ hearing process in accordance with section 1869(b)(1) of the Act, and attorney adjudicators as employees of OMHA who are authorized to take actions under subpart I on requests for ALJ hearing.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.908 as proposed without modification.

f. Appointed representatives (§405.910)

As described below, we proposed a number of revisions to the rules in §405.910 concerning the appointment of a representative to act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. 81 FR 43790, 43798–43799. The 2002 Proposed Rule (67 FR 69318 through 69319) explained that the §405.910 requirements for a valid appointment of a representative are necessary to help ensure that adjudicators are sharing and disseminating confidential information with the appropriate individuals. The 2005 Interim Final Rule (70 FR 11428 through 11431) adopted a general requirement to include a beneficiary's health insurance claim number (HICN) for a valid appointment of a representative in §405.910(c)(5). The SMART Act Final Rule (80 FR 10614, 10617) revised §405.910(c)(5) to explicitly limit the requirement to include a beneficiary's HICN to instances in which the beneficiary is the party appointing a representative. However, the Medicare manual provision for

completing a valid appointment of representative (Medicare Claims Processing Manual (Internet-Only Manual 100-4), chapter 29, section 270.1.2) details the requirements for an appointment of representation to contain a unique identifier of the party being represented. Specifically, if the party being represented is the beneficiary, the Medicare number must be provided, and if the party being represented is a provider or supplier, the National Provider Identifier (NPI) number should be provided. Additionally, the official form for executing a valid appointment of representative (form CMS-1696 (OMB No. 0938-0950), available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1696.pdf>) provides a blank space for the party to include a Medicare or NPI number. To assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, we proposed to revise §405.910(c)(5) to add a requirement to include the Medicare NPI of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative. We stated in the proposed rule that we were retaining the requirement to identify the beneficiary's Medicare HICN when the beneficiary is the party appointing a representative.

Section 405.910 also addresses defective appointments, and delegations and revocations of appointments. However, there has been confusion on the effects on the adjudication of an appeal when a defective appointment must be addressed, or when an adjudicator is not timely informed of a delegation or revocation of an appointment. To address the effect of a defective appointment on the adjudication of an appeal to which an adjudication time frame applies, we proposed to add §405.910(d)(3), which would extend an applicable adjudication time frame from the later of (1) the date that a defective appointment of representative was filed or (2) the date the current appeal request was filed by the prospective appointed representative, to the date that the defect in the appointment was cured or the party notifies the adjudicator that he or she will

proceed with the appeal without a representative. We proposed this revision because, in accordance with §405.910(d)(1) and (d)(2), a prospective appointed representative lacks the authority to act on behalf of a party and is not entitled to obtain or receive any information related to the appeal. Thus, contact with the party may be necessary to obtain missing information from the appointment, which may delay adjudicating the appeal until the appointment is cured or the party decides to proceed with the appeal without a representative. However, we proposed that if the request was filed by a prospective appointed representative, the request would be considered filed for the purpose of determining timeliness of the request, even if the individual is not the appointed representative after the appointment is cured, or the party decides to proceed with the appeal without a representative.

We also proposed at §405.910(f)(1) to replace “ALJ level” with “OMHA level” so there would be no confusion that proceedings at the OMHA level are considered proceedings before the Secretary for purposes of appointed representative fees, regardless of whether the case is assigned to an ALJ or attorney adjudicator.

Section 405.910(i)(2) and (i)(3) provide that if an appeal involves an appointed representative, an ALJ sends notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative. We proposed to insert “or attorney adjudicator” after “ALJ” in §405.910(i)(2) and (i)(3). This would provide that attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), like an ALJ under the current provisions, would send notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative.

A representative and/or the represented party is responsible for keeping the adjudicator of a pending appeal current on the status of the representative. In practice, sometimes adjudicators are not informed of a delegation or revocation of an appointment of representative that has been filed for an appeal, which results in confusion and potentially duplicative or unnecessary proceedings. We proposed to revise §405.910(1)(2) (which, as described later, we proposed to re-designate as (1)(1)(ii)) to add that a delegation is not effective until the adjudicator receives a copy of the party's written acceptance of the delegation, unless the representative and designee are attorneys in the same law firm or organization, in which case the written notice to the party of the delegation may be submitted if the acceptance is not obtained from the party. This revision would emphasize the importance of keeping adjudicators current on the status of the representative and also state the effects of failing to do so. The revisions we proposed to §405.910(1)(2) (re-designated as proposed (1)(1)(ii)) would also serve to assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, and to provide adjudicators with appropriate contact information for scheduling purposes. To accommodate proposed paragraph (1)(2), we proposed to re-designate current paragraph (1), except for the title of the paragraph, as paragraph (1)(1), and to also re-designate the current subparagraphs accordingly. In addition, we proposed to add a missing "by" in current paragraph (1)(1)(ii) (re-designated as (1)(1)(i)) of §405.910 to indicate that a designee accepts to be obligated "by" and comply with the requirements of representation. We also proposed to revise language in current paragraph (1)(2) (re-designated as proposed (1)(1)(ii)) of §405.910 to clarify that "this signed statement" refers to the "written statement signed by the party," and the written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice of intent to delegate under

paragraph (l)(1)(i) indicates that fact. To further emphasize the importance of keeping adjudicators current on the status of the representative and clarify the effects of failing to do so, we also proposed to add at §405.910(l)(3) and (m)(4) that a party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated or revoked, respectively, is not good cause for missing a deadline or not appearing at a hearing.

We did not propose any changes for part 423, subpart U because it does not have a corresponding provision for representative appointments.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: Two commenters expressed concern that the proposed changes will not resolve the inefficiencies and inconsistencies that parties currently experience when appointing and changing representatives. The commenters recommended that instead of adding additional regulations, changes are needed in OMHA's internal procedures for receiving and processing appointments of representatives and changes in representatives to ensure that these appointments and changes are processed efficiently and consistently.

Response: OMHA is currently implementing several tools that we believe will assist with making our internal processing procedures more consistent, more efficient, and more appellant-friendly. The OCPM, available on the OMHA website, establishes uniform day-to-day procedures for processing appeals at the OMHA level of adjudication, including a detailed chapter outlining procedures related to representatives. OMHA is also developing an electronic case management system that will streamline case processing and will have a public facing portal for appellants and representatives to electronically file documents, including relevant appointment of representative forms, and to check the status of appeals online. OMHA maintains

a toll free beneficiary help line and an OMHA national toll free line to assist beneficiaries and other appellants with questions regarding their appeals. Finally, OMHA provides in-house training periodically to its ALJs, attorneys, and other staff to help ensure understanding and compliance with all regulations and internal policy applicable to processing appeals. We anticipate that these tools and ongoing training will help improve OMHA's case processing and address the commenters' concerns. However, we note that OMHA is responsible for protecting the personally identifiable information and protected health information contained in the administrative record, and as such, requires changes in representation to be filed for each appeal to which the change is applicable. We believe the tools discussed above and the proposed changes to the regulation that we are adopting in this final rule, will help to ensure the administrative record for the appeal is complete, and the authorization for the representative to receive appeal-related information is present for each appeal.

Comment: One commenter asked whether the regulations required use of the beneficiary's entire Medicare health insurance claim number (HICN) for a valid appointment of representative or if an abbreviated HICN is adequate, and whether it is statutorily required to send a copy of the appointment of representative form to the other parties when the representative files an appeal or if it is sufficient to include it only in the copy of the appeal request that is sent to the "DME MAC, QIC, ALJ, or adjudicator."

Response: We note as an initial matter that the proposed changes to §405.910 do not specifically address or impact either of the questions asked by the commenter. The regulation at §405.910(c)(5), which is also carried over into §405.910(c)(5) as finalized in this rule, requires that when a beneficiary is the represented party, a valid appointment must include the beneficiary's HICN. The language of the regulation does not permit an abbreviated or partial

identification and therefore a complete HICN is required. With respect to the commenter's second question, the regulation at §405.910(c)(7), which is carried over into the §405.910(c)(7) as finalized in this rule, states that to be valid, the appointment of representation must be filed with the entity processing the party's initial determination or appeal. There is no requirement in section 1869 of the Act or in part 405, subpart I to send a copy of an appointment of representative to other parties to the appeal. While section III.A.3.g.v of the proposed rule (discussed in section II.B.3.g.v of the final below) addresses certain copy requirements when submitting a request for hearing, the Appointment of Representative form is not specifically addressed in that section. Section 405.1014(d)(1), as finalized in this rule, states that if additional materials submitted with a request are necessary to provide the information required for a complete request in accordance with §405.1014(b), copies of those materials must be sent to the other parties as well. With respect to representative information, §405.1014(a)(1)(iii), as finalized in this rule, specifies that a request for hearing must contain the name, address, and telephone number of the designated representative and does not separately require that the appellant also provide a copy of the Appointment of Representative form. However, to the extent the request for hearing does not otherwise contain this information, a copy of the Appointment of Representative form may be sent to the other parties to fulfill this requirement. With regard to appeals filed with a Medicare Administrative Contractor and QIC, there is no requirement, statutory or otherwise, that an appellant provide a copy of a request for appeal or any other filings to the other parties to the appeal. Although the commenter did not specifically mention requests for review filed with the Council, we note that §405.1106(a) and (b), as finalized in this rule, require that appellants send requests for Council review or request for escalation to the entity specified in the notice of the ALJ's or attorney adjudicator's action or to OMHA

respectively, and copies of the request to the other parties who received notice of the ALJ or attorney decision or dismissal or the QIC reconsideration, respectively. Section 405.1112, as finalized, requires that the request for review or escalation contain the name and signature of the representative. As with requests for an ALJ hearing, if the request for Council review or escalation does not otherwise include the representative's name or signature, a copy of the Appointment of Representative form may be sent to the other parties in fulfillment of the copy requirements in §405.1106(a) and (b).

Comment: Two commenters noted that the official form used for appointment of a representative (CMS-1696) required revisions to address certain appointments and representatives. One commenter indicated that the form did not provide for a physician's National Provider Identification number (NPI) when the party being represented is a physician. Another commenter noted that the form should include a place for a health plan to indicate "the name/title of [its] representative and whether they will be attending as a witness, representative, or medical expert."

Response: Form CMS-1696 provides that when the party being represented is a provider, the provider's NPI must be provided, and contains a box at the top of the form after the party name for either the HICN or National Provider Identifier number. In the context of an NPI, the term "provider" has been given a broader definition than in other Medicare contexts. When the final rule adopting the NPI as the standard unique health identifier for health care providers for use in the health care system was published in 2004, the term "health care provider" was defined as "a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in

the normal course of business.”45 CFR §160.103. In §405.902, the term “provider” is defined more narrowly as “a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.” “The term “supplier” is separately defined as “unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.”

Consistent with existing Medicare manual provisions found in chapter 29, section 270.1.2 of the Medicare Claims Processing Manual (Internet-Only Manual 100-4), §405.910(c)(5), as finalized in this rule, expressly requires that when a provider or supplier is the party appointing a representative, the provider’s or supplier’s NPI must be provided in order to create a valid appointment, and a physician is included in the §405.902 definition of supplier. We thank the commenters for the suggestion to revise form CMS-1696, and may consider the suggestion for potential future clarification to the form. However, we note that the regulation is the binding authority, and parties wishing to appoint a representative must comply with the requirements of §405.910.

With respect to the second comment, the commenter is correct that form CMS-1696 does not currently address appointment of a representative by a health plan. The MAO is a party to a Part C MA appeal, and an applicable plan (which may be a health plan) may be a party to an appeal involving a Medicare Secondary Payer (MSP) overpayment recovery assessed against the applicable plan. Although the form does not currently address health plans, health plans may use

form CMS-1696, instead of a providing a separate notice that complies with §405.910(c). However, in our experience, the individuals who file an appeal or appear at a hearing on behalf of health plans are generally employees of the plan, including medical directors, physician or nurse advisors, regulatory analysts, or in-house counsels. Indeed, this appears consistent with the commenter's request for a space to indicate whether the "representative" will be attending as a witness, representative, or medical expert. An appointment of representation under §405.910 is not necessary where an individual who is employed by the plan is the person filing the appeal or appearing on behalf of the plan, and a representative, as that term is used in §405.910, generally does not serve as a witness or medical expert in an appeal. Nevertheless, there may be instances where a health plan or applicable plan wishes to appoint a non-employee representative. In these instances §405.910(a) is clear that any party to an appeal may appoint a representative. We note, however, that health plans and applicable plans that opt to use form CMS-1696 to appoint a representative would not have HICNs or NPIs, and would not need to complete that box, and we did not propose to require that another unique identifier be included in appointments of representative where a health plan or applicable plan is the party being represented.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes noted above to §405.910 as proposed without modification.

g. Actions that are not initial determinations (§405.926)

Current §405.926(l) provides that an ALJ's decision to reopen or not to reopen a decision is not an initial determination, and in accordance with the introductory language of §405.926, is therefore not appealable under subpart I. In section III.A.2.1 of the proposed rule, we proposed to revise the reopening rules to provide that attorney adjudicators would have the authority to

reopen their decisions to the same extent that ALJs may reopen their decisions under the current provisions. We proposed to insert “or attorney adjudicator’s” after “ALJ’s” in §405.926(l) to provide that the attorney adjudicator’s decision to reopen or not reopen a decision also is an action that is not an initial determination and therefore not an appealable action under subpart I. 81 FR 43790, 43799.

Current §405.926(m) provides that a determination that CMS or its contractors may participate in or act as parties in an ALJ hearing is not an initial determination, and in accordance with the introductory language of §405.926, is therefore not appealable under subpart I. As explained in section III.A.3.f of the proposed rule and II.B.3.f of this final rule below, we proposed to revise §405.1010, which currently discusses when CMS or a contractor may participate in an ALJ hearing. As explained in the proposal to revise §405.1010, CMS or a contractor may elect to participate in the proceedings on a request for an ALJ hearing for which no hearing is conducted, in addition to participating in an ALJ hearing as a non-party participant. To align with our proposed revision to §405.1010, we proposed to revise §405.926(m) to indicate that CMS or its contractors may participate in the full scope of the proceedings on a request for an ALJ hearing, including the hearing, by replacing “participate in or act as parties in an ALJ hearing,” with “participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing.” 81 FR 43790, 43799.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 of the final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments

discussed in sections III.A.3.f.i through III.A.3.f.iii of this final rule below related to our proposals regarding CMS and CMS contractors as participants or parties in the adjudication process. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.926 as proposed without modification.

h. Notice of a redetermination (§405.956)

Current §405.956(b)(8) requires that the notice of a redetermination include a statement that evidence not submitted to the QIC is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously. We proposed to remove “an ALJ hearing” and add “the OMHA level” in its place so that the notice of a redetermination is clear that, absent good cause and subject to the exception in §405.956(d) for beneficiaries not represented by a provider or supplier, evidence that was not submitted to the QIC is not considered by an ALJ or an attorney adjudicator, as defined in section II.B of the proposed rule and II.A.2 of this final rule above. 81 FR 43790, 43799.

We received no comments on this proposal, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.956 as proposed without modification.

i. Time frame for making a reconsideration following a contractor redetermination, withdrawal or dismissal of a request for a reconsideration, and reconsideration (§§405.970, 405.972, and 405.974)

As discussed in the 2005 Interim Final Rule (70 FR 11444 through 11445) and the 2009 Final Rule (74 FR 65311 through 65312), HHS adopted a policy of providing for one level of administrative review of a dismissal of a request for appeal. As a result, an adjudicator's decision or dismissal when reviewing a dismissal action issued at the previous level is binding and not subject to further review. The policy balances a party's need for review and the need for administrative finality. The policy is embodied in the rules relating to reviews of dismissals at the next adjudicative level in §§405.972(e), 405.974(b)(3), 405.1004(c), 405.1102(c), 405.1108(b), and 405.1116.

At the QIC level of appeal, a review of a contractor redetermination and a review of a contractor's dismissal of a request for a redetermination are both characterized as a "reconsideration." While the outcome of a QIC's reconsideration of a contractor dismissal is differentiated and further reviews are not permitted in accordance with §405.974(b)(3), an ambiguity exists with regard to the time frame for completing this type of reconsideration and escalation options when that time frame is not met. Current §405.970 establishes the time frame for making a reconsideration without further qualification. However, section 1869(b)(1)(D)(i) of the Act establishes that a right to a reconsideration of an initial determination (which includes a redetermination under section 1869(a)(3)(D) of the Act) exists if a timely request for a reconsideration is filed within 180 days following receipt of a contractor's redetermination, which is discussed in §405.962. In contrast, §405.974(b)(1) requires that a request for a QIC reconsideration of a contractor's dismissal of a request for redetermination be filed within 60 calendar days after receiving the contractor's notice of dismissal. Section 1869 of the Act does not address dismissals. Rather, section 1869(c)(3)(C)(i) and (c)(3)(C)(ii) of the Act only provide

for a time frame to complete a reconsideration of an initial determination, and an option to escalate a case if that time frame is not met.

The effect of the ambiguity in §405.970 is the potential escalation of a request for a QIC reconsideration of a contractor's dismissal when the reconsideration is not completed within 60 calendar days of a timely filed request for a reconsideration of the dismissal, and a potential hearing being required in accordance with §405.1002(b). The potential effect of this ambiguity is contrary to the policy of limiting reviews of dismissals to the next adjudicative level of administrative appeal, as well as the statutory construct for providing ALJ hearings after QIC reconsiderations of redeterminations, or escalations of requests for reconsiderations following a redetermination. We also note that in the parallel context of an ALJ review of a QIC's dismissal of a request for reconsideration, §§405.1002 and 405.1004 establish a clear distinction between a request for hearing following a QIC reconsideration and a request for a review of a QIC dismissal, and §§405.1016 and 405.1104 address the adjudication time frames for ALJ decisions, and the option to escalate an appeal to the Council when a time frame is not met, only in the context of a request for hearing, in accordance with section 1869(d)(1) and (d)(3)(A) of the Act.

To address this unintended outcome of §405.970, we proposed to amend the title of §405.970 and paragraphs (a), (b)(1), (b)(2), (b)(3), (c), (e)(1), and (e)(2)(i) to provide that the provisions would only apply to a request for a reconsideration following a contractor redetermination, and not to a request for QIC review of a contractor's dismissal of a request for redetermination. We stated in the proposed rule that these revisions would further our policy on reviews of dismissals and help appellants better understand what may be escalated to OMHA for an ALJ hearing. We also proposed to replace "the ALJ hearing office" in current paragraph (e)(2)(ii) with "OMHA" because the QIC sends case files for escalated cases to a centralized

location, not to individual field offices. We did not propose any parallel changes for part 423 because subpart U does not address IRE reconsiderations and subpart M does not have a provision with the same ambiguity. 81 FR 43790, 43799–43800.

To provide additional clarity to the procedures for reviews of dismissal actions, we also proposed to amend the text in §§405.972(b)(3), (e) and 405.974(b)(3), and the introductory text of §405.974(b) to replace the references to a “reconsideration” of a contractor’s dismissal of a request for redetermination with the word “review” so that the QIC’s action is referred to as a review of a contractor’s dismissal of a request for redetermination. We also proposed to revise the section heading of §405.972 to read “Withdrawal or dismissal of a request for reconsideration or review of a contractor’s dismissal of a request for redetermination,” and the section heading of §405.974 to read, “Reconsideration and review of a contractor’s dismissal of a request for redetermination.” We stated in the proposed rule that these revisions are consistent with the description of a reconsideration in section 1869(c)(3)(B)(i) of the Act and §405.968(a). As we stated in the proposed rule, a QIC’s review of a contractor dismissal action is limited to the appropriateness of the dismissal action and does not consist of a review of the initial determination and redetermination, which is the meaning attributed to a reconsideration. In reviewing a contractor dismissal action, the QIC either affirms or vacates the dismissal of the request for redetermination. If a dismissal action is vacated, the appeal is remanded back to the MAC to conduct a redetermination on the merits (§405.974). 81 FR 43790, 43800.

Current §405.972(e) provides that a QIC’s dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ under §405.1004. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we proposed that an attorney adjudicator may conduct a review of a QIC’s dismissal of a request for reconsideration and in

section III.A.3.c of the proposed rule (discussed in section II.B.3.c of this final rule below), we proposed to revise §405.1004 to provide the effect of an attorney adjudicator's action taken in reviewing the QIC dismissal is equivalent to the effect of an ALJ's action taken in reviewing the QIC dismissal. To align with our proposed revision to §405.1004, we proposed to insert "or attorney adjudicator" after "an ALJ" in §405.972(e) to indicate that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under §405.1004. 81 FR 43790, 43800.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.970, 405.972, and 405.974 as proposed without modification.

j. Notice of reconsideration (§405.976)

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the reconsideration conducted by a QIC unless there is good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. Under this authority, §405.976(b)(5)(ii) provides that a notice of reconsideration must include a summary of the rationale for the reconsideration that specifies that all evidence

that is not submitted prior to the issuance of the reconsideration will not be considered at the ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration; however, it does not apply to a beneficiary unless the beneficiary is represented by a provider or supplier or to state Medicaid agencies. The statement that the evidence will not be made part of the administrative record is inconsistent with our practice of making a complete record of the administrative proceedings for further reviews, including documents submitted by parties that were not considered in making the decision. Current §405.1028(c) states that if good cause does not exist, the ALJ must exclude the evidence from the proceedings and may not consider it in reaching a decision. However, it does not instruct the ALJ to remove the evidence from the administrative record, and to do so would preclude an effective review of the good cause determination. In addition, we noted in the 2005 Interim Final Rule (70 FR 11464) that under current §405.1042(a)(2), excluded evidence is part of the record because it states that in the record, the ALJ must also discuss any evidence excluded under §405.1028 and include a justification for excluding the evidence. To help ensure that the evidence is preserved in the administrative record, we proposed to delete "or made part of the administrative record" from the paragraph in §405.976(b)(5)(ii). 81 FR 43790, 43800.

Current §405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. As further discussed in section III.A.3.d of the proposed rule and II.B.3.d of the final rule below, we proposed revisions to §405.976(b)(7) along with revisions to the methodology for calculating the amount in controversy required for an ALJ hearing under §405.1006(d) to better align the amount in controversy with the actual amount in

dispute. Please refer to section III.A.3.d of the proposed rule and II.B.3.d of this final rule below for a discussion of these proposals.

We did not propose any changes to part 423 because subpart U does not address IRE reconsiderations and subpart M does not contain similar provisions.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter requested that the notice of reconsideration contain language clarifying that good cause does not exist for a provider's submission of new evidence for the first time at the OMHA level, if the documentation was in the provider's possession during an audit that results in an initial determination.

Response: We appreciate the commenter's input, but believe the regulations as finalized in this rule clearly indicate that providers and suppliers should submit all evidence that is relevant to their appeal as early in the appeal process as possible, and the circumstances in which an ALJ or attorney adjudicator may find good cause for the introduction of new evidence at the OMHA level (see §§405.966(a)(2), 976(b)(5)(ii), 405.1018, 405.1028, and 405.1030). We understand that appellants may not always know which documents are necessary to support their appeal. To assist appellants, contractors issuing redetermination notices are instructed at §405.956(b)(6) to identify "specific missing documentation," that should be submitted with the request for reconsideration. We encourage appellants to submit any and all evidence that may help with their appeal before the OMHA level. Section 405.1018 requires a provider, supplier, or a beneficiary represented by a provider or supplier, that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. We also believe the regulations, as finalized in this rule, clearly set forth

the consequences for not showing good cause. We proposed that §405.1018(c)(2) be added to state that if the provider or supplier, or beneficiary represented by a provider or supplier, fails to include the statement explaining why the evidence was not previously submitted, the evidence will not be considered. To strengthen the existing requirement for the full and early presentation of evidence, we are finalizing our proposed changes at §405.1018(c)(2), as discussed in section II.B.3.i below.

We proposed at §405.1028(a)(2)(i) through (v) to include specific instances when an ALJ or attorney adjudicator may find good cause for the introduction of new evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is submitted for the first time at the OMHA level, but the ultimate finding of whether there is good cause under these provisions would be at the discretion of the ALJ or attorney adjudicator. We believe that the proposed changes to §405.1028 that we are adopting provide sufficient guidance regarding the circumstances in which an ALJ or attorney adjudicator may find good cause, and thus we do not believe it is necessary to include the commenter's requested revision in the notice of reconsideration. As explained above (and discussed in section III.A.2.j of the proposed rule), the proposed change to the notice of reconsideration at §405.976(b)(5)(ii) was intended to reflect that evidence submitted after the reconsideration that does not meet the good cause standard will still be preserved in the administrative record, as the statement in §405.976(b)(5)(ii) that the evidence would not be made part of the administrative record was inconsistent with current practice of making a complete record of the administrative proceedings for further review. In our ongoing effort to streamline the Medicare Appeals process, we encourage appellants to submit evidence as early on in the appeals process as possible, but do not believe the commenter's suggested revision is necessary to accomplish this goal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing without modification this change to §405.976(b)(5)(ii) as proposed.

k. Effect of a reconsideration (§405.978)

Section 405.978 discusses the effect of a QIC reconsideration, and states that a reconsideration is binding on all parties unless, among other things, an ALJ decision is issued in accordance with a request for an ALJ hearing made in accordance with §405.1014. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we proposed that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted, and in section III.A.3.v of the proposed rule (as discussed in section II.B.3.v of this final rule below), we proposed to revise §405.1048 to provide the effect of an attorney adjudicator's decision is equivalent to the effect of an ALJ's decision. To align with our proposals to provide that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted and the effect of that decision is equivalent to the effect of an ALJ's decision, we proposed to insert "or attorney adjudicator" after the first use of "ALJ" in §405.978(a) to indicate that a QIC reconsideration is binding on all parties unless, among other things, an ALJ or attorney adjudicator decision is issued in accordance to a request for an ALJ hearing made in accordance with §405.1014. 81 FR 43790, 43800–43801.

We received no comments on this proposal, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed

above and in the proposed rule, we are finalizing this change to §405.978 as proposed without modification.

I. Reopenings (§§405.980, 405.982, 405.984, 423.1978, 423.1980, 423.1982, and 423.1984)

As discussed below, we proposed a number of revisions to the rules governing reopening and revision of initial determinations and appeal decisions. 81 FR 43790, 43801. Sections 405.980 and 423.1980 set forth the rules governing reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews; §§405.982 and 423.1982 set forth the rules governing notice of a revised determination or decision; and §§405.984 and 423.1984 set forth the rules on the effect of a revised determination or decision. Pursuant to §§405.1038 and 423.2038, an ALJ may issue a decision on a request for hearing without conducting a hearing in specified circumstances. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney adjudicator also would be able to issue decisions on requests for an ALJ hearing in specified circumstances, issue dismissals when a party withdraws a request for hearing, and issue decisions on requests to review QIC or IRE dismissals.

We proposed to insert “or attorney adjudicator” or “attorney adjudicator’s,” after “ALJ” or “ALJ’s” in §§405.980(a)(1)(iii), (a)(4), (a)(5), (d) introductory text, (d)(2), (e)(2); 405.982(a), (b); 405.984(d); 423.1980(a)(1)(iii), (a)(4), (d) introductory text, (d)(2), (e)(2); 423.1982(a), (a)(1), (a)(2), (b), (b)(1), and (b)(2); 423.1984(d); 423.1978(a); 423.1980(a)(2). We stated in the proposed rule that these revisions would provide that decisions issued by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), may be reopened in the same manner as decisions issued by an ALJ (that is, when there is good cause in accordance with §§405.986 or 423.1986, or the decision was procured by fraud

or similar fault), and with the same limitations, requirements, and effects as reopening an ALJ decision. We stated in the proposed rule that we believe it is necessary for an attorney adjudicator or the Council to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ or the Council may reopen the ALJ's decision under the current rules; to address instances in which there is good cause to reopen the attorney adjudicator's decision (in accordance with §§405.986 or 423.1986) or the attorney adjudicator's decision was procured by fraud or similar fault; and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under the provisions.

We also proposed to replace "hearing decision," "hearing decisions," or "hearings," with "decision" or "decisions" in the titles of §§405.980 and 423.1980; §§405.980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); 423.1980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); to replace "hearing" with "ALJ or attorney adjudicator decision" in §§405.980(a)(1)(iv), (a)(4), (e)(2); 423.1980(a)(1)(iv), (a)(2), and (e)(2); and to replace "ALJ hearing decisions" and "hearing decision," with "ALJ or attorney adjudicator decisions" and "ALJ or attorney adjudicator decision", respectively, in §§405.984(d) and 423.1984(d). We stated in the proposed rule that these revisions would avoid any confusion that reopening under these provisions is limited to decisions for which an oral hearing was conducted, whether the decision is issued by an ALJ without conducting a hearing, as permitted under current rules or by an attorney adjudicator without conducting a hearing, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above).

In addition, we proposed to add in §§405.980(a)(1)(iii), (d)(2), (e)(2), and 423.1980(a)(1)(iii), (d)(2), (e)(2) that an ALJ, or attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), revises "his or her"

decision and may reopen “his or her” decision, which reflects our current policy that the deciding ALJ may reopen his or her decision, and avoids any potential confusion that an ALJ or attorney adjudicator may reopen the decision of another ALJ or attorney adjudicator. We also proposed to insert “its” before “review” in §§405.980(a)(1)(iv) and 423.1980(a)(1)(iv) to indicate that the Council’s review decision may only be reopened by the Council, to differentiate it from an ALJ or attorney adjudicator decision that the Council may also reopen. In addition, we proposed to specify in §§405.980(d)(2) and (e)(2), and 423.1980(d)(2) and (e)(2) that the Council may reopen “an ALJ or attorney adjudicator” decision consistent with the current policy that the Council may reopen an ALJ decision, and to differentiate the provisions from §§405.980(d)(3) and (e)(3), and 423.1980(d)(3) and (e)(3), which provide for the Council to reopen its review decision. We also proposed in §405.980(e)(3) to insert “Council” before “review” to clarify that a party to a Council review may request that the Council reopen its decision.

Finally, we proposed at §405.984(c) to replace “in accordance with §405.1000 through §405.1064” with “in accordance with §405.1000 through §405.1063” to account for the proposed removal of §405.1064 discussed below.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing our proposals as discussed above, without modification, to revise the rules governing the reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

m. Expedited access to judicial review (§§405.990 and 423.1990)

Sections 405.990 and 423.1990 set forth the procedures governing expedited access to judicial review (EAJR). Current §§405.990(d) and 423.1990(d) allow a requesting party to file an EAJR request with an ALJ or the Council, which is then responsible for forwarding the request to the EAJR review entity within 5 calendar days of receipt. In accordance with §§405.990(f) and 423.1990(e), a request for EAJR must be acted upon by the EAJR review entity within 60 calendar days after the date that the review entity receives a request and accompanying documents and materials. In practice, this process has resulted in confusion and delays for requesting parties when EAJR requests are sent directly to an ALJ or the Council. To simplify the process for requesting parties and to help ensure the timely processing of EAJR requests, we proposed to revise §§405.990(d)(1) and 423.1990(d)(1) to direct EAJR requests to the DAB, which administers the EAJR process. Specifically, we proposed at §§405.990(d)(1)(i) and (ii), and 423.1990(d)(1)(i) and (ii) that the requestor or enrollee may file a written EAJR request with the DAB with the request for ALJ hearing or Council review if a request for ALJ hearing or Council review is not pending, or file a written EAJR request with the DAB if an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council. We also proposed to revise §§405.990(i)(1) and (2) and 423.1990(h)(1) and (2) so that the review entity would forward a rejected EAJR request to OMHA or the Council instead of an ALJ hearing office or the Council, to align with the revised EAJR filing process in which a request for ALJ hearing is submitted to the DAB with an EAJR request; we stated that this would also help ensure OMHA can process the request for an ALJ hearing as quickly as possible in the event an EAJR request is rejected.

Sections 405.990(i)(2) and 423.1990(h)(2) provide that a 90 calendar day time frame will apply to an appeal when a rejected EAJR request is received by the hearing office or the Council. Section 405.990(b)(1)(ii) states that an EAJR request may be filed when a request for a QIC reconsideration has been escalated for an ALJ hearing, and in accordance with current §405.1016(c), a 180 calendar day time frame will apply in that circumstance. In addition, §§405.1036(d) and 423.2036(d) allow an appellant or enrollee to waive the adjudication period for an ALJ to issue a decision specified in §§405.1016 and 405.2016, respectively, at any time during the hearing process. To address the possibility that a time frame other than 90 calendar days applies to an appeal, or no adjudication time frame applies to an appeal, we proposed to revise §§405.990(i)(2) and 423.1990(h)(2) to remove the reference to 90 calendar days and provide that if an adjudication time frame applies to an appeal, the adjudication time frame begins on the day the request for hearing is received by OMHA or the request for review is received by the Council, from the EAJR review entity.

In addition, we proposed at §405.990(i)(1) to remove the redundant “request” after “EAJR request” in current paragraph (i)(1), which was a drafting error; and at §423.1990(b)(1)(i) to remove “final” before referring to a decision, dismissal, or remand order of the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), because as we explained in the 2009 Final Rule (74 FR 65307 through 65308), final decisions of the Secretary are those for which judicial review may be immediately sought under section 205(g) of the Act and the use of “final” in current §423.1990(b)(1)(i) may cause confusion with such a final decision.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney

adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.990 and 423.1990 as proposed without modification.

3. ALJ hearings

a. Hearing before an ALJ and decision by an ALJ and attorney adjudicator: General rule (§§405.1000 and 423.2000)

As described below, we proposed a number of revisions to §§405.1000 and 423.2000, which provide a general overview and rules for hearings before an ALJ and decisions on requests for hearings. 81 FR 43790, 43802–43803. We proposed to revise §§405.1000(d), (e), (g); and 423.2000(d), (e), (g) to include decisions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to retitle the sections to reflect that the provisions of the section extend to decisions by both ALJ and attorney adjudicators. We proposed to change the language in §§405.1000(a), (b), (c), and (d); and 423.2000(a) and (b) to state that a hearing may only be conducted by an ALJ. We stated in the proposed rule that these revisions would provide readers with an accurate overview of how a request for an ALJ hearing would be adjudicated, including the potential that a decision could be issued without conducting a hearing by an ALJ or an attorney adjudicator as proposed in section

II.B of the proposed rule (and discussed in section II.A.2 above), while informing readers that if a hearing is conducted, an ALJ will conduct the hearing.

Section 405.1000(c) provides that CMS or a contractor may elect to participate in a hearing, and §423.2000(c) provides that CMS, the IRE or Part D plan sponsor may request to participate in a hearing. As discussed in section III.A.3.f of the proposed rule and II.B.3.f of this final rule below, we proposed to revise §§405.1010 and 423.2010 so that these entities may elect (for §405.1010) or request (for §423.2010) to participate in the proceedings on a request for hearing, including participation before a hearing is scheduled. We proposed to revise §§405.1000(c) and 423.2000(c) so that the sections would reference §§405.1010 and 423.2010, respectively, with regard to participating in the proceedings. We stated in the proposed rule that by referencing §§405.1010 and 423.2010, the proposed revisions would direct readers to those sections addressing the full scope of potential participation by CMS or its contractors, or a Part D plan sponsor, on a request for an ALJ hearing, including participating in the proceedings on a request for an ALJ hearing, which as discussed in proposed §§405.1010 and 423.2010, may include any proceedings before an oral hearing is scheduled. We also proposed in §405.1000(c) to state that CMS or its contractor may join the hearing before an ALJ as a party under §405.1012, which would direct readers to the appropriate section addressing the full scope of CMS or its contractor acting as a party. (Because CMS, the IRE, and the Part D plan sponsor may not be a party to a hearing under part 423, subpart U, there is no corollary to §405.1012 in that subpart and therefore a similar revision was not proposed for §423.2000(c).)

Sections 405.1000(d) and 423.2000(d) provide that a decision is based on the hearing record, and §§405.1000(g) and 423.2000(g) reference a hearing record in describing when a decision can be issued based on the record, without a hearing. However, §§405.1042 and

423.2042 identify the record as the administrative record. We stated in the proposed rule that the references to a hearing record in paragraphs (d) and (g) may cause confusion when no hearing is conducted. To make the terminology consistent throughout the rules, account for decisions that are issued without a hearing being conducted, and minimize confusion, we proposed to revise §§405.1000(d) and 423.2000(d) so that a decision is based on the administrative record, including, for an ALJ, any hearing record, and §§405.1000(g) and 423.2000(g) to provide that a decision is based on the administrative record.

Section 405.1000(e) and (g) discuss two circumstances in which a decision on a request for hearing can be issued by an ALJ without conducting a hearing, either where the parties waive the hearing or where the record supports a fully favorable finding. Related to §405.1000(e), §405.1000(f) discusses the ALJ's authority to conduct a hearing even if the parties waive the hearing. As discussed in section III.A.3.r of the proposed rule and II.B.3.r of this final rule below, we proposed to revise §405.1038 to modify the circumstances in which a decision on a request for hearing can be issued without conducting a hearing. As discussed in the proposed revisions to §405.1038, we proposed in §405.1038 that a case could be decided without a hearing before an ALJ if: (1) waivers are obtained by the parties entitled to a notice of hearing in accordance with §405.1020(c) (§405.1038(b)(1)(i)); or (2) the record supports a fully favorable finding for the appellant on every issue and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing (§405.1038(a)). We proposed to revise §405.1000(e), (f), and (g) for consistency with the §405.1038 proposals and to accurately summarize when a decision on a request for hearing can be issued without conducting a hearing in accordance with proposed §405.1038. We did not propose similar changes in

§423.2000(e), (f), and (g) because we did not propose changes to when a decision on a request for hearing can be issued without conducting a hearing in §423.2038.

Current §405.964(c) requires a QIC to consolidate requests for a reconsideration filed by different parties on the same claim before a reconsideration is made on the first timely filed request. While current §405.1044 permits an ALJ to consolidate requests for hearing if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing pending before the same ALJ, the provision is discretionary and dependent on the requests being assigned to the same ALJ. To mitigate the potential of requests for hearing on the same claim filed by different parties being separately adjudicated, we proposed to add §405.1000(h) to require that when more than one party files a timely request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued. We noted in the proposed rule that if a decision was issued on the first timely request before an additional request is timely filed or good cause is found to extend the period to file the additional request for hearing, a reopening of the decision could be considered by the deciding adjudicator in accordance with §405.980. For example, we stated that if a request is submitted with new and material evidence that was not available at the time of the decision and may result in a different conclusion, the reopening provisions at §405.980 would apply. Because only the enrollee is a party in a part 423, subpart U proceeding on a request for an ALJ hearing, no corresponding changes were proposed for §423.2000.

Provided below are summaries of the specific comment received and response to the comment:

Comment: We received one comment on these proposals. The commenter strongly supported our proposal to revise §405.1000(e), (f), and (g) for consistency with our §405.1038 proposals which, among other things, would preclude an ALJ from issuing a fully favorable decision on the record if CMS or a CMS contractor has elected to be a party to the hearing in accordance with §405.1012. The commenter stated that when audit contractors have an opportunity to present their findings, it helps ensure that ALJ decisions reflect a fuller understanding of the circumstances.

Response: We thank the commenter for its support. As the commenter indicated, we proposed to revise §405.1000(e), (f), and (g) for consistency with proposed §405.1038. However, we note that we inadvertently included language in proposed §405.1000(g) that is not consistent with the language in proposed §405.1038(a) (relating to fully favorable decisions issued on the record). Proposed §405.1000(g) states that an ALJ or attorney adjudicator may issue a decision on the record if the evidence in the administrative record supports a fully favorable finding for the appellant, “and there is no other party or no other party is entitled to a notice of hearing in accordance with §405.1020(c).” However, proposed §405.1038(a) states that an ALJ or attorney adjudicator may issue a decision without an ALJ conducting a hearing if the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue “and no other party to the appeal is liable for the claims at issue ... unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012.” Thus, consistent with our proposal to revise §405.1000(g) for consistency with §405.1038(a), in this final rule, we are revising the language in §405.1000(g) to be consistent with the language of §405.1038(a) as finalized in this rule. We are revising §405.1000(g) to state that, “An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the

administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012.”

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, and in section II.B.3.r below concerning §405.1038 (which also explains the circumstances in which a decision on a request for hearing can be issued without conducting a hearing), we are finalizing §§405.1000 and 423.2000 as proposed with the modifications discussed above.

b. Right to an ALJ hearing (§§405.1002 and 423.2002)

As discussed below, we proposed a number of revisions to §§405.1002 and 423.2002, which discuss a right to an ALJ hearing. 81 FR 43790, 43803. Current §§405.1002(a) and 423.2002(a) provide that a party to a QIC reconsideration or the enrollee who receives an IRE reconsideration, respectively, may “request” a hearing before an ALJ if the party or enrollee files a timely request and meets the amount in controversy requirement. However, a party or enrollee is entitled to a hearing only when those requirements are met. See sections 1860D-4(h) and 1869(b)(1)(A) of the Act. Therefore, we proposed to revise §§405.1002(a) and 423.2002(a) introductory text to state that the party to a QIC reconsideration or the enrollee who receives an IRE reconsideration has a right to a hearing rather than may request a hearing. These revisions would align the provisions with the statute and clarify that the party or enrollee has a right to a hearing before an ALJ when the criteria are met.

Current §§405.1002(a)(4) and 423.2002(e) provide that the request is considered filed on the date it is received by the entity specified in the QIC’s or IRE’s reconsideration. There has been confusion when a request is sent to an OMHA office that is not specified in the

reconsideration, and this error causes delays in processing the request. We proposed to revise §§405.1002(a)(4) and 423.2002(e) to replace “entity” with “office” to avoid confusion that the request may be filed with OMHA as an entity, and therefore any OMHA office, rather than the specific OMHA office identified in the QIC’s or IRE’s reconsideration. We stated in the proposed rule that this would help ensure appellants are aware that a request for hearing must be filed with the office indicated in the notice of reconsideration to avoid delays. For example, when the notice of reconsideration indicates that a request for hearing must be filed with the OMHA central docketing office, an appellant will cause a delay if the request is sent to the QIC or IRE, or an OMHA field office. We also noted in the proposed rule that as explained in the 2009 Final Rule (74 FR 65319 through 65320), pursuant to current §405.1014(b)(2), if a request for hearing is timely filed with an entity other than the entity specified in the notice of reconsideration, the request is not treated as untimely or otherwise rejected. We stated that this would remain true for requests that are timely filed with an office other than the office specified in the notice of reconsideration, pursuant to proposed §405.1014(c)(2), which incorporates the requirement from current §405.1014(b)(2). This would also apply in part 423, subpart U adjudications because the same language appears in current §423.2014(c)(2) and is incorporated in proposed §423.2014(d)(2).

Current §405.1002(b)(1) provides that when a party files a request with the QIC to escalate the appeal, it is escalated to “the ALJ level.” We proposed to revise §405.1002(b)(1) to replace “to the ALJ level” with “for a hearing before an ALJ” so that when a request for a QIC reconsideration is escalated, it is escalated “for a hearing before an ALJ.” We stated in the proposed rule that this would help ensure that the right to a hearing is clear when an appeal is escalated from the QIC. There is no corresponding provision in part 423, subpart U.

Current §423.2002(c) provides that the ALJ must document all oral requests for expedited hearings. However, an ALJ is not assigned to an appeal until after the request for hearing is received and processed. Thus, we proposed to revise §423.2002(c) to state that “OMHA” must document all oral requests for expedited hearings. There is no corresponding provision in part 405, subpart I.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: Two commenters generally supported the proposal to replace “entity” with “office” in proposed §§405.1002(a)(4) and 423.2002(e), but expressed concern that beneficiaries may nevertheless continue to send requests for hearing to the wrong entity or office. The commenters therefore urged OMHA to continue its policy of accepting requests that are timely filed with the wrong entity or office, and to incorporate this policy in regulation.

Response: As we explained in section III.A.3.g.iv of the proposed rule (and discussed in section II.B.3.g.iv below), §§405.1014(b)(2) and 423.2014(c)(2)(i) state that if a request for hearing is timely filed with an entity other than the entity specified in the QIC's or IRE's reconsideration, the deadline specified in §405.1016 or §423.2016 for deciding the appeal begins on the date the entity specified in the QIC's or IRE's reconsideration receives the request for hearing. We proposed to incorporate portions of §§405.1014(b)(2) and 423.2014(c)(2)(i) in proposed §§405.1014(c)(2) and 423.2014(d)(2)(i), respectively, but to replace “entity” with “office” in both sections (to help ensure appellants are aware that a request for hearing or request for review of a QIC or IRE dismissal must be filed with the office indicated in the QIC's or IRE's notice of reconsideration or dismissal in order to avoid delays) and “submitted” with “filed” in §423.2014(d)(1) (for consistency with §405.1014 and §422.602). We also noted above

and in section III.A.3.b and section III.A.3.g.iv of the proposed rule (discussed in section II.B.3.g.iv below) that, for those few requests for hearing that are misrouted by a party, the date the request for hearing was received in the incorrect office would be used to determine the timeliness of the request, as explained in the 2009 Final Rule (74 FR 65319 through 65320).

We agree with the commenter that OMHA's policy of not treating as untimely a request for an ALJ hearing that is timely filed with an office other than the office specified in the QIC's or IRE's reconsideration should be expressly stated in the regulation. Thus, as discussed in section II.B.3.g.iv below, we are finalizing the additional language in proposed §§405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that, if the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.1002 and 423.2002 as proposed without modification. In addition, as discussed above and in section II.B.3.g.iv below, we are adding language in §§405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that, if the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely.

c. Right to a review of QIC or IRE notice of dismissal (§§405.1004 and 423.2004)

As discussed below, we proposed several revisions to §§405.1004 and 423.2004, which discuss the right to an ALJ review of a QIC notice of dismissal or IRE notice of dismissal, respectively. 81 FR 43790, 43803–43804. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), attorney adjudicators or ALJs would conduct reviews of QIC or IRE dismissals. Accordingly, we proposed to remove references to an ALJ in the titles of proposed §§405.1004 and 423.2004, though ALJs would continue to have the authority to

conduct reviews of QIC or IRE dismissals if a request for a review of a QIC or IRE dismissal is assigned to an ALJ. We also proposed to insert “or attorney adjudicator” after ALJ in §§405.1004(a) introductory language, (b), (c); and 423.2004(a) introductory language, (b), and (c), to provide that an attorney adjudicator could review a QIC or IRE dismissal, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to replace the reference to “entity” in current §§405.1004(a)(4) and 423.2004(a)(4), with “office,” for the same reasons discussed in III.A.3.b of the proposed rule and II.B.3.b of this final rule above, for amending parallel language in §§405.1002 and 423.2002.

Current §§405.1004(b) and 423.2004(b) provide that if an ALJ determines that the QIC’s or IRE’s dismissal was in error, he or she vacates the dismissal and remands the case to a QIC or IRE. As discussed in III.A.3.p of the proposed rule and II.B.3.p of this final rule below, we proposed to revise the remand provisions and add new §§405.1056 and 405.1058, 423.2056, and 423.2058 to govern when remands may be issued, whether and to what extent remands may be reviewed, providing notice of a remand, and the effect of a remand. We also proposed to revise §§405.1004(b) and 423.2004(b) to add references to proposed §§405.1056 and 423.2056, respectively, to explain that the remand would be in accordance with proposed §§405.1056 and 423.2056, which as discussed in section III.A.3.p of the proposed rule and II.B.3.p of this final rule below, would address issuing remands and notices thereof, including for remands of QIC or IRE dismissals.

Current §§405.1004(c) and 423.2004(c) state that an ALJ’s decision regarding a QIC’s or IRE’s dismissal of a reconsideration request is binding and not subject to further review, and that the dismissal of a request for ALJ review of a QIC’s or IRE’s dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the Council under

§405.1108(h) or §423.2108(b), respectively. In our experience, these sections as currently drafted have been a source of confusion for adjudicators and appellants. The two sentences convey different actions that can result from a request for review of a QIC or IRE dismissal—a decision regarding whether the QIC’s or IRE’s dismissal was correct, or a dismissal of the appellant’s request for an ALJ review of the QIC’s or IRE’s dismissal. We proposed to separate and further distinguish the two situations to avoid the current confusion that results from two of the three possible outcomes that may result from a request to review a QIC or IRE dismissal (the third being a remand of the dismissal, addressed in paragraph (b) in the respective sections) being in the same paragraph by proposing a separate paragraph for each outcome currently addressed in paragraph (c).

We proposed to revise §§405.1004(c) and 423.2004(c) to include the possible outcome in the first sentence of current §§405.1004(c) and 423.2004(c) of a decision affirming the QIC’s or IRE’s dismissal. We also proposed to move language in current §§405.1004(c) and 423.2004(c) stating that the decision of an ALJ on a request for review of a QIC dismissal is binding and not subject to further review, to proposed §§405.1048(b) and 423.2048(b), which as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below, would address the effects of decisions on requests to review a QIC or IRE dismissal. In addition, we proposed in §§405.1004(c) and 423.2004(c), respectively, to state that a decision affirming a QIC or IRE dismissal would be issued in accordance with proposed §§405.1046(b) and 423.2046(b), which as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below, would address issuing decisions on requests for review of a QIC or IRE dismissal and notices thereof.

The 2009 Final Rule (74 FR 65311 through 65312) also explained that if a request for ALJ review of a QIC dismissal was invalid and thus subject to dismissal, the dismissal of the

request to review a QIC dismissal was binding and not subject to further review (however, a party could request that the dismissal be vacated by the Council pursuant to §405.1108(b)). We proposed to add §§405.1004(d) and 423.2004(d) to state that the ALJ or attorney adjudicator may dismiss a request for review of a QIC's or an IRE's dismissal in accordance with proposed §§405.1052(b) or 423.2052(b), respectively, which as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule below, would address dismissals of requests for review of a QIC or IRE dismissal and notices thereof. We also proposed to move language in current §§405.1004(c) and 423.2004(c) stating that the dismissal is binding and not subject to further review unless the dismissal is vacated, to proposed §§405.1054(b) and 423.2054(b), which would address the effects of a dismissal of a request for review of a QIC's or an IRE's dismissal and as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule below, would provide authority for an ALJ or attorney adjudicator to vacate a dismissal and therefore replace the current reference to the Council.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.1004 and 423.2004 as proposed without modification.

d. Amount in controversy required for an ALJ hearing (§§405.976, 405.1006, 422.600, 423.1970, and 478.44)

As described below, we proposed a number of changes to the amount in controversy provisions in §§405.1006, 423.1970, and 478.44, as well as an associated change to §405.976(b)(7) regarding the content of a QIC's notice of reconsideration. 81 FR 43790, 43804–43810, 43854. Current §405.1006 sets forth the requirements for meeting the amount in controversy for an ALJ hearing. The title of current §405.1006 states that the amount in controversy is required to “request” an ALJ hearing and judicial review. However, as discussed in III.A.3.b of the proposed rule and II.B.3.b of this final rule above, section 1869(b)(1)(A) of the Act states that a party is entitled to a hearing before the Secretary and judicial review, subject to the amount in controversy and other requirements. To align the title of §405.1006 with the statutory provision, we proposed that the amount in controversy is required “for” an ALJ hearing and judicial review rather than “to request” an ALJ hearing and judicial review. Put another way, a party may request an ALJ hearing or judicial review, albeit unsuccessfully, without satisfying the amount in controversy requirement.

Section 1869(b)(1)(E) of the Act establishes the minimum amounts in controversy for a hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy. Current §405.1006(d) states that the amount remaining in controversy is calculated based on the actual amount charged to the individual (a beneficiary) for the items or services in question (commonly referred to as billed charges), reduced by any Medicare payments already made or awarded for the items or services, and any deductible and coinsurance amounts applicable to the particular case. In an effort to align the amount in controversy with a better approximation of the amount at issue in an appeal, we proposed to revise the basis (that is, the starting point before any deductions for any payments already made by Medicare or any coinsurance or deductible that may be collected) used to calculate the amount in controversy. For

appeals of claims submitted by providers of services, physicians, and other suppliers that are priced based on a published Medicare fee schedule or published contractor-priced amount (as discussed below), rather than using the actual amount charged to the individual as the basis for the amount in controversy, we proposed to use the Medicare allowable amount for the items and/or services being appealed, subject to the exceptions discussed below. An allowable amount is the maximum amount of the billed charge deemed payable for the item or service. For the purposes of the amount in controversy under §405.1006, we proposed at §405.1006(d)(2)(i)(A) that for items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy would be the allowable amount, which would be the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service.

We stated in the proposed rule that for a vast majority of items and services furnished and billed by physicians and other suppliers, allowable amounts are determined based on Medicare fee schedules. Fee schedules generally are updated and published on an annual basis by CMS through rulemaking, and CMS and its contractors have tools and resources available to inform physicians and other suppliers of allowable amounts based on these fee schedules, including the Physician Fee Schedule Look-up Tool available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/> and spreadsheets for other fee schedules that can be accessed on the CMS website through the fee schedule main page at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html>. Allowable amounts for many contractor-priced items and services are also included in these tools and resources. Allowable amounts are included on the Medicare remittance advice for paid items and services, but not for items and services that

are denied. However, where the allowable amount for an item or service is determined based on a published fee schedule or contractor-priced amount, we stated that we anticipated that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, would be able to use the existing CMS and contractor tools and resources to determine allowable amounts for denied services when filing a request for hearing, and those amounts could be verified by OMHA in determining whether the claims included in the request meet the amount in controversy requirement. As discussed below, where the appellant is a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, we proposed that CMS would require the QIC to specify in the notice of reconsideration, for partially or fully unfavorable reconsideration decisions, whether the amount remaining in controversy is estimated to meet or not meet the amount required for an ALJ hearing under proposed §405.1006(d).

We stated in the proposed rule that, due to the pricing methodology for many items and services furnished by providers of services, such as hospitals, hospices, home health agencies, and skilled nursing facilities, at the present time an allowable amount is not easily discerned or verified with existing CMS and contractor pricing tools (for example, there is no pricing tool available for hospital outpatient services paid under the outpatient prospective payment system (OPPS)) for pre-payment claim denials (where items or services on the claim are denied, in full or in part, before claim payment has been made). Similarly, we stated that items and services furnished by providers or suppliers that are always non-covered, as well as unlisted procedures, may not have published allowable amounts based on a fee schedule or a published contractor-priced amount. Therefore, we proposed at §405.1006(d)(2)(i)(B) to continue using the provider's or supplier's billed charges as the basis for calculating the amount in controversy for appeals of

claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (except as discussed below). We noted that the method for calculating the amount in controversy in this scenario would be the same as under current §405.1006(d), and we stated that we believe that all appellants have access to this information through claims billing histories, remittance advices, or the column titled “Amount Provider [or Supplier] Charged” on the Medicare Summary Notice. However, we solicited comment on whether existing tools and resources are available that would enable providers, suppliers, and Medicaid State agencies to submit an allowable amount in their request for hearing, as proposed in section III.A.3.g.i of the proposed rule (and discussed in section II.B.3.g.i below) for items and services not subject to published fee schedules or published contractor-priced amounts, and whether those amounts could also be verified by OMHA. We also solicited comment on how such tools and resources could be used in appeals filed by beneficiaries.

Current §405.1006(d)(1) introductory text uses “the actual amount charged the individual for the items and services in question” as the basis (starting point) for calculating the amount in controversy, before any reductions described in paragraphs (d)(1)(i) and (ii) (for any Medicare payments already made or awarded and any deductible and coinsurance applicable in the particular case) occur. For the reasons discussed above, we proposed to revise paragraph (d)(1) introductory text to state that in situations other than those described in §405.1006(d)(3) through (7) (discussed below), the amount in controversy is computed as “the basis for the amount in controversy for the items and services in the disputed claim as defined in paragraph (d)(2)”, less applicable reductions described in paragraphs (d)(1)(i) and (ii), and proposed to revise paragraph (d)(2) to specify the amount that would be used as the basis for the amount in controversy on a

situational basis. We also proposed at §405.1006(d)(3) through (7) five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

There has also been confusion in calculating the amount in controversy when an appealed reconsideration involves multiple claims. Section 1869 of the Act and part 405, subpart I provide for an appeals process in which each claim decision is appealed and separately adjudicated. However, in some instances, claims are considered together based on an appellant's request. To address confusion with calculating the amount in controversy when reconsiderations involve multiple claims and to help ensure §405.1006 clearly conveys that the amount in controversy requirement must be met for each appealed claim unless the claim can be aggregated as discussed below, we proposed in §405.1006(d)(1) to clarify that the amount in controversy is based on the items or services in the disputed "claim."

We proposed to maintain the current reduction to the calculation of the amount in controversy in §405.1006(d)(1)(i), which states that the basis for the amount in controversy is reduced by any Medicare payments already made or awarded for the items or services. In addition, current §405.1006(d)(1)(ii) provides that the basis for the amount in controversy is further reduced by "[a]ny deductible and coinsurance amounts applicable in the particular case." We proposed to revise §405.1006(d)(1)(ii) to read, "Any deductible and/or coinsurance amounts that may be collected for the items or services." We stated in the proposed rule that we believe revising this provision is appropriate to better align the amount at issue in the appeal and the amount in controversy so that in situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible, or must refund any such amounts already collected, the basis for the amount in controversy is not reduced by that amount (for example, if a provider or supplier is held liable for denied services under the limitation on liability provision

in section 1879 of the Act, any amounts collected for the denied service, including coinsurance and/or deductible must be refunded).

As discussed above, we proposed at §405.1006(d)(2)(i) that, for situations other than those described in §405.1006(d)(2)(ii) and (iii), the basis for calculating the amount in controversy under §405.1006(d)(1) would be the Medicare allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service if there is a published Medicare fee schedule or published contractor-priced amount for the items or services in the disputed claim; or if there is no published Medicare fee schedule or contractor-priced amount for the items or services in the disputed claim, the basis for the amount in controversy would be the provider or supplier's billed charges submitted on the claim for the items and services. We stated that we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS and CMS contractor tools and resources to determine the allowable amount for items and services with published fee schedule or published contractor-priced amounts, and for items or services without a published fee schedule or published contractor-priced amount, the calculation methodology for the amount in controversy would be the same as the calculation methodology specified in current §405.1006(d). However, we stated there may be instances where a beneficiary would appeal a claim for items and services for which the allowable amount would be the basis for the amount in controversy under proposed §405.1006(d)(2)(i)(A) (for example, a claim for items or services with a published fee schedule or published contractor-priced amount that does not involve an overpayment and for which the beneficiary has not been determined to be financially responsible). We stated that we believe most beneficiaries are not familiar with published fee schedule or contractor-priced amounts and may be unable to determine the amount

in controversy in these circumstances with the resources currently available to them. However, as discussed below, we proposed at §405.976(b)(7) that the QIC include in the notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable to the appellant. For appeals filed by beneficiaries, often the amount at issue is aligned not with the Medicare allowable amount, but rather with the billed charges of the provider or supplier. For example, where a beneficiary is held financially responsible for a denied claim under the limitation on liability provisions in section 1879 of the Act because he or she received an Advance Beneficiary Notice of Noncoverage (ABN), the beneficiary is responsible for the billed charges on the claim. Or, for a claim not submitted on an assignment-related basis that is denied, the beneficiary may be responsible for the billed charges, or the billed charges subject to the limiting charge in section 1848(g) of the Act. Medicare notifies the beneficiary of the amount he or she may be billed for denied services on the Medicare Summary Notice in a column titled, “Maximum You May Be Billed.” For appeals filed by a provider, supplier, or Medicaid State agency for denied items or services for which the beneficiary was determined to be financially responsible, we stated in the proposed rule that we believed providers, suppliers, and Medicaid State agencies would have sufficient access to the provider or supplier’s billing information and Medicare claims processing data to determine the amount charged to the beneficiary. Accordingly, we proposed at §405.1006(d)(2)(ii) that for any items or services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been

received) for the items or services in the disputed claim. As discussed above, this amount would be set forth on the Medicare Summary Notice in the column titled “Maximum You May Be Billed.”

We also proposed at §405.1006(d)(2)(iii) that if a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authorities, the basis for the amount in controversy would be the actual amount originally charged to the beneficiary for the items or services in the disputed claim, as we stated in the proposed rule we believed that the amount originally charged to the beneficiary is more reflective of the actual amount at issue for the beneficiary and for the provider or supplier in this situation. We also stated we believed appellants would have access to and would use the same information for determining the basis for the amount in controversy under paragraph §405.1006(d)(2)(iii) as they would under §405.1006(d)(2)(ii).

As discussed above, we proposed at §405.1006(d)(3) through (7) five exceptions to the general methodology used to calculate the amount in controversy specified in §405.1006(d)(1). Current §405.1006(d)(2) provides that, notwithstanding current §405.1006(d)(1), when payment is made for items or services under section 1879 of the Act or §411.400, or the liability of the beneficiary for those services is limited under §411.402, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under §411.400 or if that liability was not limited under §411.402, reduced by any deductible and coinsurance amounts applicable in the particular case. We proposed to re-designate current §405.1006(d)(2) as §405.1006(d)(3) and to revise the paragraph to state that when payment is made for items or services under section 1879 of the Act

or §411.400, or the liability of the beneficiary for those services is limited under §411.402, the amount in controversy would be calculated in accordance with §405.1006(d)(1) and (2)(i), except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under §411.400 or as a result of liability that is limited under §411.402. For example, when a claim for items or services is denied under section 1862(a)(1)(A) of the Act because the items or services were not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, Medicare payment may nonetheless be made under the limitation on liability provisions of section 1879 of the Act if neither the provider/supplier nor the beneficiary knew, or could reasonably have been expected to know, that payment would not be made. In instances such as these, we proposed that the amount in controversy would be calculated as if the items or services in the disputed claim were denied and no payment had been made under section 1879 of the Act. We stated in the proposed rule that we believed this exception was appropriate because appellants may still wish to appeal findings of non-coverage related to items and services for which liability of the party was limited or payment was made under section 1879 of the Act or §411.400 or for which the beneficiary was indemnified under §411.402, but if these payments or indemnifications were deducted from the basis for the amount in controversy, the amount in controversy could be zero. As this exception relates only to whether deductions are made under §405.1006(d)(1)(i) for any Medicare payments already made or awarded for the items or services, and the amount in controversy would otherwise be calculated in accordance with proposed §405.1006(d)(1) and (d)(2)(i), we stated we believed appellants would have access to and would use the same information for determining the amount in controversy under §405.1006(d)(3) as they would under §405.1006(d)(1) and (d)(2)(i).

Current §405.1006 does not address calculating the amount in controversy for matters involving a provider or supplier termination of a Medicare-covered item or service when the beneficiary did not elect to continue receiving the item or service (for example, §405.1206(g)(2) provides that if a beneficiary is dissatisfied with a QIO's determination on his or her discharge and is no longer an inpatient in a hospital, the determination is subject to the general claims appeal process). In this circumstance, items and services have not been furnished, and therefore, a claim has not been submitted. Yet the beneficiary may elect not to continue receiving items or services while appealing the provider or supplier termination due to potential financial responsibility for the items or services. While an amount in controversy cannot be assessed for a period of time during which no items or services were furnished, a beneficiary may assert a continuing need for the items or services based on his or her condition at the time an appeal is heard. To address this circumstance, we proposed new §405.1006(d)(4), which would provide that when a matter involves a provider or supplier termination of Medicare-covered items or services and the beneficiary did not elect to continue receiving the items or services that are disputed by a beneficiary, the amount in controversy is calculated as discussed above regarding proposed (d)(1) and (d)(2)(ii) (which addresses situations where the beneficiary is determined to be financially responsible), except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services that the beneficiary asserts should be covered by Medicare based on the beneficiary's current condition at the time an appeal is heard, and Medicare payment was not made. We stated that this proposal would allow the beneficiary to pursue coverage for an item or service and potentially meet the amount in controversy requirement in instances in which he or she would

not otherwise be able to pursue a hearing before an ALJ because no items or services have been rendered and therefore no amount in controversy exists because there is no disputed claim. In these instances, the beneficiary has been notified of a preliminary decision by a provider or supplier that Medicare will not cover continued provision of the items or services in dispute. Therefore, we stated in the proposed rule that we believed using the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services that the beneficiary asserts should be covered and if Medicare payment were not made for these items or services (in other words, the amount the beneficiary would be charged if the beneficiary were financially responsible for these items or services) is most reflective of the actual amount in dispute. Most beneficiary appeals of provider or supplier terminations of Medicare-covered items or services involve the termination of Part A services and, therefore, we stated that we expected it would be rare that the amount in controversy would be less than that required for an ALJ hearing. However, we also stated that we expected that beneficiaries wishing to determine if the amount in controversy required for an ALJ hearing was met could obtain from the provider or supplier the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services and Medicare payment were not made. In addition, as discussed below, we proposed at §405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We considered using Medicare payable amounts for denied items and services as the basis for the amount in controversy calculation specified in proposed §405.1006(d)(1), as we

stated that would be a more precise estimate of the amount at issue in the appeal than either the Medicare allowable amount or the billed charges. Payable amounts would take into account payment rules related to the items and services furnished that may increase or decrease allowable amounts (for example, multiple surgery reductions, incentive payments, and competitive bidding payments). However, we stated that CMS systems do not currently calculate payable amounts for denied services, and undertaking major system changes would delay implementation and has been determined not to be cost effective. While payable amounts may be a better representation of the amount at issue in the appeal, we stated in the proposed rule that we believed the Medicare allowable amount and the other amount in controversy calculations provided in proposed §405.1006(d) are appropriate and reliable estimates that align well with the amount at issue for claims for which a payable amount has not been calculated.

However, we stated that for post-payment denials, or overpayments, a payable amount has been determined and would be the most reliable indicator of the amount actually at issue in the appeal. Therefore, we proposed new §405.1006(d)(5) to state that, notwithstanding the calculation methodology in proposed paragraphs (d)(1) and (2), when a claim appeal involves an overpayment determination, the amount in controversy would be the amount of the overpayment specified in the demand letter. In a post-payment denial, the amount of the overpayment identified in the demand letter is readily available to appellants, and is the most accurate reflection of the amount actually at issue in the appeal. In addition, current §405.1006 does not address appeals that involve an estimated overpayment amount determined through the use of sampling and extrapolation. In this circumstance, the claims sampled to determine the estimated overpayment may not individually meet the amount in controversy requirement, but the estimated overpayment determined through the use of extrapolation may meet the amount in

controversy requirement. To address this circumstance, we also proposed in new §405.1006(d)(5) that when a matter involves an estimated overpayment amount determined through the use of sampling and extrapolation, the estimated overpayment as extrapolated to the entire statistical sampling universe is the amount in controversy. We stated that this proposal would provide appellants the opportunity to appeal claims that may not individually meet the amount in controversy requirement if such claims were part of the sample used in making an overpayment determination that does meet the amount in controversy requirement. Because the overpayment determination reflects the amount for which the appellant is financially responsible, we stated in the proposed rule that we believed it would be appropriate to allow appellants to appeal individual claims in the sample that was used to determine the overpayment. Whether an appeal involves an individual overpayment or an estimated overpayment determined through the use of sampling and extrapolation, we stated in the proposed rule that we believed appellants against whom an overpayment was assessed would need only to consult the demand letter they received in order to determine the amount in controversy. However, we also stated that we expected there may be circumstances where a beneficiary wishes to appeal an overpayment that was assessed against a provider or supplier, and in these situations the beneficiary may not have a copy of the demand letter that was received by the provider or supplier. For this reason, and as discussed below, we proposed at §405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We also proposed new §405.1006(d)(6), which would provide that when a beneficiary files an appeal challenging only the computation of a coinsurance amount, or the amount of a remaining deductible applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct. We stated in the proposed rule that we believed this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in §405.1006(d)(1) would be zero for a paid claim. In addition, we also stated that we believed that the calculation proposed at §405.1006(d)(6) would appropriately reflect the amount at issue for the beneficiary in these appeals where the computation of a coinsurance amount, or the amount of a remaining applicable deductible is challenged. We further stated that we believed beneficiaries would have access to the coinsurance and/or deductible amounts determined by the contractor for the paid claim on the beneficiary's Medicare Summary Notice, in the column titled "Maximum You May Be Billed," and would need only to subtract the amount of coinsurance and/or deductible the beneficiary believes he or she should have been charged in order to arrive at the amount in controversy. We stated we expected it would be extremely rare for a non-beneficiary appellant to file an appeal challenging the computation of a coinsurance amount or the amount of a remaining deductible.

In addition, we proposed new §405.1006(d)(7) to provide that for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected in the published Medicare fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have

been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services. We stated in the proposed rule that we believed this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in §405.1006(d)(1) would be zero for such paid claims. In addition, we stated we believed that the calculation proposed at §405.1006(d)(7) would appropriately reflect the amount at issue for the appellant in these appeals. We also stated that we believed that, generally, these types of appeals are filed by providers and suppliers who are already familiar with the allowable amount for the items or services in the disputed claim based on information obtained from published fee schedules or contractor-priced amounts. Further, we stated that we believed that a fee schedule or contractor price challenge filed by a beneficiary on a paid claim would be a very rare occurrence. However, as discussed below, in the event a beneficiary would want to file such an appeal, the beneficiary could obtain an estimate of the amount in controversy from the QIC reconsideration. As discussed further below, we proposed at §405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

In the event that a reconsideration, or a redetermination if the appeal was escalated from the QIC without a reconsideration, involves multiple claims and some or all do not meet the amount in controversy requirement, section 1869 of the Act states that, in determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be

aggregated if the appeals involve the delivery of similar or related services to the same individual by one or more providers or suppliers, or common issues of law and fact arising from services furnished to two or more individuals by one or more providers or suppliers. Under this authority, §405.1006(e) provides for aggregating claims to meet the amount in controversy requirement.

The title of current §405.1006(e)(1) for aggregating claims when appealing a QIC reconsideration is phrased differently than the corresponding title for aggregating claims when escalating a request for a QIC reconsideration in current §405.1006(e)(2), which may cause confusion. We proposed to revise the title to §405.1006(e)(1) to “Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing” so it clearly applies to aggregating claims in appeals of QIC reconsiderations, and is parallel to the phrasing used in the title of §405.1006(e)(2). The proposed titles of §405.1006(e)(1) and (e)(2), and proposed §405.1006(e)(2)(ii) would also replace “to the ALJ level” with “for an ALJ hearing” to again highlight that the appeal of a QIC reconsideration or escalation of a request for a QIC reconsideration is for an ALJ hearing.

Current §405.1006(e)(1)(ii) provides that to aggregate claims, the request for ALJ hearing must list all of the claims to be aggregated. We stated in the proposed rule that this has caused confusion because some appellants read current §405.1006(e)(1)(ii) as allowing appeals of new claims to be aggregated with claims in previously filed appeals, provided the new request for hearing lists the claims involved in the previously filed appeals. However, current §405.1006(e)(2)(i), which applies to aggregating claims that are escalated from the QIC for a hearing before an ALJ, requires that the claims were pending before the QIC in conjunction with the same request for reconsideration. We noted in the proposed rule that in the context of a request for hearing, aggregating new claims with claims from previously filed requests could

delay the adjudication of the requests and is inconsistent with the current rule for aggregating claims that are escalated from the QIC. To address these issues and bring consistency to the aggregation provisions, we proposed to revise §405.1006(e)(1)(ii) to require the appellant(s) to request aggregation of the claims in the same request for ALJ hearing or in multiple requests for an ALJ hearing filed with the same request for aggregation. We stated that this would allow an individual or multiple appellants to file either one request for an ALJ hearing for multiple claims to be aggregated, or multiple requests for an ALJ hearing for the appealed claims when requesting aggregation, while requiring them to be filed together with the associated request for aggregation. We also proposed in §405.1006(e)(1)(iii) and (e)(2)(iii) that an ALJ or attorney adjudicator may determine that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, but only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. We proposed this because an attorney adjudicator adjudicating requests for an ALJ hearing when no hearing is conducted, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), would not be permitted under this proposed rule to dismiss a request for an ALJ hearing due to procedural issues such as an invalid aggregation request. Because only an ALJ would be permitted to dismiss a request for an ALJ hearing because there is no right to a hearing, which includes not meeting the amount in controversy requirement for a hearing, in accordance with proposed §405.1052(a), an attorney adjudicator could not make a determination that the aggregation criteria were not met because that determination would result in a dismissal of a request for an ALJ hearing.

Current §405.976(b)(7) requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. We proposed to revise §405.976(b)(7) to require that the QIC notice of reconsideration include a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable. In line with current practice, we did not propose to require that the QIC indicate what it believes to be the exact amount in controversy, but rather only an estimate of whether it believes the amount in controversy is met, because, as we stated in the proposed rule, we believe the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator (though, as discussed in section II.B of the proposed rule and II.A.2 of this final rule above, only an ALJ would be able to dismiss a request for hearing for failure to meet the amount in controversy required for an ALJ hearing). We stated in the proposed rule that we believe that providers, suppliers, and Medicaid State agencies have the tools, resources, and payment information necessary to calculate the amount in controversy in accordance with §405.1006(d), and are familiar with the allowable amounts for the places of service in which they operate. Furthermore, applicable plans against whom a Medicare Secondary Payer overpayment is assessed would have access to the overpayment amount specified in the demand letter, which would be used to determine the amount in controversy under proposed §405.1006(d)(5). Thus, we stated that we did not believe it was necessary for the QICs to continue to provide this statement for providers, suppliers, applicable plans, Medicaid State agencies, or beneficiaries represented by providers,

suppliers or Medicaid State agencies. Furthermore, as discussed in section III.A.3.g.i of the proposed rule and II.B.3.g.i of this final rule below, we proposed that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, include the amount in controversy in their requests for hearing (unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). As providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency would be responsible for calculating the amount in controversy and including it on the request for hearing as proposed in section III.A.3.g.i of the proposed rule (and discussed in section II.B.3.g.i below), we stated that we did not believe a statement by the QIC that indicates only whether the amount in controversy was or was not met adds significant value to such appellants. Furthermore, we expected that the Medicare allowable amount under proposed §405.1006(d)(2)(i)(A) would be the basis for the amount in controversy in the majority of Part B appeals filed by non-beneficiary appellants. While QICs have access to the amount charged to an individual based on billed charges, the allowable amounts for claims vary based on where these items and services were furnished, and the applicable fee schedules and contractor-priced amounts, and continuing to require the QICs to include a statement whether the amount in controversy needed for an ALJ hearing is met in all instances in which the decision is partially or fully unfavorable to the appellant would require substantially more work by the QIC, and could delay reconsiderations and increase costs to the government.

Although we did not propose that beneficiaries who are not represented by a provider, supplier, or Medicaid State agency would need to include the amount in controversy on their requests for hearing (as discussed later in this preamble), we stated in the proposed rule that we

believed there may be instances where a beneficiary would want to know if the amount in controversy meets the amount required for an ALJ hearing when deciding whether to file a request for hearing. We also stated we believed there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not currently have sufficient information to determine whether the amount in controversy required for an ALJ hearing is met under proposed §405.1006. For example, under proposed §405.1006(d)(2)(i)(A), for items and services with a published Medicare fee schedule or published contractor-priced amount (and for which the beneficiary was determined to be not financially responsible), the basis for the amount in controversy would generally be the allowable amount, which is the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service. Beneficiaries not represented by a provider, supplier, or Medicaid State agency would not generally be expected to be familiar with fee schedule and contractor-priced amounts, and we stated we believed they may have difficulty determining whether the amount in controversy required for an ALJ hearing is met in these cases. We also stated we believed beneficiaries not represented by a provider, supplier, or Medicaid State agency might be unable to determine the amount of an overpayment assessed against a provider or supplier for items or services furnished to the beneficiary for purposes of calculating the amount in controversy under proposed §405.1006(d)(5), as the beneficiary might not have access to the demand letter received by the provider or supplier, and may no longer have access to the Medicare Summary Notice reflecting the original payment amount.

Accordingly, because there are situations where such beneficiaries may not have sufficient information to determine the amount in controversy, we proposed to revise §405.976(b)(7) to state that the QIC would include in its notice of reconsideration a statement of whether the

amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

Current §423.1970 describes the amount in controversy requirement for part 423, subpart U proceedings. For the same reasons we proposed to revise §405.1006(e)(1)(ii), we proposed in §423.1970(c)(1)(ii) and (c)(2)(ii) to provide that a single enrollee's or multiple enrollees' request for aggregation, respectively, must be filed at the same time the request (or requests) for hearing for the appealed reconsiderations is filed. In addition, we proposed to revise §423.1970(c)(1)(ii) and §423.1970(c)(2)(ii) to state that the request for aggregation and requests for hearing must be filed within 60 calendar days after receipt of the notice of reconsideration for each reconsideration being appealed, unless the deadline is extended in accordance with §423.2014(d). Our proposal would help ensure there is no confusion that the timely filing requirement applies to each of the requests for hearing filed with the request for aggregation. Because we proposed to directly reference the 60 calendar day filing requirement under §423.1972(b) and the possible extension of the filing requirement under §423.2014(d), we also proposed to remove the current references in §423.1970(c)(1)(ii) and (c)(2)(ii) to the filing requirement in §423.1972(b). In addition, for the same reasons we proposed to revise §405.1006(e)(1)(iii) and (e)(2)(iii), we proposed in §423.1970(c)(1)(iii) and (c)(2)(iii) that an ALJ or attorney adjudicator may determine that the appeals that a single enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate involve the same prescription drugs, but only an ALJ may determine appeals that a single enrollee seeks to aggregate do not involve the delivery of

prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate do not involve the same prescription drugs. We proposed to replace “prescription” in current §423.1970(c)(2)(iii) with “prescription drugs” in proposed §423.1970(c)(2)(iii) for consistency with current and proposed §423.1970(c)(1)(iii). Finally, we also proposed to correct the spelling of “prescription” in current §423.1970(c)(2)(iii).

Current §422.600(b) provides that the amount in controversy for appeals of reconsidered determinations to an ALJ (under the Part C MA program), is computed in accordance with part 405. However, if the basis for the appeal is the MAO’s refusal to provide services, current §422.600(c) provides that the projected value of those services are used to compute the amount in controversy. We did not propose to revise these provisions because, as we stated in the proposed rule, we believed the proposed revisions to §405.1006 described above encompass and have application to the scenarios appealed under part 422, subpart M. In particular, we noted that as is the case under current §405.1006, if an enrollee received items or services and is financially responsible for payment because the MAO has refused to cover the item or services, the amount in controversy would be calculated using the billed charges as the basis for the amount in controversy, as provided in proposed §405.1006(d)(2)(ii). We stated that if the enrollee did not receive the items or services, the provisions of current §422.600(c) would apply. We also noted that current §§422.622(g)(2) and 422.626(g)(3) provide for an appeal to an ALJ, the Council, or federal court of an IRE’s affirmation of a termination of provider services “as provided for under [part 422, subpart M],” thus triggering the amount in controversy rules in 422.600, which cross-reference part 405 (that is, the rules proposed here). We stated that proposed §405.1006 would address scenarios appealed under part 422, subpart M that are not clearly addressed in current §405.1006, such as provider service terminations, which would be addressed in proposed

§405.1006(d)(4), and coinsurance and deductible challenges, which would be addressed in proposed §405.1006(d)(6).

Current §478.44(a) also references back to part 405 provisions for determining the amount in controversy when requesting an ALJ hearing after a QIO reconsidered determination. We proposed revisions to §478.44 in section III.D.3 of the proposed rule (as discussed in section II.E.3 below), to update part 405 references, but we did not propose in §478.44 to revise how the current or proposed part 405 provision would be applied in calculating the amount in controversy. Similar to the part 422, subpart M provisions discussed above, we stated that we believe the proposed revisions to §405.1006 described above encompass and have application to the scenarios appealed under part 478, subpart B.

We received 14 comments on these proposals. Provided below are summaries of the specific comments received and responses to these comments:

Comment: Two commenters supported our proposal to revise the title of §405.1006 to reflect that the amount in controversy threshold is required “for an ALJ hearing and judicial review” rather than “to request an ALJ hearing and judicial review.” One commenter felt that this revision would more closely align the regulation with the corresponding statutory provision at §1869(b)(1)(E) of the Act. The other commenter believed that the current title of §405.1006 may have resulted in beneficiaries not filing a request for hearing if they were confused or unsure about whether the minimum amount in controversy was met.

Response: We thank the commenters for their support, and we are finalizing the proposal to revise the title of §405.1006 without modification.

Comment: Six commenters opposed our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that

are priced based on a published Medicare fee schedule or published contractor-priced amount, and recommended we withdraw the proposal or publish user-friendly, online resources to help the public better understand the proposed calculation methodology. In general, the commenters felt that the proposal would prevent physicians, beneficiaries, and other appellants from appealing low-dollar claims and, rather than streamlining the appeals process, the proposal would create confusion among appellants, ALJs, and attorney adjudicators. One commenter recommended that the higher of the Medicare allowable amount or the amount charged the individual for the items or services in question be used to determine the amount in controversy.

Response: As explained above, we proposed to revise the calculation methodology for the amount in controversy in order to arrive at an amount that more accurately reflects the amount at stake for appellants. We estimated in section VI (Regulatory Impact Statement) of the proposed rule (81 FR 43790, 43856) that our proposals could remove appeals related to over 2,600 low-value Part B claims per year from the ALJ hearing process, after accounting for the likelihood that appellants would aggregate claims to meet the minimum amount in controversy required for an ALJ hearing. However, we noted in the proposed rule that appeals filed by Medicare beneficiaries and MA and Part D prescription drug plan enrollees would be minimally impacted because these individuals often appeal claim or coverage denials for which they are financially responsible, and for which we would continue basing the amount in controversy on the provider or supplier's billed charges.

After considering the comments received and further analysis of our proposal to revise the calculation of the amount in controversy to use the Medicare allowable amount as set forth in proposed §405.1006(d)(2)(i)(A), we have decided not to finalize proposed §405.1006(d)(2)(i)(A) at this time. While we continue to believe that the amount in controversy should more closely

reflect the actual amount at stake in an appeal, we believe that the costs to the appellant community and the government outweigh the benefits of fewer appeals entering the ALJ hearing process under the proposed methodology for calculating the amount in controversy.

Based on further analysis spawned by the public comments, we believe the costs of the proposal are likely higher than originally anticipated. These costs include costs to the appellant community in identifying the published Medicare fee schedule or published contractor-priced amount to include in the request for hearing; and the administrative costs to the government of calculating the amount for certain appellants, and verifying and resolving conflicts over the calculation. While our estimation of 2,600 fewer appeals for low-value claims that we believe would enter the appeals process if the proposal were finalized does provide a clear benefit, we estimate the costs to the Federal government would be roughly twice the projected benefit and recognize the appellant community would incur additional costs as well. Therefore, we do not believe this estimated benefit outweighs the potential costs at this time based on our revised analysis.

Thus, at this time we are not finalizing our proposal under §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we are not finalizing proposed §405.1006(d)(2)(i)(B), because, given that we are not finalizing proposed §405.1006(d)(2)(i)(A), there is no longer a need to distinguish between items and services with and without a published Medicare fee schedule or contractor-priced amount. Instead, we will continue to use the methodology specified in §405.1006(d)(1) as the general methodology for calculating the amount in controversy, except that we are finalizing our proposal to replace “for the items and services in question” with “for the items and services

in the disputed claim” in §405.1006(d)(1) introductory text because the amount in controversy is calculated on a claim-by-claim basis, and there has been confusion when a single reconsideration decision involves multiple claims. We are also replacing “applicable in the particular case” with “that may be collected for the items or services” in §405.1006(d)(1)(ii) because, as explained above and in section III.A.3.d of the proposed rule, there may be situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible amounts, or must refund any such amounts already collected, and in these situations the amount in controversy should not be reduced by that amount. Furthermore, because we will continue to use §405.1006(d)(1), as revised above, we are not finalizing proposed §405.1006(d)(1).

In addition, we also are not finalizing proposed §405.1006(d)(2)(ii) and (iii) because there is no need to define the basis for the amount in controversy in specific situations, as the amount in controversy would be calculated on the basis of the amount charged the individual in all of the scenarios described in proposed §405.1006(d)(2)(i) through (iii). However, for the reasons discussed above and in section III.A.3.d of the proposed rule, we continue to believe that it would be appropriate to finalize separate calculations of the amount in controversy to address the situations in proposed §405.1006(d)(3) through (7). Therefore, we are finalizing, with the modifications discussed below, the exceptions to the general calculation methodology that we proposed at §405.1006(d)(3) through (7), which are being renumbered as §405.1006(d)(2) through (6) in this final rule.

Comment: One commenter supported our proposal to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. Another commenter supported our proposal to continue using the provider’s or supplier’s billed charges as the basis

for calculating the amount in controversy for appeals of claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (subject to the exceptions delineated in the proposed rule).

Response: We thank the commenters for their support. However, for the reasons explained above, we are not finalizing our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount.

Comment: One commenter stated that the proposed rule “establishes the minimum amounts in controversy for a hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy.” The commenter also stated that the proposal to use the Medicare allowable amount as the basis for the amount in controversy for appeals of claims that are priced based on a published Medicare fee schedule or published contractor-priced amount, could be burdensome for MAOs, who would need to provide their contracted rates for every provider and plan type for appeals that involve supplemental benefits offered by the plan. Finally, the commenter requested clarification on how the proposal would affect pre-service requests for coverage.

Response: We disagree with the comment that the proposed rule would establish the minimum amounts in controversy for an ALJ hearing and judicial review, but that it would not establish how to calculate the amount in controversy. Section 1869(b)(1)(E) of the Act establishes the amount in controversy threshold amounts for an ALJ hearing and judicial review at \$100 and \$1,000, respectively, for Medicare Part A and Part B appeals, adjusted annually by the percentage increase in the medical care component of the consumer price index (CPI) for all urban consumers (U.S. city average) for July 2003 to July of the year preceding the year

involved and rounded to the nearest multiple of \$10. Section 1869(b)(1)(E) of the Act is then referenced and the same amount in controversy thresholds and adjustments are made applicable to competitive medical plan (also known as cost plan) appeals in section 1876(c)(5)(b) of the Act, to Part C MA appeals in section 1852(g)(5) of the Act, and to Part D Prescription Drug appeals in section 1860D-4(h) of the Act (by reference back to section 1852(g) of the Act). Thus, the minimum amount in controversy thresholds required for an ALJ hearing and judicial review are established by statute, and are reflected in the regulations at current §405.1006(b) and (c).

However, as we explained above and in the proposed rule, the statute does not specify how to calculate the amount in controversy. Section 405.1006(d)(1) provides that, subject to the exception in paragraph (d)(2), the amount in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by any Medicare payments already made or awarded for the items or services and any deductible or coinsurance amounts applicable in the particular case. Because the actual amount charged the individual may not always be an accurate reflection of the amount at issue for appellants, we proposed to revise the calculation methodology in §405.1006(d) in a manner that better aligns the amount in controversy with the amount at stake in an appeal. In general, we proposed in §405.1006(d)(1) that, subject to certain exceptions, the amount in controversy would be the calculated as the basis for the amount in controversy as defined in paragraph (d)(2), reduced by any Medicare payments already made or awarded for the items or services and any deductible and/or coinsurance amounts that may be collected for the items or services. In proposed §405.1006(d)(2), we explained how the basis for the amount in controversy would be calculated in different situations, and in §405.1006(d)(3) through (7) we proposed five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

With regard to the commenter's concern that under our proposal at §405.1006(d)(2)(i)(A), MAOs would need to provide their contracted rates for appeals that involve supplemental plan benefits, and the commenter's request for clarification regarding how this proposal would affect pre-service requests for coverage, we note that, for the reasons explained above, we are not finalizing our proposal in §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, nor are we finalizing proposed §405.1006(d)(2)(ii) or (d)(2)(iii).

Comment: Two commenters suggested HHS consider increasing the minimum amount in controversy required for an ALJ hearing. One of these commenters recommended raising the minimum amount in controversy from \$100 to \$300, and the other recommended raising it from \$100 to \$500. (As the annually adjusted amount in controversy threshold for an ALJ hearing was \$150 at the time the comments were received, we presume the commenters are referring to the amount in controversy without regard to the annual adjustments required under section 1869(b)(1)(E)(iii) of the Act.) The commenters stated that raising the amount in controversy would reduce the number of appeals for small-dollar claims and generate savings in adjudication costs for the government and staffing costs for health plans.

Response: The amount in controversy threshold required for an ALJ hearing is specified in section 1869(b)(1)(E) of the Act. We appreciate the commenters' recommendations, but we do not have the authority to change the amount in controversy threshold specified in the statute.

Comment: One commenter observed that claim determinations resulting from a single audit are frequently separated into multiple overpayment recovery actions, which increases administrative burden on appellants and CMS, and also may make it difficult for appellants to

aggregate claims to meet the amount in controversy requirement because the overpayment recovery actions often occur on different dates. The commenter recommended the agency prohibit Medicare contractors from separating claims that result from the same audit or investigation. Another commenter felt our proposals at §§405.1006(e)(1)(iii), (e)(2)(iii), 423.1970(c)(1)(iii), and (c)(2)(iii) providing that only an ALJ could determine that a request for aggregation was invalid were overly complicated, could make the role of an attorney adjudicator duplicative, and, without appropriate safeguards, could result in an ALJ merely adopting an attorney adjudicator's recommendation on whether a request for aggregation was valid without further review.

Response: With regard to the recommendation that the agency prohibit contractors from separating claims that result from the same audit or investigation, we note that permitted practices for CMS contractor audits are not within the scope of this rulemaking. We do not agree with the commenter that our proposal that only an ALJ can determine the invalidity of a request for aggregation is overly complicated. As explained above and in section III.A.3.d of the proposed rule, we believe that only an ALJ can determine the invalidity of a request for aggregation, because that determination would result in a dismissal of a request for an ALJ hearing. However, we believe it would be unnecessary and inefficient to require an ALJ to determine that a request for aggregation was valid for an appeal that was assigned to an attorney adjudicator. With respect to the concern that the ALJ could merely adopt the attorney adjudicator's recommendation on whether a request for aggregation was valid without further review, we note that §405.1006(e)(1) and (2), as finalized in this rule, provide that only an ALJ may determine that the claims were not properly aggregated and therefore do not meet the minimum amount in controversy required for an ALJ hearing. Thus, the ALJ is required to make

this determination, and would not be permitted to simply adopt the attorney adjudicator's preliminary determination without doing an independent review. We address the commenters concerns regarding the role of an attorney adjudicator compared to that of an ALJ more fully in section II.A.2 above.

Comment: One commenter stated that, for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) claims, in the case of an unrepresented beneficiary, the amount in controversy should include any set-up, handling or freight charges incurred in delivering the item to the beneficiary. The commenter stated that this amount is included in the allowable amount, but that the basis for the amount in controversy in situations described in proposed §405.1006(d)(2)(iii) (where the beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority) would be the actual amount originally charged to the beneficiary for those items and services as delivered to the beneficiary.

Response: We believe the commenter is requesting to define the basis in proposed §405.1006(d)(2)(iii) as the amount originally charged to the beneficiary for the items or services, including any set-up or delivery fees. Because we are not finalizing our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, as discussed above, we are not finalizing proposed §405.1006(d)(2)(iii) to define the basis for the amount in controversy when a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority. Under proposed §405.1006(d)(2)(iii), the basis for the amount in

controversy would be the actual amount originally charged to the beneficiary. We proposed §405.1006(d)(2)(iii) as an exception to the calculation in proposed §405.1006(d)(2)(i) in situations where the beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier under applicable authority. Because we are no longer finalizing §405.1006(d)(2)(i) as proposed, there is no longer a need to finalize §405.1006(d)(2)(iii). Therefore, as discussed above, the amount in controversy in this situation would be calculated as provided under §405.1006(d)(1) as finalized in this rule (the actual amount charged the individual for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded and any deductible and/or coinsurance amounts that may be collected for the items or services). In most cases, we expect that the amount charged the individual for the items and services in the disputed claim would be inclusive of delivery and set-up expenses. Subject to a few exceptions, suppliers rarely include a separate charge for delivery and set-up. Delivery and service are an integral part of a DME supplier's cost of doing business, and such costs are ordinarily assumed to have been taken into account by suppliers in setting the prices they charge for covered items and services (see Medicare Claims Processing Manual (Internet-Only Manual 100-04), chapter 20, section 60). As such, and as noted by the commenter, these costs have already been accounted for in the calculation of the fee schedules, and separate delivery and service charges for DME items are not permitted except in rare and unusual circumstances. In the rare and unusual circumstances where a separate charge is permitted (for example, when a supplier delivers an item outside the area in which the supplier normally does business), that charge, if billed on the same claim, would be factored into the amount charged the individual for purposes of calculating the amount in controversy under §405.1006(d)(1) as finalized in this rule.

Comment: One commenter opposed our revision to current §405.1006(d)(2), which we proposed to re-designate as §405.1006(d)(3), because the commenter felt that current §405.1006(d)(2) was easier to understand.

Response: Because we are not finalizing our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount, we are also not finalizing our proposal to revise and re-designate current §405.1006(d)(2), except the proposal to add “Limitation on liability” as a paragraph heading. In addition, for consistency with paragraph (d)(1)(ii) as finalized in this rule, we are also replacing the phrase “any deductible and coinsurance amounts applicable in the particular case” as set forth in current §405.1006(d)(2) with “any deductible and/or coinsurance amounts that may be collected for the items or services.”

Comment: One commenter asked how to calculate the amount in controversy when Medicare is secondary to another insurer and makes a supplemental payment under §411.32 because the primary payment is less than the charges for the services, but the supplemental payment amount is less than required under §411.33(a) or (e). The commenter also asked why in these instances the beneficiary’s Medicare Summary Notice (MSN) does not include a footnote stating that the amount of Medicare’s payment was determined in accordance with §411.33(a) or (e).

Response: Under current §405.1006(d), the amount in controversy in this situation is calculated as the amount charged the individual for the items and services in question, reduced by any Medicare payments already made or awarded for the items or services and any deductible and coinsurance amounts applicable in the particular case, regardless of any payment amounts

made or awarded by the primary insurer. Because the scenario raised by the commenter does not fall under any of the exceptions in §405.1006(d)(2) through (6) as finalized in this rule, the amount in controversy would continue to be calculated as provided under §405.1006(d)(1) as finalized in this rule (the amount charged the individual for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services and any deductible and/or coinsurance amounts that may be collected for the items or services). The commenter's question regarding footnotes on Medicare Summary Notices is outside the scope of this rulemaking.

Comment: One commenter supported the addition of proposed §405.1006(d)(4) to address how the amount in controversy is calculated for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. The commenter, a beneficiary advocacy organization, also asked what relief could be sought when a provider refuses to furnish or reinstate the terminated item or service after an ALJ determines the termination was not appropriate, or when the ALJ lacks the authority to rule on whether Medicare payment should be made for items or services that the beneficiary continued to receive (and paid for) after the termination date. The commenter was concerned that beneficiaries receive inadequate notice of the limited scope of an ALJ's authority in these matters, and earlier notice on the scope of expedited appeals under part 405, subpart J and the right to request a demand bill could help avoid these situations.

Response: We thank the commenter for its support of our proposal to address how the amount in controversy is calculated for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue

receiving the items or services. The comments regarding what relief may be sought when a provider refuses to furnish the terminated item or service after the ALJ determines the termination was not appropriate or when the ALJ lacks authority to rule on whether payment should be made for items or services that the beneficiary continued to receive after termination, and the suggestions regarding notice on the scope of expedited appeals and the right to request a demand bill are all outside the scope of this rulemaking. However, we may take them into consideration when making any future revisions to the provider service termination process.

Comment: We received two comments in support of our proposal at §405.976(b)(7) to require QICs to include in their notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

Response: We thank the commenters for their support. As discussed in section II.B.3.d below, we are not finalizing our proposal under §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. However, we continue to believe that the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator. Therefore we are finalizing without modification our proposal to require QICs to include in their notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only if the request for reconsideration was filed by a beneficiary who is not represented

by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable. As we stated above and in section III.A.3.d of the proposed rule, we believe providers, suppliers, Medicaid State agencies, and applicable plans have the tools, resources, and payment information necessary to calculate the amount in controversy, and we believe that to be especially true in light of our decision not to finalize proposed §405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. However, we recognize that beneficiaries may not have access to these same tools, resources, and payment information, and we believe it is appropriate for the QIC to continue furnishing an estimate of whether the amount in controversy is met for reconsiderations that are partially or fully unfavorable on requests for reconsideration filed by beneficiaries who are not represented by a provider, supplier, or Medicaid State agency.

Comment: We received several comments on our proposal under §405.1014(a)(1)(viii) to require that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, to include the amount in controversy in their requests for hearing.

Response: We address these comments in sections II.B.3.g.i below.

After review and consideration of the comments received, for the reasons discussed above, we are finalizing proposed §405.1006 with the following modifications. We are not finalizing our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we are not finalizing §405.1006(d)(2)(i)(B), because, given that we are not finalizing §405.1006(d)(2)(i)(A), there is no longer a need to distinguish between items and services with and without a published

Medicare fee schedule or contractor-priced amount. We also are not finalizing proposed §405.1006(d)(2) or (d)(2)(i) introductory text, as there is no need for this language given that we are not finalizing §405.1006(d)(2)(i)(A) or (B). Accordingly, we are maintaining the text of current §405.1006(d)(1), except that we are: (1) adding “In general” as a paragraph heading as proposed; (2) replacing “for the items and services in question” with “for the items and services in the disputed claim” in §405.1006(d)(1) introductory text as proposed; and (3) replacing “Any deductible and coinsurance amounts applicable in the particular case” in current §405.1006(d)(1)(ii) with “Any deductible and/or coinsurance amounts that may be collected for the items or services” as proposed. Furthermore, as discussed above, because we will continue to use current §405.1006(d)(1) as revised above to calculate the amount in controversy, we are not finalizing proposed §405.1006(d)(1) introductory text.

In addition, we also are not finalizing proposed §405.1006(d)(2)(ii) and (iii) because there is no need to define the basis for the amount in controversy in specific situations, as the amount in controversy would be calculated on the basis of the amount charged the individual in all of the scenarios described in proposed §405.1006(d)(2)(i) through (iii). Furthermore, we are not finalizing our proposal to revise and re-designate current §405.1006(d)(2) as §405.1006(d)(3), except for the proposal to add “Limitation on liability” as a paragraph heading. However, for consistency with paragraph (d)(1)(ii) as finalized, we are replacing “any deductible and coinsurance amounts applicable in the particular case” in current §405.1006(d)(2) with “any deductible and/or coinsurance amounts that may be collected for the items or services.”

We are finalizing proposed §405.1006(d)(4), (5), (6), and (7) with the modifications discussed below, but re-designating them as paragraphs (d)(3), (4), (5), and (6), respectively, because we are not finalizing proposed §405.1006(d)(2) or re-designating current

§405.1006(d)(2) as §405.1006(d)(3). We are replacing “in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy” in paragraph (d)(3) as finalized (proposed paragraph (d)(4)) with “in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual.” In addition, we are replacing “Notwithstanding paragraphs (d)(1) and (2) of this section” in paragraphs (d)(4), (5), and (6) as finalized (proposed paragraphs (d)(5), (6), and (7)) with “Notwithstanding paragraph (d)(1) of this section.”

Finally, we are finalizing our proposal to revise §405.976(b)(7), the section heading of §405.1006, and the changes to §405.1006(e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory text, (e)(2)(ii) and (iii), and §423.1970(c)(1)(ii) and (iii), (c)(2)(ii) and (iii) as proposed, without modification.

e. Parties to an ALJ hearing (§§405.1008 and 423.2008)

Current §§405.1008 and 423.2008 discuss the parties to an ALJ hearing. Because current §§405.1002(a) and 423.2002(a) already address who may request a hearing before an ALJ after a QIC or IRE issues a reconsideration and current §405.1002(b) addresses who may request escalation of a request for a QIC reconsideration, we proposed to remove current §§405.1008(a) and 423.2008(a). 81 FR 43790, 43810.

We proposed to retain and revise the language as discussed below in current §§405.1008(b) and 423.2008(b), but remove the paragraph designation. Current §§405.1008(b) and 423.2008(b) identify the parties “to the ALJ hearing,” but this could be read to be limited to parties to an oral hearing, if a hearing is conducted. To address this potential confusion, we proposed to revise §§405.1008 and 423.2008 to replace “parties to an ALJ hearing” with “parties to the proceedings on a request for an ALJ hearing” and “party to the ALJ hearing” with “party

to the proceedings on a request for an ALJ hearing.” Likewise, we also proposed to revise the titles to §§405.1008 and 423.2008 from “Parties to an ALJ hearing” to “Parties to the proceedings on a request for an ALJ hearing.” 81 FR 43790, 43810.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received one comment on proposed §§405.1008 and 423.2008 regarding parties to an ALJ hearing. The comment was submitted by a Recovery Auditor trade/advocacy group and expressed concerns about how the proposals related to status at ALJ hearings would impact CMS audit contractors’ interests in the hearings and their ability to elect party status.

Response: As we explain above, these proposals removed some redundancies in current §§405.1008(a) and 423.2008(a) and clarified the language to address potential confusion that the sections applied only to parties to an oral hearing, if a hearing is conducted, rather than to parties to the proceedings on a request for an ALJ hearing. Although the commenter included the caption to this proposal in its submission, the comments relate to proposed §§405.1010, 405.1012 and 423.2010. Therefore, we respond to this comment in section II.B.3.f.i below.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.1008 and 423.2008 as proposed without modification.

f. CMS and CMS contractors as participants or parties in the adjudication process (§§405.1010, 405.1012, and 423.2010)

As further described below, we proposed significant revisions to §§405.1010 and 405.1012 regarding CMS and CMS contractors as participants or parties in proceedings on a request for an ALJ hearing, and to §423.2010 regarding CMS, the IRE, or a Part D plan sponsor

as participants in proceedings on a request for an ALJ hearing. 81 FR 43790, 43810–43816, 43862–43863, and 43879–43880.

i. Section 405.1010: When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing

Current §405.1010(a) provides that an ALJ may request, but may not require, CMS and/or its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any, and CMS or its contractors may elect to participate in the hearing process. Under current §405.1010(b), if that election is made, CMS or its contractor must advise the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 calendar days after receiving the notice of hearing. Section 405.1010(c) sets forth what participation includes and §405.1010(d) states that participation does not include CMS or its contractor being called as a witness during the hearing. Section 405.1010(e) requires CMS or its contractors to submit any position papers within the time frame designated by the ALJ. Finally, §405.1010(f) states that the ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

We stated in the proposed rule that the reference to the period in which an election to participate must be filed beginning upon receipt of the notice of hearing in current §405.1010(b) has caused confusion when CMS or its contractors attempt to enter proceedings before a hearing is scheduled, or when no notice of hearing is necessary because an appeal may be decided on the record. To help ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process prior to a hearing being scheduled or when a hearing may not be conducted, we proposed in §405.1010(a)(1) to provide that CMS or its contractors may elect to participate in the proceedings on a request for an ALJ

hearing upon filing a notice of intent to participate in accordance with paragraph (b), at either of, but not later than, two distinct points in the adjudication process described in paragraph (b)(3).

As provided in current §405.1010(a) and (f), we proposed at §405.1010(a)(2) that an ALJ may request but may not require CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any; and the ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings.

We proposed in §405.1010(b) to address how CMS or a contractor makes an election to participate in an appeal, before or after receipt of a notice of hearing or when a notice of hearing is not required. Under §405.1010(b)(1), we proposed that if CMS or a contractor elects to participate before receipt of a notice of hearing (such as during the 30 calendar day period after being notified that a request for hearing was filed as proposed in §405.1010(b)(3)(i)) or when a notice of hearing is not required, CMS or the contractor must send written notice of its intent to participate to the parties who were sent a copy of the notice of reconsideration, and to the assigned ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), or if the appeal is not yet assigned, to a designee of the Chief ALJ. We proposed at §405.1010(b)(1) to provide for sending the written notice of intent to participate to an ALJ or attorney adjudicator assigned to an appeal because, as we discussed in section II.B of the proposed rule and II.A.2 of this final rule above, an attorney adjudicator also would have the authority to issue decisions on a request for an ALJ hearing when no hearing is conducted, and in accordance with proposed §405.1010, CMS or its contractors are permitted to participate in the proceedings on such a request. We also proposed at §405.1010(b)(1) to provide for sending the notice of intent to participate to a designee of the Chief ALJ if a request for an ALJ hearing is not yet assigned to an ALJ or attorney adjudicator because CMS or a contractor

could file an election to be a participant in the proceedings before the assignment process is complete. We stated in the proposed rule that proposed §405.1010(b)(1) would help ensure that the potential parties to a hearing, if a hearing is conducted, would receive notice of the intent to participate, and also help ensure that adjudicators who are assigned to an appeal after an election is made would be aware of the election. Because only an ALJ may conduct a hearing and the parties to whom a notice of hearing is sent may differ from the parties who were sent a copy on the notice of reconsideration, we proposed at §405.1010(b)(2) that if CMS or a contractor elects to participate after receiving a notice of hearing, CMS or the contractor would send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

We proposed at §405.1010(b)(3)(i) that CMS or a contractor would have an initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed with OMHA, if no hearing is scheduled. CMS and its contractors have the capability to see that a QIC reconsideration had been appealed to OMHA in the case management system used by QICs. This system would provide constructive notice to the QICs when the system indicates an appeal has been filed with OMHA, which OMHA can monitor through the date that the reconsideration data is transferred to OMHA to adjudicate the request for an ALJ hearing. Under proposed §405.1010(b)(3)(ii), a second opportunity to elect to be a participant in an appeal would become available if a hearing is scheduled; as in the current rule, CMS or a contractor would have 10 calendar days after receiving the notice of hearing to make the election.

As we stated in the proposed rule, we considered allowing CMS or a contractor to make an election at any time prior to a decision being issued if a hearing was not scheduled, or sending

a notice that a decision would be issued without a hearing and establishing an election period after such notice. However, both of these options would disrupt and delay the adjudication process, as well as add administrative burdens on OMHA. We stated in the proposed rule that we believed the 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS or a contractor to determine whether to elect to be a participant in the appeal while the record is reviewed for case development and to prepare for the hearing, or determine whether a decision may be appropriate based on the record in accordance with §405.1038.

We proposed to consolidate current §405.1010(c) through (e) in proposed §405.1010(c) to address the roles and responsibilities of CMS or a contractor as a participant. Proposed §405.1010(c)(1) would incorporate current §405.1010(c), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we proposed to revise §405.1010(c) to state in §405.1010(c)(1) that participation may include filing position papers "and/or" providing testimony to emphasize that either or both may be done, and to state that participation would be subject to proposed §405.1010(d)(1) through (3) (discussed below). We proposed to incorporate current §405.1010(d) in proposed §405.1010(c)(2) to provide that when CMS or a contractor participates in a hearing, they may not be called as witnesses and, thus, are not subject to examination or cross-examination by parties to the hearing. However, to be clear about how a party and the ALJ may address statements made by CMS or a contractor during the hearing given that limitation, we also proposed in §405.1010(c)(2) that the parties may provide testimony to rebut factual or policy statements made by the participant, and the ALJ may question the participant about the testimony.

We proposed to incorporate current §405.1010(e) in proposed §405.1010(c)(3) with certain revisions as discussed below. Current §405.1010(e) states that CMS or its contractor must submit any position papers within the time frame designated by the ALJ. We proposed in §405.1010(c)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed §405.1010(b), and require that copies of position papers and written testimony be sent to the parties. Specifically, we proposed in §405.1010(c)(3)(i) that CMS or a contractor position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the scheduled hearing unless additional time is granted by the ALJ. We proposed to add “written testimony” to recognize that CMS or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We proposed to require position papers and written testimony be submitted within 14 calendar days after an election if no hearing is scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with §405.1038. We also proposed to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time) to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Additionally, under proposed §405.1010(c)(3)(ii), CMS or a contractor would need to send a copy of any position paper or written testimony submitted to OMHA to the parties who were sent a copy of the notice of reconsideration if the position paper or written testimony is submitted to OMHA before receipt of a notice of hearing, or to the parties who were sent a copy of the notice of hearing if the

position paper or written testimony is submitted after receipt of a notice of hearing. Current §405.1010 does not address the repercussions of a position paper not being submitted in accordance with the section. Therefore, we proposed in §405.1010(c)(3)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper or written testimony to the parties, or fails to submit its position paper or written testimony within the established time frames. We stated in the proposed rule that this would help ensure CMS or contractor position papers and written testimony are submitted timely and shared with the parties.

Current §405.1010 does not limit the number of entities that may elect to be participants, which currently includes participating in a hearing if a hearing is conducted, and current §405.1012 does not limit the number of entities that may elect to be a party to a hearing. We stated in the proposed rule that this has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we proposed at §405.1010(d)(1) that when CMS or a contractor has been made a party to the hearing under §405.1012, CMS or a contractor that elected to be a participant under §405.1010 may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case (oral testimony and attendance at the hearing would not be permitted). Similarly, we proposed at §405.1010(d)(1) that CMS or a contractor that elected to be a party to the hearing, but was made a participant under §405.1012(d)(1), as discussed below, would also be precluded from participating in the oral hearing, but would be permitted to file a position paper and/or oral testimony to clarify factual or policy issues in the case. We proposed at §405.1010(d)(2) that if CMS or a contractor did not elect to be a party to the hearing under §405.1012, but more than one entity elected to be a participant under §405.1010, only the first

entity to file a response to the notice of hearing as provided under §405.1020(c) may participate in the oral hearing, but additional entities that filed a subsequent response to the notice of hearing could file a position paper and/or written testimony to clarify factual or policy issues in the case (though they would not be permitted to attend the hearing or provide oral testimony). We proposed that the first entity to file a response to the notice of hearing as provided under §405.1020(c) may participate in the hearing for administrative efficiency. Under this approach, if multiple entities elected to participate in the proceedings prior to the issuance of a notice of hearing, in accordance with proposed §405.1010(b)(1), any of these entities wishing to participate in the oral hearing would need to indicate this intention in the response to the notice of hearing. If more than one entity indicated its intention to attend and participate in the oral hearing, only the first entity to file its response would be permitted to do so. The remaining entities would be permitted only to file a position paper and/or written testimony (unless the ALJ grants leave to additional entities to attend the hearing, as discussed below). We considered an alternate proposal of the first entity that made an election to participate being given priority for participating in the hearing, but believed that would result in other participants being uncertain whether they will be participating in the hearing until as few as 5 days prior to the hearing. We also considered a process in which the ALJ would assess which participant that responded to the notice of hearing would be most helpful to the ALJ at the hearing, or in the alternative, permitting all participants to be at the hearing unless the ALJ determined a participant is not necessary for the hearing, but we were concerned that both of these approaches would add administrative burden to the ALJ and could result in participants and parties being uncertain of which participants will be at the hearing until shortly before the hearing. We solicited comments on the alternatives considered above, and other potential alternatives.

Notwithstanding the limitations on CMS and CMS contractor participation in proposed §405.1010(d)(1) and (2), we proposed in §405.1010(d)(3) that the ALJ would have the necessary discretion to allow additional participation in the oral hearing when the ALJ determines an entity's participation is necessary for a full examination of the matters at issue. For example, we stated in the proposed rule that if an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. Similarly, if an overpayment determined through the use of a statistical sample and extrapolation is at issue, the ALJ may determine that allowing the contractor that conducted the sampling to participate in the hearing is necessary to address issues related to the sampling and extrapolation, in addition to another contractor that made an election to clarify the policy and factual issues related to the merits of claims in the sample.

Currently, there are no provisions in §405.1010 to address the possibility of CMS or a contractor making an invalid election. We proposed to revise §405.1010(e) to add new provisions to establish criteria for when an election may be deemed invalid and provide standards for notifying the entity and the parties when an election is deemed invalid. We proposed in §405.1010(e)(1) that an ALJ or attorney adjudicator may determine an election is invalid if the election was not timely filed or the election was not sent to the correct parties. We stated that this would help ensure that CMS and its contractors make timely elections and inform parties of elections. To provide notice to the entity and the parties that an election was deemed invalid, we proposed in §405.1010(e)(2) to require a written notice of an invalid election be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election. We proposed in §405.1010(e)(2)(i) that if no hearing is scheduled for the appeal or the election was submitted after the hearing occurred, the notice of an invalid election would be sent

no later than the date the decision, dismissal, or remand notice is mailed. We proposed in §405.1010(e)(2)(ii) that if a hearing is scheduled for the appeal, the written notice of an invalid election would be sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided.

ii. Section 423.2010: When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing

Current §423.2010 is similar to current §405.1010, except that CMS, the IRE, or the Part D plan sponsor may only request to participate, and the time periods to request to participate are shorter than the time periods to elect to participate under §405.1010, which provides the ALJ with time to consider the request to participate and make a determination on whether to allow participation by the entity. In addition, current §423.2010 addresses participation in Part D expedited appeals. Like proposed §405.1010(a), we proposed at §423.2010(a) to provide CMS, the IRE, and the Part D plan sponsor with an opportunity to participate in the proceedings on a request for an ALJ hearing at two distinct points in the adjudication process, but the current policy of requiring the entity to request to participate is maintained. We proposed at §423.2010(b)(3)(i) and (ii) that, if no hearing is scheduled, CMS, the IRE and/or the Part D plan sponsor would have an initial opportunity to request to be a participant in an appeal within 30 calendar days after notification that a standard request for hearing was filed with OMHA, or within 2 calendar days after notification that a request for an expedited hearing was filed. We stated in the proposed rule that the initial 30 calendar day period after notification that a standard request for hearing was filed with OMHA would be the same time frame provided under §405.1010 for initial CMS and contractor elections, and we stated that we believed that the 30

calendar day period after notification that a request for hearing was filed is sufficient time for CMS, the IRE, and the Part D plan sponsor to determine whether to request to be a participant in the proceedings and for the request to be considered and granted or denied as the case is reviewed to determine whether a decision may be appropriate based on the record in accordance with §423.2038. We also stated we believed the 2 calendar day period after notification that an expedited request for hearing was filed is a reasonable period of time for CMS, the IRE, or the Part D plan sponsor to determine whether to request to be a participant in the proceedings given the 10-day adjudication time frame. We proposed at §423.2010(b)(3)(iii) and (iv) to provide a second opportunity to request to be a participant in an appeal if a hearing is scheduled. We proposed at §423.2010(b)(3)(iii) that if a non-expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 5 calendar days after receiving the notice of hearing to make the request. We proposed at §423.2010(b)(3)(iv) that if an expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 1 calendar day after receiving the notice of hearing to make the request. These time frames were carried over from current §423.2010(b)(1) and (b)(3), and provide the ALJ with time to consider the request and notify the entity of his or her decision on the request to participate. As provided in current §423.2010(a) and (g), we proposed at §423.2010(a)(2) to provide that an ALJ may request but may not require CMS, the IRE, or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any, and that the ALJ may not draw any adverse inferences if CMS, the IRE, or the Part D plan sponsor declines to be a participant to the proceedings.

We proposed in §423.2010(b) to adopt the standards governing how an election is made in proposed §405.1010(b) in governing how a request to participate is made, except that an oral

request to participate could be made for an expedited hearing, and OMHA would notify the enrollee of the request to participate in such cases.

Current §423.2010(b)(2) and (b)(4) provide that an ALJ will notify an entity requesting to participate of the decision on the request within 5 calendar days for a request related to a non-expedited hearing, or 1 calendar day for a request related to an expedited hearing. We proposed to incorporate these time frames into proposed §423.2010(c). In addition, we proposed in §423.2010(c)(1) that if no hearing is scheduled, the notification is made at least 20 calendar days before the ALJ or attorney adjudicator (as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above)) issues a decision, dismissal, or remand. This would provide the participant with time to submit a position paper in accordance with proposed §423.2010(d)(3)(i), as discussed below. We also proposed to incorporate current §423.2010(c) into proposed §423.2010(c), so that the provision clearly states that the assigned ALJ or attorney adjudicator (as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above)) has discretion to not allow CMS, the IRE, or the Part D plan sponsor to participate. We proposed in §423.2010(c) that an attorney adjudicator as well as the ALJ may make a decision on a request to participate because a request to participate may be submitted for appeals that may be assigned to an attorney adjudicator and those appeals could also benefit from CMS, the IRE, or the Part D plan sponsor participation in the proceedings. We did not propose to limit the number of participants in a hearing similar to proposed §405.1010(d) because the ALJ has the discretion to deny a request to participate under §423.1010 and may therefore deny a request to participate if the ALJ determines that a hearing would have sufficient participant involvement or does not need participant involvement.

We proposed at §423.2010(d) to consolidate current §423.2010(d) through (f), to address the roles and responsibilities of CMS, the IRE, or the Part D plan sponsor as a participant. Specifically, we proposed at §423.2010(d)(1) to generally incorporate current §423.2010(d), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we proposed in §423.2010(d)(1) that participation may include filing position papers “and/or” providing testimony to emphasize that either or both may be done, and to remove the limitation that testimony must be written because participation may include providing oral testimony during the hearing. We proposed at §423.2010(d)(2) to incorporate current §423.2010(e), which provides that when participating in a hearing, CMS, the IRE, or the Part D plan sponsor may not be called as a witness during the hearing and, thus, are not subject to examination or cross-examination by the enrollee at the hearing. However, to be clear about how an enrollee and the ALJ may address statements made by CMS, the IRE, or the Part D plan sponsor during the hearing given that limitation, we also proposed in §423.2010(d)(2) that the enrollee may rebut factual or policy statements made by the participant, and the ALJ may question the participant about its testimony.

We proposed at §423.2010(d)(3) to incorporate current §423.2010(f) with certain revisions as discussed below. Current §423.2010(f) states that CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the time frame designated by the ALJ. We proposed in §423.2010(d)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation requests in proposed 423.2010(b), and require that copies of position papers and written testimony be sent to the enrollee. Specifically, we proposed in §423.2010(d)(3) that, unless the

ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a CMS, the IRE, or the Part D plan sponsor position paper or written testimony must be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled, or no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing. We proposed to add "written testimony" to recognize that CMS, the IRE, or the Part D plan sponsor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We proposed to require that position papers and written testimony be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with §405.1038. We also proposed to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing (unless the ALJ grants additional time) to help ensure the ALJ and the enrollee have an opportunity to review the materials prior to the hearing. Similar to proposed §405.1010(c)(3)(iii), we also proposed at §423.2010(d)(3)(ii) that a copy of the position paper or written testimony must be sent to the enrollee, and at §423.2010(d)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of the position paper or written testimony to the enrollee or fails to submit the position paper or written testimony within the established time frames. This would help

ensure CMS, IRE, or Part D plan sponsor position papers and written testimony are submitted timely and shared with the enrollee.

Currently, there are no provisions in §423.2010 to address the possibility of CMS, the IRE, and/or the Part D plan sponsor making an invalid request to participate. We proposed to revise §423.2010(e) to add new provisions to establish criteria for when a request to participate may be deemed invalid and provide standards for notifying the entity and the enrollee when a request to participate is deemed invalid. We proposed in §423.2010(e)(1) that an ALJ or attorney adjudicator may determine a request to participate is invalid if the request to participate was not timely filed or the request to participate was not sent to the enrollee. We stated that this would help ensure that CMS, the IRE, and/or the Part D plan sponsor make timely requests to participate and inform the enrollee of requests. To provide notice to the entity and the enrollee that a request to participate was deemed invalid, we proposed in §423.2010(e)(2) to require that a written notice of an invalid request be sent to the entity that made the request and the enrollee. We proposed in §423.2010(e)(2)(i) that if no hearing is scheduled for the appeal or the request was made after the hearing occurred, the notice of an invalid request would be sent no later than the date the decision, dismissal, or remand order is mailed. We proposed in §423.2010(e)(2)(ii) that if a non-expedited hearing is scheduled for the appeal, written notice of an invalid request would be sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We proposed in §423.2010(e)(2)(iii) that if an expedited hearing is scheduled for the appeal, oral notice of an invalid request must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We proposed to require the oral notice for expedited hearings because the very short

time frames involved in expedited hearing proceedings often do not allow for delivery of a written notice and the oral notice will help ensure the entity is made aware of the invalid request prior to the hearing.

iii. Section 405.1012: When CMS or its contractors may be a party to a hearing

Current §405.1012(a) states that CMS and/or its contractors may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary. Current §405.1012(b) states that CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. Current §405.1012(c) states that, when CMS or its contractors participate in a hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ. Finally, current §405.1012(d) states that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party. As stated previously, we proposed significant changes to §405.1012.

Current §405.1012 does not limit the number entities that may elect to be a party to the hearing. We stated in the proposed rule that this has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we proposed at §405.1012(a)(1), except as provided in proposed paragraph (d) discussed below, to only allow either CMS or one of its contractors to elect to be a party to the hearing (unless the request for hearing is filed by an unrepresented beneficiary, which precludes CMS

and its contractors from electing to be a party to the hearing). Current §405.1012(b) states that CMS or a contractor advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. We proposed at §405.1012(a) to incorporate and revise a portion of current §405.1012(b), to require that an election to be a party must be filed no later than 10 calendar days after the QIC receives the notice of hearing, because notices of hearing are sent to the QIC in accordance with §405.1020(c) (the remaining portion of current §405.1012(b) is incorporated with revisions into proposed §405.1012(b), as discussed below).

Current §405.1012 does not have a provision similar to current §405.1010(a), which states that an ALJ may request that CMS and/or one or more of its contractors participate in the proceedings, but current §405.1012(d) does provide that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inference if CMS or a contractor decided not to enter as a party. In practice, ALJs do at times request that CMS or a contractor elect to be a party to the hearing, in conjunction with a request for participation under current §405.1010(a). To align the provisions and reflect ALJ practices, we proposed at §405.1012(a)(2) to state that an ALJ may request but not require CMS and/or one or more of its contractors to be a party to the hearing. We also proposed in §405.1012(a)(2) to incorporate current §405.1012(d) to provide that that an ALJ cannot draw any adverse inferences if CMS or a contractor decides not to enter as a party.

We proposed at §405.1012(b) to address how CMS or a contractor elects to be a party to the hearing. We proposed to follow the same process in current §405.1012(b) so that under proposed §405.1012(b), CMS or the contractor would be required to send written notice of its

intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant.

We proposed to set forth the roles and responsibilities of CMS or a contractor as a party in §405.1012(c). Proposed §405.1012(c)(1) would incorporate current §405.1012(c) with some changes in wording, both of which provide that as a party to the hearing, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses, or cross-examine the witnesses of other parties. We proposed in §405.1012(c)(2) to include written testimony, such as an affidavit or deposition, in the provision; establish deadlines for submission of position papers, written testimony, and evidence; and require that copies of position papers, written testimony, and evidence be sent to the parties that were sent a copy of the notice of hearing. Specifically, we proposed in §405.1012(c)(2)(i) and (c)(2)(ii) that any position papers, written testimony, and evidence must be submitted no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the materials, and copies must be sent to the parties who were sent a copy of the notice of hearing. We proposed to add “written testimony” to recognize that CMS or a contractor may submit written testimony, in addition to providing oral testimony at a hearing. We also proposed to require that position papers, written testimony, and/or evidence be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time), and that copies be submitted to the parties sent notice of the hearing, to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Current §405.1012 does not address the consequence of failure to submit a position paper or evidence in accordance with the section. We proposed in §405.1012(c)(2)(iii) that a position paper, written testimony, and/or evidence would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper,

written testimony, and/or evidence to the parties or fails to submit the position paper, written testimony, and/or evidence within the established time frames. We stated in the proposed rule that this would help ensure CMS or contractor position papers and evidence are submitted timely and shared with the parties.

As discussed above, current §405.1012 does not limit the number of entities (that is, CMS and its contractors) that may elect to be a party to the hearing and, as also discussed above, we proposed to revise §405.1010 and 405.1012 to limit the number of entities that participate in a hearing unless an ALJ determines that an entity's participation is necessary for a full examination of the matters at issue. We proposed to revise §405.1012(d)(1) to provide that if CMS and one or more contractors, or multiple contractors file elections to be a party to a hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under §405.1010, subject to §405.1010(d)(1) and (3) (and as such may file position papers and provide written testimony to clarify factual or policy issues in the case, but may not participate in the oral hearing unless the ALJ grants leave to the entity to participate in the oral hearing in accordance with §405.1010(d)(3)). Similar to proposed §405.1010(d)(3), we also proposed in §405.1012(d)(2) that, notwithstanding the limitation in proposed §405.1012(d)(1), an ALJ may grant leave for additional entities to be parties to the hearing if the ALJ determines that an entity's participation as a party is necessary for full examination of the matters at issue.

We stated in the proposed rule that we believed allowing the first entity to file an election after a notice of hearing is issued to be a party to the hearing is administratively efficient and provides an objective way to determine which entity is made a party based on the competing elections, while providing an opportunity to participate in the appeal by filing a position paper

and/or written testimony under §405.1010 for those that file later in time, or to be made a participant or party to the hearing by the ALJ under the ALJ's discretionary authority under proposed §§405.1010(d)(3) and 405.1012(d)(2). We considered an alternate proposal of the first entity that had elected participant status under §405.1010, if any, being given priority for being made a party to the hearing, but stated that we believed that would result in other entities making a party election being uncertain whether they will be made a party to the hearing until as few as 5 days prior to the hearing (assuming the notice of hearing is sent 20 days prior to the scheduled hearing, as required by §405.1022(a), the QIC receives the notice of hearing 5 days later, and the entity or entities responding to the notice of hearing can make their election as late as 10 calendar days after the QIC's receipt of the notice, leaving only 5 days prior to the hearing). We also considered a process by which the ALJ would assess which entity making a party election would be most helpful to the ALJ at the hearing, or in the alternative, permitting all entities that filed a party election to be made a party to the hearing unless the ALJ determined an entity is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in CMS, contractors and parties being uncertain of which entities will be parties to the hearing until shortly before the hearing. We solicited comments on the alternatives considered above.

Finally, we proposed to add new §405.1012(e) to address the possibility of CMS or a contractor making an invalid election. Proposed §405.1012(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination

of the matters at issue. We stated that this would help ensure that CMS and its contractors make timely elections and inform parties of elections, and also provide a mechanism to address an election when the request for hearing was filed by an unrepresented beneficiary or when another entity has already filed an election to be a party to the hearing. To provide notice to the entity and the parties that an election was deemed invalid, we proposed in §405.1012(e)(2) to require that a written notice of an invalid election be sent to the entity that made the election and the parties who were sent the notice of hearing. We proposed in §405.1012(e)(2)(i) that if the election was submitted after the hearing occurred, the notice of an invalid election would be sent no later than the date the decision, dismissal, or remand notice is mailed. We proposed in §405.1012(e)(2)(ii) that if the election was submitted before the hearing occurs, the written notice of invalid election would be sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice would be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing would be sent as soon as possible after the oral notice is provided.

Provided below are summaries of the specific comments we received relating to our proposed revisions to §§405.1010, 405.1012, and 423.2010, and responses to these comments. Because many commenters submitted comments that touched on all three proposals, we are collectively addressing in this section comments that related to sections III.A.3.f.i, ii, and iii of the proposed rule:

Comment: We received five comments expressing support of proposed §§405.1010, 405.1012, and 423.2010 and discussing some specific benefits that commenters believed the proposal will have on the hearing process. One commenter noted that the clarifications in the

proposed rules will help appellants better prepare their arguments if they are aware that CMS or a contractor will be participating in the hearing process. Several commenters noted that the proposed limitation on the number of entities that may be a party to a hearing and participate in the oral hearing will eliminate unnecessary delays and duplicative and redundant argument and testimony that currently occur when multiple contractors elect or request to be a participant or party to the same hearing. One commenter indicated that the proposals will make scheduling hearings easier. One commenter indicated that the proposed changes will help ALJs make better use of limited time, allowing them to hear more cases. The same commenter noted that because the quality and credibility of the evidence, rather than the quantity, influences decision making, having more than one contractor present during the hearing does not add value to the process.

Response: We thank the commenters for their support and agree that the proposed rules set necessary parameters that will help ensure that hearings involving CMS or a contractor as a participant or a party will be as efficient as possible and that the expectations and roles of those entities when they elect either status are clear.

Comment: Two commenters suggested that the rules should go further and prohibit CMS or one of its contractors from participating in the proceedings on a request for an ALJ hearing if CMS or one of its contractors has entered the appeal as a party. The commenters argued that the rights of a party encompass all the rights of a participant and it is unclear what additional value would be gained from allowing another entity to enter as a participant in such instances.

Response: Section 405.1010(d)(1), as finalized in this rule, states that if CMS or a contractor has been made a party to a hearing in accordance with §405.1012, no entity that elected to be a participant in the proceedings in accordance with §405.1010 (or that elected to be a party to the hearing but was made a participant in accordance with §405.1012(d)(1) as finalized

in this rule) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case. We believe that involvement by CMS or its contractors in the proceedings on a request for hearing may be beneficial and can assist in clarifying factual and policy issues and providing a fuller examination of the matters at issue that may be necessary to resolve appeals.

While the interest of administrative efficiency supports limiting participation at the oral hearing, we do not believe the same rationale applies to position papers and written testimony. The submission of position papers and written testimony adds minimal burden to the appeals process, may assist with clarifying facts and policy, and allows for a fuller presentation of the appeal. While it is possible that there may be some repetition in the written submissions, we believe that there is potential added value in permitting contractors to submit position papers and written testimony for consideration in this situation.

Comment: Two commenters that currently hold QIC contracts submitted comments opposed to the limitations placed on CMS and its contractors participating in an oral hearing pursuant to §405.1010(d). According to one commenter, contractors often bring a unique perspective to ALJ hearings and participation of all interested parties and participants allows for a robust and complete presentation of the case and often yields greater consistency in decisions. The commenter noted that given the involvement of multiple contractors in any given appeal prior to the OMHA level—such as MACs, Zone Program Integrity Contractors (ZPICs), and Recovery Auditors—one contractor cannot always effectively address all issues in an appeal, and argued that when multiple contractors participate in an oral hearing, the contractors coordinate their presentations so that they do not repeat testimony when they are in agreement to keep the hearing duration at a minimum. The second commenter argued that the limitations proposed in

§405.1010(d) would significantly impact the QIC's ability to meet its contractual requirements for oral non-party participation at hearings and that QICs, in response, would have to elect participation in many additional hearings in order to meet those requirements, placing an administrative burden on OMHA to manage the participation requests.

Response: We agree that there is value in having CMS and its contractors involved in the proceedings at OMHA as participants, but we believe that limiting the number of participants at the oral hearing while still providing CMS and its contractors with an opportunity to share their unique perspectives through position papers and written testimony strikes an appropriate balance between administrative efficiency and obtaining as much information as possible for the ALJ to render a decision on the matter. In addition, we note that §405.1010(d)(3), as finalized in this rule, also permits additional participation in the oral hearing if the ALJ determines that a precluded entity's participation is necessary for a full examination of the matters at issue such as cases involving multiple MAC jurisdictions, significant dollar amounts at issue, extrapolation, and pre-pay or post-pay audits. Finally, with respect to concerns related to a contractor's ability to satisfy its contractual obligations, after the final rule is effective, CMS intends to make necessary contract modifications to account for the provisions of this final rule related to contractor participation, and encourage the contractors to coordinate participation in the hearings.

Comment: We also received one comment, jointly submitted by four entities holding DME MAC contracts, opposing the limitation on the number of contractor participants at oral hearings. The commenters noted that in the case of a large appeal involving statistical sampling and extrapolation or consolidated hearings, multiple DME MACs may have processed claims that are at issue in the appeals, and the restriction on the number of participants at the oral

hearing makes it impossible for each to have its “day in court.” The commenters argued that the contractor permitted to participate at the oral hearing may not have access to information on the beneficiaries and claims from other DME MAC jurisdictions and could not present any argument or defense for those denials. Finally, the commenters noted that it is impossible for those contractors who are not permitted to participate at the oral hearing to anticipate and refute arguments in a position paper written in the absence of knowledge of the appellant’s defense.

Response: Section 405.1010(d)(3), as finalized in this rule, provides that if CMS or a contractor is precluded from participating in the oral hearing under the provisions limiting the number of participants, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity’s participation is necessary for a full examination of the matters at issue. This paragraph provides the ALJ with necessary discretion to permit additional participants at the hearing in situations such as the ones noted above by the commenter, where multiple contractor participants at hearing may be necessary for a full examination of the issues. We provided examples above highlighting when an ALJ may find it necessary to exercise the discretion afforded to the ALJ in §405.1010(d)(3). In one example, we indicated that when an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. In another example, we suggested that in overpayment cases involving statistical sampling and extrapolation, the ALJ may allow participation in the oral hearing by both the contractor that conducted the sampling who is necessary to address issues related to the sampling and extrapolation and another contractor that made an election to participate to clarify the policy and factual issues related to the merits of the claims in the sample. The examples presented by the commenter—cases involving statistical sampling and

extrapolation or consolidated hearings in which multiple contractor jurisdictions are involved and a single contractor does not have information on all beneficiaries or claims involved—are similar instances when the ALJ may use his or her discretion to permit additional participants at the oral hearing because the additional participants may be necessary for a full examination of the matters at issue.

With respect to the commenter's concern that the contractor permitted to participate in the oral hearing may not have access to information on the beneficiaries and claims from other DME MAC jurisdictions and could not present any argument or defense for those denials, we note that even when a contractor is not permitted to participate in the oral hearing under §405.1010(d)(1), the contractor can still submit position papers and written testimony, which may provide helpful information to the contractor participating in the oral hearing. However to help further ensure that CMS or a CMS contractor that has elected party status is able to fully represent the position of CMS in cases where the entity that elected party status does not have information on all beneficiaries or claims involved, or where the entity that has elected party status deems it necessary to call another CMS contractor as a witness, we are amending proposed §405.1010(d)(3) to provide that CMS or a contractor that is precluded from participating in the oral hearing under paragraph §405.1010(d)(1) may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012. We expect the need for CMS or a contractor as a party to call another CMS contractor as a witness would be an infrequent occurrence, and believe this approach strikes the appropriate balance between administrative efficiency and addressing the commenter's concerns.

With respect to the commenter's concern that position papers and written testimony will be inadequate to refute arguments that are made at the hearing, we note that the role of

participants, both in written submissions and participating in the oral hearing, is to provide testimony to clarify factual or policy issues, and does not include calling witnesses or cross-examining the witness of a party to the hearing. In addition, we believe that CMS and its contractors are already familiar with the appellant's arguments based on the contractors' review of the record and involvement in the lower-level appeal decisions or the initial determination. Accordingly, we believe that contractors have generally set forth their positions on those arguments in the lower-level decisions or will have an opportunity to do so through the written submissions to OMHA. .

Comment: One commenter requested that OMHA institute a notification process to notify contractors of which entity submitted its election to participate first and, therefore, is permitted to participate in the oral hearing. The commenter noted that timely notification is important because it takes additional time and resources to plan for participation at the hearing. The commenter also suggested that instead of adopting a rule in which the first entity to file a response to the notice of hearing may participate in the oral hearing, OMHA should give priority to MACs and QICs over RAs because initial determinations, redeterminations, and reconsiderations are formal steps in the appeals process.

Response: The proposed rules do not specifically address notification to the entities regarding whether they will participate at the oral hearing or participate by submission of position papers and/or written testimony. If a hearing is scheduled, the assigned ALJ will notify the contractors regarding their participation prior to the hearing. OMHA will develop a consistent notification process, including guidance on when notification to the contractors should be made and the method of delivery of such notification, which will be made part of the OCPM. The OCPM describes OMHA case processing procedures in greater detail, provides frequent

examples to aid understanding, and it is accessible by the public on the OMHA website (www.hhs.gov/omha).

As discussed in the comment summary above, we considered alternatives to the proposed rule that the first entity to file a response to a notice of hearing be given priority for participating at the hearing, however we decided that giving the first entity priority is administratively efficient and provides an objective and clear way of determining which contractor is allowed to participate at the oral hearing. We do not agree with the commenter that OMHA should give priority to MACs and QICs over RAs as we believe, from our experience and from feedback we received from stakeholders, that there are valid and equal arguments why each of these entities' participation may be valuable in the proceedings. We again note that §405.1010(d)(3), as finalized in this rule, would allow the ALJ to permit multiple participants to attend the hearing if the participation of multiple entities at the hearing would be necessary for a full examination of the matters at issue.

Comment: We received one comment in support of proposed §405.1010(b)(3) allowing two distinct points in the adjudication process for contractors to elect to participate. However, the commenter suggested that the timing of the election periods specified in §405.1010(b)(3)(i) and (ii) be calculated starting with notification to the contractor rather than notification to the QIC. The commenter indicated that notice to the QIC does not give equal notice to the contractors and that there are delays in the transmission of information regarding whether a request for hearing has been filed and when the case is advanced in the Medicare appeals case processing system from the QIC level to the OMHA level.

Response: We thank the commenter for its support of proposed §405.1010(b)(3) and believe that by providing two distinct points governing the timing of an election to participate in

the proceedings helps ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process. The proposed regulation on timing of the election to participate provides that if no hearing is scheduled, CMS or its contractors must make the election no later than 30 calendar days after the notification that a request for hearing was filed or, if a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing. We believe that the 30 calendar day and 10 calendar day timeframes set forth in §405.1010(b)(3)(i) and (ii) (as finalized) provide adequate time for all contractors to receive notice and to file an election to be a participant. With respect to the commenter's concern regarding notice to the contractors when a request for hearing is filed, in addition to the constructive notice provided to the QICs, OMHA and CMS will begin the process of modifying contract provisions with regards to hearing request notifications after the effective date of this final rule. CMS and OMHA will develop a process to notify the contractors of the hearing requests and CMS will convey the process to the contractors when it is ready to be operationalized.

Pursuant to §405.1020(c)(1) (as finalized in this rule), if a hearing is scheduled, the ALJ would send notice of the hearing to the QIC, to CMS and any contractor that the ALJ believes would be beneficial to the hearing, and, as discussed below, to CMS or any contractor that elected to participate in the proceedings in accordance with §405.1010(b). Therefore, if a contractor has elected to participate in the proceedings before a notice of hearing has been sent, under §405.1020(c)(1), if a hearing is ultimately scheduled that entity will receive a copy of the notice of hearing directly from OMHA. While contractors not specified in §405.1020(c)(1) will not receive a copy of the notice of hearing directly from OMHA, we believe that limiting the number of notices provided to those entities specified in §405.1020(c)(1) is necessary to

minimize the administrative burden on OMHA. Further, we do not believe that limiting the number of notices will compromise the interests of contractors because we plan to issue sub-regulatory guidance, including educational materials and contractual modifications that will establish processes to accommodate the regulatory changes. These processes will relate to timely notice, information sharing, and coordination among affected contractors that may have an interest in participating in the same hearing. CMS will begin the process of issuing sub-regulatory guidance and contractual modifications after the effective date of this final rule.

Comment: We received a comment asking whether the submission of a written notice of intent to participate will be the same for cases assigned to an attorney adjudicator and cases assigned to an ALJ, and whether the notice of intent to participate will be accepted in electronic form. The comment also asked, with respect to the filing of a notice of intent to participate prior to assignment of the appeal to an ALJ or attorney adjudicator, if the Chief ALJ will have only one designee and, if not, how contractors will know to whom to send the notices.

Response: The process for submission of a notice of intent to participate under §405.1010(b) is the same regardless of whether the appeal is assigned to an ALJ or an attorney adjudicator. Rather, the distinctions in §405.1010(b) regarding the notice of intent to participate are based on whether a notice of hearing has been issued and the timing of the election. After the final rule becomes effective, OMHA will develop consistent procedures for the receipt of notices of intent to participate in ALJ and attorney adjudicator proceedings, including specific instructions regarding where notices of intent to participate for appeals that are not yet assigned to an ALJ or attorney adjudicator should be directed. We will also consider including an option for submitting notices of the intent to participate in electronic form. These case processing details will be made part of the OCPM, a reference guide outlining the day-to-day operating

instructions, policies, and procedures of OMHA. The OCPM describes OMHA case processing procedures in greater detail and is accessible to the public on the OMHA website (www.hhs.gov/omha).

Comment: We received two comments in support of proposed §§405.1010(c)(3) and 423.2010(d)(3), which place time frames on the submission of position papers and written testimony by CMS or its contractors, and by CMS, the IRE, and/or Part D plan sponsor, respectively, require that copies are sent to other parties, and provide that if the participating entities fail to submit the items within the specified time frame or to send copies to the other parties, then the position paper and/or written testimony will not be considered in deciding the appeal. The commenters recommended that the time frames in proposed §§405.1010(c)(3) and 423.2010(d)(3) for submitting position papers and written testimony also apply to the requirement to send copies to other parties. We also received one comment requesting that the same revision be made to §405.1012(c)(2)(ii) regarding the time frame for sending to the other parties copies of any position papers, written testimony, and evidentiary submissions that CMS or one of its contractors submits to OMHA as a party to the hearing.

Response: We thank the commenters for their support. We intended that the time frames in §§405.1010(c)(3)(i), 423.2010(d)(3)(i), and 405.1012(c)(2)(i) also be applied to copies of position papers and written testimony sent to the other parties. Given this was not clear to the commenters, we are modifying the language in proposed §§405.1010(c)(3)(ii), 423.2010(d)(3)(ii), and 405.1012(c)(2)(ii) to better convey the requirement. We are revising §405.1010(c)(3)(ii) to state that a copy of any position paper or written testimony submitted to OMHA must be sent to the other parties within the same time frame specified in §405.1010(c)(3)(i). Because §405.1010(c)(3)(i) requires the submission to OMHA to be sent

within 14 calendar days of an election to participate, if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled, unless the ALJ grants additional time, the requirement that the copies be sent to the other parties within these same time frames will ensure that the copies are also timely received by the parties. Similarly, we are revising §423.2010(d)(3)(ii) to state that a copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent to the enrollee within the same time frames that it must be submitted to OMHA as provided in §423.2010(d)(3)(i)(A) and (B). Finally, we also are revising §405.1012(c)(2)(ii) to state that a copy of any position paper, written testimony, or evidence submitted to OMHA must be sent to the other parties within the same time frame specified in §405.1012(c)(2)(i).

Comment: We received one comment supporting the 14 calendar day time frame proposed in §405.1010(c)(3)(i) for submitting a position paper or written testimony after an election to participate if no hearing is scheduled, but suggesting that the start for calculating the 14 calendar days should begin with “response to the contractor and not the QIC.”

Response: We thank the commenter for its support but believe that the commenter misinterpreted when the 14 calendar day time frame proposed in §405.1010(c)(3)(i) begins. The time frame for submission of a position paper or written testimony specified in proposed §405.1010(c)(3)(i) begins on the date of the contractor’s election to participate if no hearing has been scheduled, not on the date the QIC or the contractor receives the notice of hearing.

Comment: We received one comment that expressed concern that the stated time frame in §405.1010(c)(3)(i), requiring the submission of CMS or contractor position papers and written testimony no later than 5 calendar days prior to the scheduled hearing, unless additional time is granted by the ALJ, is an unreasonably short period and does not allow sufficient time for an

appellant to react to new arguments or proposed theories that may be contained in those written submissions prior to the hearing. The commenter suggested that this short time frame is unfavorable to appellants.

Response: Current §405.1010 does not set forth specific time frames for submitting position papers and written testimony. Current §405.1010(e) states only that CMS or its contractor must submit any position papers within the timeframe designated by the ALJ. ALJs, however, would often accept written submissions up to and including on the day of the hearing. We believe that the requirement to submit any position papers or written testimony not later than 5 calendar days prior to the scheduled hearing provides sufficient time for the ALJ and the parties to review the submissions prior to the hearing and will provide a clear and consistent time frame regarding these submissions. In addition, we believe that §405.1010(c)(3)(iii) (as finalized in this rule), which provides that if CMS or a contractor fails to submit its position paper or written testimony within the set time frames then the submissions will be excluded from consideration, provides additional protections that are favorable to appellants.

Comment: Another commenter noted that when CMS or its contractor “is called to provide position papers and written testimony” but fails to submit the position paper or written testimony on time, the entities should be required to provide the requested written submissions or provide a valid reason for why the requested information could not be provided. The commenter noted that the information may have a significant impact on the outcome of an appeal.

Response: We first want to clarify that, under the rules as finalized, when CMS or a contractor makes an affirmative election to participate and wishes to submit a position paper and/or written testimony, it must do so within the specified time frames provided in §405.1010(c)(3)(i) or the submissions are excluded from consideration pursuant to

§405.1010(c)(3)(iii). We believe that providing time frames for submissions by CMS or its contractors when they elect to participate helps to ensure that any submissions are timely received and that appellants and other parties will have an opportunity to review them prior to the hearing, if a hearing is conducted. The comment suggests that the position paper and written testimony of concern was requested by the ALJ, however §§405.1010(a)(2) and 405.1012(a)(2) (both as finalized in this rule) provide that although an ALJ may request CMS and/or one of its contractors to participate in any proceedings before the ALJ, or to be a party at the hearing, the ALJ cannot require such participation or party status and cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings or to be a party at the hearing. The language set forth in proposed §405.1010(a)(2) was not changed from the current regulations, but rather combines the rules currently found at §405.1010(a) and (f). Similarly, the language in proposed §405.1012(a)(2) was carried forward from current §405.1012(d). We do not believe that the commenter's suggestion of making the submissions mandatory or requiring that CMS or its contractor provide valid reasons for failing to submit certain requested written testimony is consistent with the established rule that an ALJ may not require that CMS or a contractor participate in the proceedings or be a party at the hearing. The limited resources and broad programmatic responsibilities facing CMS and its contractors may not allow for participation or party status election in all appeals. We believe that CMS and its contractors must have some discretion in determining when election of participant or party status under §§405.1010 and 405.1012 is most appropriate given those resources and other responsibilities.

Finally, we disagree with the commenter's suggestion that when CMS or a contractor fails to provide requested position papers and/or written testimony that it will have a significant impact on the appeal. First, if an ALJ or attorney adjudicator believes that the written record is

missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successors under §405.1034, as finalized in this rule.

Second, CMS or its contractors will likely elect participation or party status in those appeals that involve more complex issues of fact or law and where their participation or party status will be most useful. Finally, while position papers and/or written testimony submitted by CMS or its contractors may be helpful in clarifying factual issues or policy, we do not believe that the failure to submit position papers or written testimony is likely to result in any negative impact on the appellant or other parties. The appellant and other parties obviously may still present their full testimony and arguments and the ALJ or attorney adjudicator will consider evidence in the administrative record as appropriate, including all administrative proceedings, prior to issuing a decision.

Comment: We received two comments supporting the clarification in proposed §405.1010(c)(2) that even though CMS or its contractor is not subject to examination or cross-examination by the parties, the parties “may provide testimony to rebut factual or policy statements made by a participant, and the ALJ may question the participant about its testimony.” The commenters requested that this language be modified to more affirmatively require that the parties be given the opportunity to provide testimony and to ensure that beneficiaries are made aware of this option at the hearing. The commenter also requested that CMS provide advocate education about this provision. We received one comment that made this same request with respect to the enrollee’s ability to rebut factual or policy statements made by CMS, the IRE, or the Part D plan sponsor participant in the course of Part D hearings as provided in proposed §423.2010(d)(2).

Response: We thank the commenters for their support. We agree that the proposed language in both §§405.1010(c)(2) and 423.2010(d)(2) helps to clarify how a party and the ALJ may address statements made by participating entities during the hearing. However, we believe that the ALJ is in the best position to help ensure that a beneficiary or enrollee is aware of this option during the course of the hearing, and that ALJs may use their discretion to regulate the course of the hearing, including by affirmatively asking parties if they want to rebut factual or policy statements made by a participant during the hearing. We anticipate that OMHA ALJs will receive training on all the rules once they become effective, including the rules in §§405.1010(c)(2) and 423.2010(d)(2). We do not agree that additional revisions to the language in §§405.1010(c)(2) and 423.2010(d)(2) are necessary because the language as finalized in this rule provides the necessary protection while still balancing the right and role of the ALJ to control the hearing. CMS provides ongoing stakeholder education and anticipates that education regarding this provision and the other rules will be available after the rules are effective.

Comment: One commenter stated that although the regulations at §405.1010(c)(2) provide that contractors participating in an ALJ hearing cannot be called as witnesses, the regulations should clarify that they cannot also voluntarily testify as a witness. The commenter noted that in its experience, Medical Directors of the contractors often participate in the hearings and offer commentary on the clinical judgment of the treating professionals, which the commenter views as inappropriate witness testimony. The commenter stated that if witness testimony is desired by a contractor, a witness must be identified and qualified, and the appellant must have the right to cross-examine the witness.

Response: We believe that §405.1010(c) as finalized in this rule clarifies the roles and responsibilities of CMS and contractors who are participants at the oral hearing. We note that

§405.1010(c)(1) and (2), as finalized in this rule, incorporate the policies from current §405.1010(c) and (d), providing that participants may file position papers or provide testimony to clarify factual or policy issues in a case, but may not call witnesses or cross-examine the witnesses of a party to the hearing, and may not be called as a witness itself, with the exception we are finalizing in §405.1010(d)(3) of this rule to allow CMS or a contractor that has been made a party to the hearing in accordance with §405.1012 to call as a witness CMS or another contractor that has been precluded from participating in the hearing. Further, §405.1010(c)(2), as finalized, now clarifies that a participant is also not subject to examination or cross examination by the parties and includes a new provision that clarifies that a party may rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony. Although the commenter suggests that contractor participants often do not follow the limitations on participation set by the regulations, including by voluntarily testifying as witnesses, we believe that the additional clarification in these provisions regarding the roles and responsibilities of CMS or a contractor as a participant will help ensure that participants only provide testimony to clarify factual or policy issues in a case. In circumstances in which a party believes that a participant is providing testimony outside of the scope of clarifying factual or policy issues, the party may raise the issue with the ALJ.

Comment: Two commenters recommended that the rules clarify how an ALJ should proceed if a contractor fails to make an appearance at the hearing after notifying the ALJ and appellant(s) of its intention to be a participant or party to the oral hearing. The commenters recommended that if CMS or a contractor fails to appear at a hearing, “no further participation or party status should be permitted for that entity.”

Response: If CMS or a contractor is a party or participant to the oral hearing but does not appear at the scheduled time and place of the hearing after notice of the hearing has been provided, the hearing may proceed without that entity. While the involvement of CMS and/or a contractor in the hearing as either a participant or a party is permitted by §§405.1010 and 405.1012, the regulations do not require or guarantee such participation or party status, and thus the election of participant or party status, and the extent of participation, is at the discretion of CMS and its contractors. We believe this is clear in the regulations as finalized at §§405.1010(a), 405.1012(a), and 423.2010(a), and that the regulations do not need to be further clarified in this regard. Therefore, we believe that if CMS or a contractor that has elected to be a participant or a party at the hearing fails to appear at the hearing and notice of the hearing time and place has been duly provided, then the ALJ may proceed without that entity. Also, there is no provision that excludes the entity from further participation in the proceedings if there are opportunities for such participation, and we do not believe it would be appropriate to limit further participation after an election is made, as we believe that CMS and contractor participation may be beneficial and can assist in clarifying factual or policy issues in a case. In addition, there may be administrative reasons, including scheduling conflicts, which prevent an entity from appearing at the hearing at the last minute. For the same reasons discussed above, we believe that any position papers or written testimony that had been previously submitted in accordance with the time frames in §§405.1010(c)(3) and 405.1012(c)(2) may still be considered by the ALJ.

Comment: One commenter requested the rules be revised to add a requirement making CMS's or its contractor's attendance mandatory "when one of the issues in the hearing concerns that entity's violation or non-compliance with existing statute or CMS policy." The commenter suggested that by inviting CMS or its contractor to the hearing, the entities are given an

opportunity to recognize that they are in violation and will have a chance of correcting the situation.

Response: Section 405.1010(a)(2), as finalized in this rule, provides that an ALJ may request that CMS and/or one of its contractors participate in the proceedings before the ALJ, including the oral hearing, if any, but also provides that the ALJ may not require the participation and may not draw any adverse inferences if CMS or the contractor decides not to participate. These provisions carry forward policies in current §405.1010(a) and (f). The limited resources and broad programmatic responsibilities facing CMS and its contractors may not allow for participation or party status election in all appeals. We believe that CMS and its contractors must have some discretion in determining when election of participant or party status under §§405.1010 and 405.1012 is most appropriate given those resources and other responsibilities. Finally, it is not clear what the commenter means when he suggests that “one of the issues in the hearing concerns that entity’s violation or non-compliance with existing statute or CMS policy.” The ALJ scope of review is on the issues related to the appealed claim in accordance with §405.1032. If the appellant believes the claim was denied in error as a result of non-compliance with relevant authority, such as a statute or regulation, or authority that is owed substantial deference, such as LCDs and program memoranda, those arguments should be articulated for the ALJ to consider in adjudicating the appealed claim. It is not necessary that CMS or a contractor be present for the ALJ to consider that argument and make a de novo determination applying the authority. On the other hand, if the commenter is suggesting that CMS or a contractor needs to be present at hearing for the ALJ to explain to that entity why that entity’s decision constituted a “violation or non-compliance with existing statute or CMS policy,” we do not agree that this is necessary because the ALJ’s decision and rationale will be explained in the ALJ’s written

decision on the case, a copy of which is sent to the QIC in accordance with §405.1046(a)(1) as finalized in this rule, and therefore available to CMS and its contractors. OMHA ALJs are responsible for administering hearings to resolve coverage and payment disputes, not to provide CMS or contractor education, and we do not believe that mandating CMS or a contractor to attend the hearing to address the appellant's assertions furthers the hearing process.

Comment: One commenter pointed out that under the proposed regulations no actual notice would be provided to CMS contractors when appeals are filed, and the “30-day constructive notice window” is the only opportunity for a contractor to participate in an appeal that could be assigned to an attorney adjudicator. The commenter stated that under the proposed rule, an ALJ hearing notice is the only actual notice to the contractors and the only opportunity for contractors to appear as parties. The commenter suggested that the proposed rule may be “a step backward in the important area of program integrity.”

Response: We do not agree with the commenter and believe that the rules as finalized make necessary clarifications in defining when and how CMS or its contractors may elect, or request (for Part D appeals), to participate in the proceedings on a request for an ALJ hearing. Current §405.1010 provides that CMS or its contractors may elect to be a participant within 10 calendar days of receiving the notice of hearing. Current §423.2010 requires CMS, the IRE, or the Part D plan sponsor to request participation no later than 5 calendar days after receipt of the notice of hearing for a non-expedited hearing, or 1 calendar day after receipt of the notice of hearing for an expedited hearing. Neither current rule specifically addresses appeals for which a hearing is not scheduled. Sections 405.1010(b) and 423.2010(b), as finalized, clarify that CMS or its contractors may elect or request participant status in proceedings even if a hearing is not conducted or is not necessary, with the applicable limitations and timeframes to help ensure that

an election or request is filed in a timely manner after notification that a request for hearing is filed. We believe that, as finalized, §§405.1010(b) and 423.2010(b) provide necessary clarity for contractors in electing or requesting participation in appeals for which no hearing is scheduled, and in providing such clarification, may encourage additional participation in such proceedings and therefore support program integrity. In response to the commenter's concern that the only notice provided to CMS contractors when a request for hearing is filed is a constructive notice to the QICs, we note that OMHA and CMS plan to establish a process for notification to CMS contractors that a request for hearing has been filed, and we will communicate that process to the contractors after the effective date of the rule. As this is an internal process, we are not including this process in the regulations, because to do so would limit our flexibility to establish and change business processes and take advantage of emerging technologies through operational policies. The APA permits OMHA to adopt internal business processes without notice and comment rulemaking.

Comment: One commenter asked OMHA to specify what sort of notice would be given to the Part D plan sponsor when no notice of hearing is issued, and what would be the acceptable forms of communication when the Part D plan sponsor elects to participate in the proceedings when no notice of hearing is required, including in appeals assigned to an attorney adjudicator.

Response: OMHA and CMS plan to establish a process for notification to Part D plan sponsors that a request for hearing has been filed, and CMS will communicate that process to the Part D plan sponsors after the final rule becomes effective.

In response to the commenter's question regarding acceptable forms of communication, §423.2010(b)(1), as finalized in this rule, provides that, if the Part D plan sponsor requests participation before it receives notice of hearing, or when no notice of hearing is required, the

Part D Plan “must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.” Written communication may be mailed or fax. However, faxes must be sent in accordance with procedures to protect personally identifiable information.

Comment: We received two comments from CMS contractors noting that the initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed as set forth in proposed §405.1010(b)(3)(i) will require additional work and resources for those entities to monitor requests for hearings being filed with OMHA. One comment stated that the proposed rules create additional work that may not be productive because QICs will have to screen cases appealed to OMHA for potential participation election even though those cases may never be heard, may be dismissed on procedural grounds, or may be withdrawn before a hearing is scheduled, which is a larger number of cases than those currently screened by contractors upon receipt of an ALJ’s notice of hearing. Another comment noted that although it is possible for DME MACs to locate cases that have been appealed beyond the QIC, the process of researching the lists of appealed cases and selecting cases for which an election of participation is desired is not part of those entities’ normal work structure. Both comments noted that additional resources, including as one commenter indicated, increased “visibility” of appeals filed at the OMHA level in the Medicare appeals case management system, and/or additional manpower, would be necessary to monitor cases appealed to OMHA. One comment stated that the DME MACs are only funded for small staffs to address ALJ

appeals and may not have the resources to monitor and respond to the greater volume of appeals that may be anticipated after these rules are effective.

Response: While §405.1010(b)(3)(i) as finalized in this rule may require increased coordination and perhaps shared resources among CMS and its contractors to monitor requests for hearing being filed at OMHA for possible participation election, we do not believe that these administrative concerns outweigh the benefits of §405.1010 as finalized in this rule, or that the final rules would impose unreasonable burdens on CMS or its contractors. We believe §405.1010 as finalized adds necessary clarifications on CMS and contractor participation, and encourages participation in a greater number of appeals by clarifying that CMS and contractors may participate in appeals for which a hearing is not scheduled. However, §405.1010 as finalized does not require a contractor to make an election or request participation, so while participation is encouraged and permitted, the rules do not obligate CMS or its contractors to perform additional work or expend any additional resources. The limited resources and broad programmatic responsibilities facing CMS and its contractors likely will not allow for participation in all appeals, so CMS and its contractors will use their discretion in determining when election of participant status is most appropriate. With regard to the commenter's concern that electing participant status for cases that have not been scheduled for a hearing would be outside DME MACs' normal work structure, CMS will address modifications to systems, contractor coordination, and contractor resources in guidance outside of this rule. If necessary, after the final rule is effective, CMS will make the necessary contract modifications to account for the provisions of this final rule.

Comment: Another comment from one of the entities that currently holds a QIC contract indicated that proposed §405.1010(b)(1) would create scheduling difficulties for contractors that

may be electing to participate in a hearing before they receive notice of the hearing date and time. The commenter argued that even under the current rules, contractors often have to choose between cases for participation because hearing dates and times with different ALJs conflict or overlap. The commenter noted that in practical terms, there is a large amount of time between when a request for hearing is filed and eventual assignment and scheduling of a hearing, and that it would be extremely challenging, if not impossible, for the QIC to plan for attendance at a hearing of unknown date and time.

Response: Although §405.1010(b)(1) as finalized in this rule permits CMS or a contractor to elect to participate in the proceedings on a request for an ALJ hearing before receipt of a notice of hearing or when a notice of hearing is not required, if a hearing is then scheduled, the participating entity is not obligated to attend the hearing and if it has not already filed a position paper and/or written testimony, it may do so up to 5 calendar days prior to the hearing. Moreover, if a hearing is ultimately scheduled, any entity that has already elected to participate in the proceedings will receive a notice of hearing pursuant to §405.1020(c)(1) as finalized in this rule, and will have at that time notice of the scheduled hearing date and time. If the entity's schedule allows and the entity still wishes to participate at the oral hearing, it may file a response to the notice of hearing. If the scheduled hearing date and time does create a scheduling conflict for that entity, the entity may still elect to participate in the proceedings by submission of position papers or written testimony no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the position paper or written testimony.

Comment: One commenter requested clarification on the recourse available to a DME MAC if it elects to be a participant in an appeal and the hearing is scheduled for a date and/or time that contractor is unable to attend, and what effect the contractor's withdrawal from

participation due to a schedule conflict would have on the decision of the ALJ or attorney adjudicator.

Response: Consistent with §405.1020(e), CMS or a contractor that has elected participant status cannot request a change in the scheduled date or time of the hearing (unlike CMS or a contractor that has elected party status). However, the contractor may respond to the notice of hearing by indicating that it will not be able to attend due to a scheduling conflict without any adverse inference on the part of the ALJ as provided in §405.1010(a)(2), and submit a position paper and/or written testimony for consideration within the time frame set forth in §405.1010(c)(3).

Comment: We received two comments, one from an entity that currently holds a QIC contract and one from the four entities that currently hold the DME MAC contracts, quoting the language in proposed §405.1010(b)(1) regarding how CMS or its contractors may make an election to participate “when a notice of hearing is not required” and indicating that it was unclear when a notice of hearing would not be required for a case.

Response: Under our regulations as finalized in this rule, a notice of hearing is not required for any case in which an on-the-record decision may be issued pursuant to §405.1038, including: when an ALJ or attorney adjudicator determines the evidence in the record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, unless CMS or a contractor has elected to be a party pursuant to §405.1012 (as provided in §405.1038(a)); when all parties who would be sent a notice of hearing indicate in writing that they do not wish to appear before an ALJ at a hearing (as provided in §405.1038(b)(1)(i)); when the appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing and there are no other parties who would be

sent a notice of hearing and who wish to appear (as provided in §405.1038(b)(1)(ii)); or if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating that the item or service should be covered or payment may be made such that an ALJ or attorney adjudicator issues a stipulated decision in favor of the appellant or other liable parties (as provided in §405.1038(c)).

Comment: We received the following questions from the four entities that currently hold the DME MAC contracts regarding administrative and procedural mechanisms related to proposed §405.1010: (1) “will the request for hearing contain a list of all parties to whom a response should be sent;” (2) what mechanisms will be in place to assist with the assignment of cases to OMHA adjudicators in a timely manner; (3) how quickly after a request for hearing has been filed will it be assigned a firm hearing date; and (4) when and how will the DME MAC contractor become aware of that firm hearing date?

Response: DME MACs would not typically receive a copy of an appellant’s request for hearing (see §405.1014(d), as finalized in this rule). Furthermore, §405.1010(b)(1), as finalized in this rule, provides that if CMS or a contractor elects to participate in the proceedings before a notice of hearing is sent, or when a notice of hearing is not required, then the contractor must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the appeal is not yet assigned, and the parties who were sent a copy of the notice of reconsideration. Therefore, we believe the commenter may have intended to ask whether the notice of reconsideration (as opposed to a request for hearing) contains a list of all parties to whom an election to participate would be sent under §405.1010(b)(1), as finalized in this rule. Under §405.976(a)(1)(i), the QIC generally sends notice of the reconsideration to all parties at their last known address, and current QIC practice involves listing all the parties to

whom the notice of reconsideration was sent in either the address block or the courtesy copy section of the notice. Therefore, CMS or a CMS contractor need only look to the notice of reconsideration to determine which parties were sent a copy of the notice of reconsideration, and send a copy of its election to participate to the same parties.

Proposed §405.1010 does not address the mechanisms for assignment of cases to OMHA adjudicators. OMHA's case assignment process is subject to the priority of the case (to help ensure appeals filed by beneficiaries are adjudicated as quickly as possible, OMHA designates these appeals as priority appeals, with some exceptions), OMHA's pending workload, and the availability of an adjudicator. More details on the OMHA case assignment process are available in the OCPM, which is accessible on the OMHA website (www.hhs.gov/omha). Contractors and others may determine whether a case has been assigned to an OMHA adjudicator and, if it is assigned, the assigned OMHA adjudicator, using AASIS, which also can be accessed through the OMHA website.

Similarly, proposed §405.1010 does not address the length of time between when an appeal is filed and when a hearing date will be selected. The length of time between when an appeal is filed and when a hearing date is selected will vary based on how quickly the case is assigned to an OMHA ALJ, because only OMHA ALJs may conduct hearings, and the assigned ALJ's availability and docket of other cases. Because this time is subject to significant variation based on the stated factors, we cannot provide a generally applicable estimate.

If and when a hearing is scheduled, the ALJ will issue a notice of hearing consistent with §405.1022 to the parties and other potential participants provided for in §405.1020(c), including, among others, to the QIC that issued the reconsideration and CMS or any contractor that the ALJ believes would be beneficial to the hearing. In consideration of the commenter's question

regarding when and how the DME MAC will become aware of the hearing date if the request for hearing is only sent to the QIC that issued the reconsideration, DME MACs and other non-QIC contractors would be notified of the hearing date by the QIC that issues the reconsideration in accordance with CMS instructions to QICs for notifying other contractors of a scheduled ALJ hearing. However, we believe it is also appropriate for the notice of hearing to be sent to CMS or any contractor that elected to participate in the proceedings consistent with §405.1010(b), and we are revising our proposal at §405.1020(c)(1) to require this. Thus, a non-QIC contractor will receive notice of the hearing either directly from OMHA, if the contractor has elected to participate before receipt of a notice of hearing or if the ALJ believes the non-QIC contractor would be beneficial to the hearing, or it will receive notice of the hearing from the QIC if it elects to participate after notice of hearing is sent.

Comment: We received one comment requesting clarification of the language in proposed §405.1012(a)(2), which in the commenter's opinion, suggests that an ALJ may request that CMS and/or one of its contractors be a party to a hearing requested by an unrepresented beneficiary. The commenter noted that although §405.1012(a)(1) expressly precludes CMS or its contractors from electing to be a party when a request for hearing is filed by an unrepresented beneficiary, the phrase "and unless otherwise provided in this section" suggests that an ALJ may request CMS or a contractor to be a party in hearings when the request is filed by an unrepresented beneficiary. The commenter requested that the language in proposed §405.1012(a)(2) expressly exclude the possibility that an ALJ may request CMS or its contractors to be a party in a hearing when the request for hearing is filed by an unrepresented beneficiary.

Response: The "unless otherwise provided in this section" language in proposed §405.1012(a)(1) was added to address situations in which CMS or a CMS contractor elected to

be a party but was precluded from being a party due to limitations on the number of CMS or CMS contractor parties in §405.1012(d), or due to an election that the ALJ determines is invalid under §405.1012(e). We agree that when the request for hearing is submitted by an unrepresented beneficiary, CMS and its contractors may not be a party at the hearing. This was our intent in current §405.1012(a) as well as our intent in proposed §405.1012(a)(2). Thus, we have revised the language in §405.1012(a)(2) as finalized in this rule to expressly state that an ALJ may request CMS or one of its contractors to be a party to a hearing unless the request for hearing is filed by an unrepresented beneficiary.

Comment: We received one comment from a Recovery Auditor trade/advocacy group that was submitted as a comment to proposed §§405.1008 and 423.2008, but was related to how proposed §§405.1010, 405.1012 and 423.2010 would impact CMS audit contractors' interests in hearings and their ability to elect party status. The commenter noted that audit contractors have both contractual obligations under the draft Statement Work for the Recovery Audit Program to support their findings at hearings and a substantial interest in being permitted to offer a defense of their findings through oral testimony, cross examination, and attendance at the hearings. The commenter recommended that there should be a clear process for deciding which contractor should have primary responsibility for participating in hearings and suggested that the contractor who first denied the claim should be granted party status, with the subsequent contractors taking participant status. As an alternative, the commenter recommended that multiple entities should be permitted to elect to be a party to the hearing, and the ALJ could limit each party to only addressing issues that have not yet been addressed by the other parties. The commenter characterized the rules regarding electing party status in §405.1012 as a "new process [that] would require frequent requests for leave, if audit contractors are not permitted to act as a party

at the ALJ hearing level” and stated that “the requirement that an entity must seek permission from an ALJ to act as a party to a hearing imposes a cumbersome, time-consuming step in the process, increasing the administrative burden on both CMS contractors and on ALJs.” Finally, the commenter noted several concerns regarding timing of the election of party status and delays in audit contractors receiving the notice of hearing. The commenter indicated that the 10-day time limit for electing party status after the QIC receives the notice of hearing is unworkable because QICs frequently do not forward notices of hearings to the audit contractors within 10 calendar days. The commenter recommended that the window to elect party status be expanded to 20 calendar days and/or that QICs should be required to forward all notices of hearings to the audit contractors in a timely fashion, and failure by the QICs to do so should result in an extension in the time that audit contractors have to elect party status. Alternatively, the commenter recommended that ALJs should be required to notify audit contractors of all ALJ hearings directly. The comment noted that if QICs, which may receive the notice of hearing first, preemptively elect party status before the audit contractors receive notice of a hearing, audit contractors would be prevented from participating at the hearing, and such exclusion would make it difficult for audit contractors to satisfy their contractual obligations and raises due process concerns.

Response: We believe that the rules we are finalizing on CMS and contractor participant and party status strike an appropriate balance between administrative efficiency and obtaining as much information as possible for the ALJ to render a decision on the matter. In addition, we believe that §§405.1010, 405.1012, and 423.2010, as finalized in this rule, continue to allow for effective participation in the ALJ hearing process for QICs and other contractors consistent with 1869(c)(3)(J) of the Act and current §§405.1010 and 405.1012, as further discussed below.

Section 405.1012(d)(1), as finalized in this rule, limits party status at the oral hearing to the first entity to elect party status after the notice of hearing is issued, but any other entity that filed an election for party status is made a participant in the proceedings under proposed §405.1010 (subject to §405.1010(d)(1) and (3)), and may file a position paper and/or written testimony to clarify factual or policy issues in the case. We believe that allowing a contractor that is precluded from being a party to the hearing to file positions papers and/or written testimony still provides the contractor with a meaningful opportunity to participate in the proceedings. As we explained in the proposed rule, we considered alternatives to the first to file provision in proposed §405.1012(d)(1). However, we believe that providing that the first entity to elect party status be made a party to the hearing is an administratively efficient and objective method of determining which contractor will be made a party to the hearing if more than one entity makes a party election. We do not agree with the commenter that the first contractor to deny the claim is necessarily the best entity or the most beneficial entity to have at the hearing. In some cases, subsequent contractors may have resolved the issue identified by the first contractor and further developed the record, and that subsequent contractor may have a more current understanding of the issues on appeal and the facts. In addition, when multiple contractors would be necessary for a full examination of the matters at issue, §§405.1010(d)(3) and 405.1012(d)(2) as finalized could be used by the ALJ to grant leave to a precluded entity to participate in the oral hearing or to be a party to the hearing, respectively. Although the commenter suggested that as an alternative, multiple parties should always be permitted to participate at the oral hearing and the ALJ could use his or her discretion to limit testimony and argument as necessary, we believe that the process finalized in this final rule is more efficient and provides more clarity regarding expectations.

We also disagree with the commenter's characterization of the process for CMS or its contractor to elect to be a party to the hearing as "new" to the extent that §405.1012(b), as finalized in this rule, follows the same process in current §405.1012(b) for electing party status by sending written notice of intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant. Although §405.1012(d), as finalized in this rule, places a new limitation on the number of contractors who have elected to be a party that may participate in the oral hearing, unless the ALJ grants leave to an entity to also be a party to the hearing, we do not believe this process imposes an additional administrative burden or time-consuming step. Section 405.1012(d)(2) states that if CMS or a contractor is precluded under the rules from being a party to a hearing, an ALJ may grant leave for CMS or a contractor to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue. We disagree that this determination by the ALJ imposes any cumbersome, time-consuming, or administratively burdensome requirements on CMS or its contractors. While the commenter has characterized the process as requiring that entities "seek permission from the ALJ to act as a party to the hearing," we do not agree that §405.1012(d)(2), as finalized in this rule, necessarily requires any additional filings or actions from the entity other than the written notice of intent to participate as a party provided for in §405.1012(b).

With respect to the commenter's concern regarding audit contractors' ability to meet contractual obligations, including the concern that QICs may preemptively elect party status and preclude participation or party status for audit contractors, we direct the commenter to our response to a similar comment above that was submitted by a QIC. As we noted above, after the final rule is effective, we intend to issue sub-regulatory guidance, including educational materials

and contractual modifications that will establish processes to accommodate the regulatory changes and help ensure contractor understanding of roles and responsibilities. These processes will relate to timely notice, information sharing, and coordination among affected contractors that may have an interest in participating in the same hearing. In addition, we intend to update the Joint Operations Agreements to capture contractor roles and establish timeframes. CMS intends to make any necessary modifications to its contractors' statements of work and contracts to require coordination among the multiple contractors who may have an interest in electing participant and/or party status in the same hearing.

Finally, we recognize that there may be some delay in certain contractors' receipt of the notice of hearing as it is processed through the QICs. However, we believe that the 10 calendar day time frame still provides adequate time to give notice to all contractors. The timeframe for forwarding a notice of hearing is reflected in the QIC contracts. CMS will take steps to help ensure that the QICs and other contractors follow the applicable regulations and contractual requirements. Because the QICs' contractual obligations already reflect a workable timeframe, and because CMS will take steps to help ensure that the QICs follow those contractual obligations, we do not agree that the first two alternatives suggested by the commenter—revising the regulations to extend the time frame to elect party status to 20 days or extending the timeframe to elect party status if a QIC fails to timely notify contractors of the receipt of a notice of hearing—are necessary. We believe that the commenter's third suggestion of requiring that OMHA always send the notice of hearing to all contractors places an unnecessary administrative burden on OMHA and would duplicate the process for notifying the various contractor entities that is already managed by CMS through the QICs' contracts. As we noted above, after the final rule is effective, we intend to issue sub-regulatory guidance that will establish processes to

accommodate the regulatory changes. CMS will begin the process of modifying contract provisions with regards to notices of hearing after the effective date of this final rule. In addition, we note that any contractor, including an audit contractor, that has elected to participate in the proceedings on a request for an ALJ hearing under §405.1010 will receive notice of a hearing, if one is scheduled, directly from OMHA pursuant to §405.1020(c)(1) as finalized in this rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.1010, 405.1012, and 423.2010 as proposed, with the following modifications. We are adding a requirement in §§405.1010(c)(3)(ii), 405.1012(c)(2)(ii) and 423.2010(d)(3)(ii) that copies of position papers and/or written testimony (and for purposes of §405.1012(c)(2)(ii), any evidence) submitted to OMHA must be sent to the other parties within the same timeframes that apply to the submissions to OMHA. In addition, we are adding language to §405.1010(d)(3) to state that if the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012. To accommodate this change, we are also revising §405.1010(c)(2) to state that when CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in §405.1010(d)(3). We are also adding clarifying language in §405.1012(a)(2) that an ALJ may not request that CMS and/or one or more of its contractors be a party to the hearing if the request for hearing was filed by an unrepresented beneficiary. Finally, we are correcting a drafting error in the text of proposed §405.1010(c)(3)(i) by replacing “by within 14 calendar days” with “within 14 calendar days.”

g. Request for an ALJ hearing or review of a QIC or an IRE dismissal (§§405.1014 and 423.2014)

Sections §§405.1014 and 423.2014 explain the requirements for requesting an ALJ hearing, including what must be contained in the request, when and where to file the request, the extension of time to request a hearing, and in §405.1014 to whom a copy of the request for hearing must be sent. We proposed to restructure the sections, clarify and provide additional instructions, and address other matters that have caused confusion for parties and adjudicators. 81 FR 43790, 43816–43820.

i. Requirements for a request for hearing or review of a QIC or an IRE dismissal

We proposed to revise the title and provisions of §§405.1014 and 423.2014 to more clearly cover a request for a review of a QIC or IRE dismissal. While the current requirements for requesting an ALJ hearing are generally used for requesting a review of a QIC or IRE dismissal in form HHS-725, we stated in the proposed rule that we believe that explicitly extending §§405.1014 and 423.2014 to cover requests for these types of review would provide clarity to parties and adjudicators on the requirements for requesting a review of a QIC or IRE dismissal. As such, we proposed in the title to §405.1014 and in subsection (a)(1) (current subsection (a)) to add “or a review of a QIC dismissal” after “ALJ hearing,” and in subsection (c) (current subsection (b)) to delete “after a QIC reconsideration” and add “or request for review of a QIC dismissal” after “an ALJ hearing.” Similarly, we proposed in the title to §423.2014 and in subsection (a)(1) (current subsection (a)) to add “or a review of an IRE dismissal” after “ALJ hearing,” and in subsection (d) (current subsection (c)) to add “or request for review of an IRE dismissal” after “IRE reconsideration.”

We proposed in §405.1014(a)(1)(i) through (a)(1)(vi) to incorporate current §405.1014(a)(1) through (a)(6) with revisions. In addition to the current requirements in subsection (a)(1), we proposed in §405.1014(a)(1)(i) to require the beneficiary's telephone number if the beneficiary is the filing party and is not represented. We stated in the proposed rule that this would help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We proposed in §405.1014(a)(1)(ii) to require the appellant's telephone number, along with the appellant's name and address as currently required in subsection (a)(2), when the appellant is not the beneficiary, and in §405.1014(a)(1)(iii) to require a representative's telephone number, along with the representative's name and address which is currently included in subsection (a)(3), if a representative is involved. Like the beneficiary telephone number requirement, we stated that these requirements would help ensure that OMHA is able to make timely contact with a non-beneficiary appellant and any representative involved in the appeal to clarify the filing or other matters related to the adjudication of the appeal, including scheduling the hearing. Current subsection (a)(4) states that the request must include the document control number assigned to the appeal by the QIC, if any. We proposed in §405.1014(a)(1)(iv) to require the Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed, to reduce confusion for appellants. We proposed in §405.1014(a)(1)(v) to add language to the current language in subsection (a)(5), so that instead of requiring the "dates of service," we would require the "dates of service for the claims being appealed, if applicable," because an appellant may appeal some but not all of the partially favorable or unfavorable claims in a QIC reconsideration and a small number of appeals

do not involve a date of service (for example, entitlement appeals). We proposed to incorporate the same language in current subsection (a)(6) into proposed subsection (a)(1)(vi).

We proposed to add a new requirement to the content of the request in §405.1014(a)(1)(vii) by requiring a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. We stated that this information is necessary to assist OMHA staff in checking whether the provider or supplier was excluded from the program on the date of service at issue prior to scheduling a hearing or issuing a decision, as well as for the ALJ to determine whether to request the participation of CMS or any program integrity contractors that may have been involved in reviewing the claims below. However, we noted that the information is only required if the filing party is aware of an investigation and proceeding, and the information would not be the basis for a credibility determination on evidence or testimony, as an investigation or allegations prior to findings of wrongdoing by a court of competent jurisdiction are not an appropriate foundation for credibility determinations in the context of part 405, subpart I administrative appeals.

As discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above, we proposed changes to the methodology for calculating the amount in controversy required for an ALJ hearing to better align the amount in controversy with the actual amount in dispute. We also proposed new §405.1014(a)(1)(viii) to require that providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim, as specified in §405.1006(d), unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. As we discussed in section

III.A.3.d of the proposed rule and II.B.3.d of this final rule above, we stated that in instances where the Medicare allowable amount would serve as the basis for the amount in controversy (which we believe would be the majority of Part B appeals), we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS tools and resources to determine the allowable amount used as the basis for the amount in controversy under proposed §405.1006(d)(2)(i)(A) and arrive at the amount in controversy after deducting any Medicare payments that have already been made or awarded and any deductible and/or coinsurance that may be collected for the items and services in the disputed claim. In addition, we stated that we believe that providers, suppliers, applicable plans, and Medicaid State agencies also would have access to the billing, payment and other necessary information to calculate the amount in controversy under other provisions of §405.1006(d). For scenarios where the basis for the amount in controversy would be calculated in accordance with proposed §405.1006(d)(2)(i)(B), (ii), (iii), or where the amount in controversy would be calculated in accordance with §405.1006(d)(3), (5), (6), or (7), we discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above how appellants would determine the amount in controversy in order to include it on their request for hearing. However, we stated that because we believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not have the information necessary to determine the amount in controversy under §405.1006(d) (as discussed above), we did not propose to require beneficiaries who are not represented by a provider, supplier, or Medicaid State agency to include the amount in controversy in their requests for hearing. Furthermore, as noted above, we did not propose that any appellant include the amount in controversy on requests for hearing where the amount in controversy would be calculated in accordance with §405.1006(d)(4) (for a provider or supplier

termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). We stated that we expected in this situation, a beneficiary could easily determine whether the minimum amount in controversy required for an ALJ hearing would be met through a conversation with the provider or supplier, or from the statement we proposed that the QIC include in its notice of reconsideration as discussed in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above. However, we stated that we believe the exact amount in controversy could be difficult to determine because it may depend on unknown factors, such as the length of continued services that may be required, and so we are not requiring appellants to include this amount in the request for hearing.

Lastly, we proposed that current §405.1014(a)(7), which requires a statement of any additional evidence to be submitted and the date it will be submitted, would be separately designated in its entirety as proposed §405.1014(a)(2) because the information in proposed §405.1014(a)(1) must be present for a request for hearing to be processed and therefore would make the request subject to dismissal if the information is not provided, as discussed below. In contrast, we stated that the information in proposed §405.1014(a)(2) is only necessary if evidence would be submitted and would not make the request subject to dismissal if not present in the request.

Similar to proposed §405.1014(a), we proposed at §423.2014(a)(1)(i) through (a)(1)(vi) to incorporate current §423.2014(a)(1) through (a)(6) with revisions. Current subsection (a)(3) states that the request must include the appeals case number assigned to the appeal by the IRE, if any. We proposed in §405.1014(a)(1)(iii) to revise the requirement to state that the request must include the Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal

being appealed, to reflect the terminology used by the IRE and thereby reduce confusion for enrollees. Current subsection (a)(6) states that the request must include the reasons the enrollee disagrees with the IRE's reconsideration. We proposed to insert "or dismissal" after "reconsideration" to again reflect the terminology used by the IRE and thereby reduce confusion for enrollees. For the same reasons as we proposed for §405.1014(a)(1)(vii), we proposed at §423.2014(a)(1)(vii) to require a statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. In addition, we proposed at §423.2014(a)(2) to incorporate the current §423.2014(a)(7) requirement to include a statement of any additional evidence to be submitted and the date it will be submitted, and at §423.2014(a)(3) to incorporate the current §423.2014(a)(8) requirement to include a statement that the enrollee is requesting an expedited hearing, if applicable.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: Several commenters objected to the introduction of proposed §405.1014(a)(1)(vii), stating that it would be unduly burdensome to require appellants to disclose any and all investigations and proceedings by any law enforcement agency, particularly for large providers such as hospital systems where the proceeding or investigation may relate to a different facility or be otherwise unrelated to the claims on appeal. In addition, the commenters indicated that the requirement was unclear with respect to whether a multi-hospital system would be considered subject to, and therefore required to disclose, an investigation of a single hospital within the system. The commenters also stated that it was unclear which individual in the appellant organization must be aware of the investigation or proceeding to trigger the obligation

to disclose, for instance, whether an individual in the hospital's claims department would be obligated to report information that was known to the hospital's legal department. Further, the commenters expressed concern that the existence of a pending investigation, which has not yet determined any wrongdoing, has the potential to unfairly prejudice the adjudicator, who should instead be focused on the merits of the specific claims on appeal. In addition, the commenters stated that there could be instances in which an individual is unable to disclose a proceeding pursuant to a court order.

Response: While we continue to believe that adjudicators in the claim appeals process should have information related to systemic issues with appellants that may have a bearing on the credibility of evidence or testimony presented to the adjudicator in an individual claim appeal, we believe the commenters have raised valid questions and concerns with proposed §405.1014(a)(1)(vii) (which would require appellants to disclose pending investigations or proceedings), that we believe require further consideration. Therefore, we are not finalizing proposed §§405.1014(a)(1)(vii) or 423.2014(a)(1)(vii) at this time.

Comment: Two commenters suggested allowing beneficiaries to furnish an e-mail address instead of, or in addition to, a telephone number on the request for hearing because beneficiaries may not have immediate or consistent access to a telephone.

Response: If the filing party is an unrepresented beneficiary, we proposed to require the beneficiary's telephone number to help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We believe that the majority of beneficiaries will be able to provide a telephone number where they can be contacted by OMHA, or receive voicemail messages regarding their appeal. However, if a beneficiary indicates that he or she does not have

a telephone number (for example, by writing “none” or “n/a” as his or her telephone number on the request for hearing or request for review of a QIC or IRE dismissal), the request will not be dismissed as incomplete because the beneficiary provided information related to the telephone number, even though an actual telephone number was not provided. To ensure that a beneficiary’s personally identifiable information is protected, any electronic communication between OMHA and a beneficiary would need to be conducted via secure e-mail or a secure portal; however, these technologies are not currently available for use by OMHA staff. Consequently, we believe it is reasonable to require a telephone number as the general rule, and address situations in which a beneficiary does not have a telephone number on an individual basis.

Comment: Three commenters opposed requiring appellants to provide the amount in controversy on the request for hearing, arguing that it would increase the burden on appellants and it would be difficult for appellants without access to billing information, such as Medicaid State agencies, to calculate the amount in controversy.

Response: As discussed in section II.B.3.d above, we are not finalizing our proposal to use the Medicare allowable amount as the basis for the amount in controversy for appeals of claims that are priced based on a published Medicare fee schedule or published contractor-priced amount. Because we will generally be retaining the existing methodology for calculating the amount in controversy under §405.1006(d), subject to certain revisions and the exceptions in §405.1006(d)(2) through (6) as finalized, we believe the information necessary to calculate the amount in controversy will be available in the record and ALJs can continue, as they do now, determining whether the amount in controversy was met on the basis of that information. Accordingly, we are not finalizing proposed §405.1014(a)(1)(viii) to require that providers,

suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim.

Comment: Two commenters suggested that OMHA should be prohibited from dismissing a timely filed request for hearing due to missing information, such as when an appellant provides incorrect dates of service. The commenters also suggested that the request for hearing form should be simplified to avoid deterring appeals by unrepresented beneficiaries. One commenter added that increasing the burden on appellants by requiring additional information in the request for hearing makes it harder for appellants to exercise their rights.

Response: We disagree with the commenters' suggestion that requests for hearing should not be dismissed if an appellant does not provide the required information. A complete request, consistent with §§405.1014 and 423.2014, provides OMHA with the minimum information necessary to process the request, identify the claims on appeal, and schedule a hearing if necessary, as efficiently as possible. In addition, if any of the required information is not included in a request, the appellant will be given the opportunity to provide the information, as discussed below in section II.B.3.g.iii of this final rule, before the request may be dismissed (see §§405.1014(b)(1) and 423.2014(c)(1) as finalized). As further discussed below in section II.B.3.x of this final rule, the proposal clarifying the ability to dismiss a request due to missing information will prevent an appeal from remaining pending indefinitely if an appellant has demonstrated an unwillingness to provide the information necessary to complete the request. In addition, we believe the information required in the regulations for a complete request for hearing or request for review of a QIC or IRE dismissal will not deter appeals by unrepresented beneficiaries or other appellants. We do not believe §§405.1014(a) and (b) and 423.2014(a) and

(b), as finalized, would create additional burdens as compared to the current rule, except for requiring a telephone number for the beneficiary, appellant, and that party's representative (as discussed above, other proposed information requirements for filing a request are not being made final). Instead, the final regulations clarify the information requirements for requesting a hearing or review of a QIC or IRE dismissal and the process for resolving missing information, thereby reducing confusion for appellants and, ultimately, reducing the number of requests that are dismissed as incomplete.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§405.1014 and 423.2014 as proposed, with the following exceptions. We are not finalizing proposed §§405.1014(a)(1)(vii), (viii), and 423.2014(a)(1)(vii).

ii. Requests for hearing involving statistical sampling and extrapolations

We proposed to add new §405.1014(a)(3) to address appeals in which an appellant raises issues regarding a statistical sampling methodology and/or an extrapolation that was used in making an overpayment determination. We stated in the proposed rule that OMHA has encountered significant issues when an appellant challenges aspects of a statistical sampling methodology and/or the results of extrapolations in separate appeals for each sampled claim involved in the statistical sampling and/or extrapolation. We stated that appeals often need to be reassigned to avoid multiple adjudicators addressing the challenges to the statistical sampling methodology and/or extrapolation, and any applicable adjudication time frames that attach to the individual appeals. Under proposed §405.1014(a)(3), if an appellant is challenging the statistical sampling methodology and/or extrapolation, the appellant's request for hearing must include the information in proposed §405.1014(a)(1) and (a)(2) for each sample claim that the appellant

wishes to appeal, be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), and assert the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation in the request for hearing. We stated in the proposed rule that we believed it would be appropriate in this situation to allow the appellant's request for hearing to be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), because if the appellant also wishes to challenge the statistical sampling methodology and/or extrapolation, the appellant would wait to file a request for hearing until all of the QIC reconsiderations for the sample units are received, which could be more than 60 calendar days after the first received QIC reconsideration of one of the sample claims. We also stated that the 60 calendar day period in proposed §405.1014(a)(3)(ii) would begin on the date the party receives the last reconsideration of a sample claim, regardless of the outcome of the claim in the reconsideration or whether the sample claim is appealed in the request for hearing. We stated we believed proposed §405.1014(a)(3) would balance the party's rights to request a hearing on individual claims when only the sample claims are appealed, with the needs to holistically address issues related to statistical sampling methodologies and extrapolations when those determinations are also challenged. We did not propose any corresponding changes to §423.2014 because sampling and extrapolation are not currently used in Part D appeals.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: Several commenters supported the proposal to allow appellants to file a single request for hearing that includes all of the sample claims the appellant wishes to appeal when the

sample claims were adjudicated in separate reconsiderations and the appellant is also challenging the sampling methodology and/or extrapolation, so that all of the sample claims and related issues are before the same adjudicator. Two of the commenters specifically noted that revising the time frames to allow an appellant to wait to file a request for hearing until the appellant receives the last reconsideration for the sample claims without losing the right to appeal earlier-decided claims will conserve time and resources for both appellants and OMHA.

Response: We thank the commenters for their support.

Comment: One commenter stated that the requirement to include information for each sample claim in the request for hearing is too vague and does not provide adequate guidance as to what must be provided, potentially resulting in more requests for hearings being dismissed as incomplete. The commenter further stated that it would be difficult to summarize the expert analyses required for statistical sampling challenges in a manner suitable for a request for hearing.

Response: With respect to the individual claim information that must be included in a request for hearing, we do not believe that the standard is vague and will result in an increased number of dismissals due to incomplete requests. Under §405.1014(a)(3)(i) as finalized in this rule, if an appellant is challenging the statistical sampling methodology and/or extrapolation, the request for hearing must include all of the information in §405.1014(a)(1) and (a)(2) for each sample claim that the appellant wishes to appeal. This individual claim information is necessary for OMHA to identify the claims on appeal and process the request for hearing. We note that some of the required information may be the same for all of the sample claims, such as the provider or supplier information, or the Medicare appeal number if the claims were all part of the same reconsideration. Because all of the sample claims must be appealed together under

§405.1014(a)(3) as finalized, any redundant information would only need to be provided once for the request for hearing to be considered complete, and would not need to be listed separately for each claim so long as it is apparent from the request that the information provided applies to all of the appealed claims.

Section 405.1014(a)(3)(iii), as finalized, requires an appellant to include in the request for hearing the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation. If an appellant is unable to summarize the reasons he or she disagrees with the statistical sampling methodology and/or extrapolation in a format suitable for a request for hearing, the appellant may choose to attach a position paper or other documentation to the request for hearing to better explain the reasons for the challenge. We also note that the requirement to include the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted does not limit the appellant's ability to provide additional information or arguments during the course of the appeal. The requirement, which is similar to the existing requirement in §405.1014 to state the reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed, provides the adjudicator with information on the appellant's basis for the appeal and is necessary to evaluate the record and prepare for the hearing. Moreover, a request for hearing may not be dismissed as incomplete based on the strength of the appellant's reasons for disagreeing with the statistical sampling methodology and/or extrapolation; a dismissal for an incomplete request would only result if no reason were provided, and only after an opportunity to cure the request had been provided, as provided at §405.1014(b)(1) as finalized.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing §405.1014(a)(3) as proposed without modification.

iii. Opportunity to cure defective filings

There has been considerable confusion on the implications of not providing the information required by current §405.1014(a) in order to perfect a request for hearing, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. To provide clearer standards and reduce confusion, we proposed in §405.1014(b)(1) that a request for hearing or request for a review of a QIC dismissal must contain the information specified in proposed §405.1014(a)(1) to the extent the information is applicable, in order to be considered a complete request, and that any applicable adjudication time frame will not begin until the request is complete because the missing information is necessary to the adjudication of the appeal. We proposed in §405.1014(b)(1) to also provide an appellant with an opportunity to complete any request found to be incomplete. However, we proposed that if the appellant fails to provide the information necessary to complete the request in the time frame provided, the incomplete request would be dismissed in accordance with proposed §405.1052(a)(7) or (b)(4). In order to reinforce the concept that an appellant's request and supporting materials is considered in its totality, we also proposed at §405.1014(b)(2) to allow for consideration of supporting materials submitted with a request when determining whether the request is complete, provided the necessary information is clearly identifiable in the materials. For example, we stated in the proposed rule that if an appellant were to submit a request for hearing and included a copy of the QIC reconsideration, the Medicare appeal number on the QIC reconsideration would generally satisfy the subsection (a)(1)(iv) requirement because it clearly provides the

required information. However, if there are multiple claims in the QIC reconsideration, the same document possibly would not satisfy subsection (a)(1)(v) because the appellant is not required to appeal all partially favorable or unfavorable claims, and subsection (a)(1)(v) requires the appellant to indicate the dates of service for the claims that are being appealed. Similarly, we stated that including medical records only for the dates of service that the appellant wishes to appeal would generally not satisfy subsection (a)(1)(v) because it would be unclear whether the appellant intended to limit the appeal to only those dates of service for which medical records were included, or those were the only dates of service for which the appellant had medical records. We proposed that the provisions of proposed §405.1014(b) also be adopted in proposed §423.2014(c) for requesting an ALJ hearing or a review of an IRE dismissal in Part D appeals.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter supported the proposal to deem a request complete if supporting materials submitted with the request clearly provide the required information. The commenter encouraged HHS to afford unrepresented beneficiaries as much flexibility and leniency as possible when applying the requirement to submit a complete request for hearing. To that end, the commenter suggested that OMHA should clearly identify any missing information and offer guidance as to where to locate the missing information.

Response: As discussed above and in section III.A.3.g.iii of the proposed rule, there has been considerable confusion and considerable time spent on procedural matters concerning the requirements for a request for hearing to be considered complete. We believe that allowing for consideration of supporting materials submitted with a request when determining whether the

request is complete, and providing appellants with an opportunity to complete the request if the request is not complete, would provide clearer standards and reduce confusion for all appellants, including unrepresented beneficiaries, with respect to the standards used to determine whether a request is complete. Providing appellants with an opportunity to complete a request for hearing when required information is missing would necessarily involve clearly identifying the missing information for the appellant. Currently, when a request for hearing is missing required information, OMHA sends the appellant a “Request for Hearing Deficiency Notice” that specifies the information that must be provided to complete the request and the time frame in which to respond (generally 60 calendar days). This practice helps ensure that appellants will have an opportunity to provide any missing information before a request is dismissed as incomplete, and this practice would continue under the final rule.

Allowing for consideration of supporting materials when determining whether a request is complete would also provide ALJs and attorney adjudicators with additional flexibility to deem the request complete, even if all of the information necessary for a complete request is not contained on the same document. We believe the rules as finalized provide all appellants, including unrepresented beneficiaries, with an appropriate level of flexibility in providing that the all documents submitted with a request for hearing will be considered in determining whether a request is complete, and an appropriate level of leniency in providing for an opportunity to supplement the request with any missing information if OMHA identifies missing information that is required for a complete request.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing §§405.1014(b) and 423.2014(c) as proposed without modification.

iv. Where and when to file a request for hearing or review of a QIC or an IRE dismissal

We proposed to incorporate portions of current §405.1014(b) in proposed §405.1014(c) and portions of current §423.2014(c) in proposed §423.2014(d) to address when and where to file a request for hearing or review. We proposed in §§405.1014(c) introductory language and (c)(1), and 423.2014(d) introductory language and (d)(1), to incorporate a request for a review of a QIC dismissal and a request for a review of an IRE dismissal, respectively, and provide that the current 60 calendar day period to file a request for hearing after a party receives a QIC or an IRE reconsideration also applies after a party receives a QIC or IRE dismissal, which is the time frame stated in §§405.1004 and 423.2004 to request a review of a QIC or IRE dismissal, respectively. We also proposed in §405.1014(c)(1) to add an exception for requests filed in accordance with proposed §405.1014(a)(3)(ii), because as discussed above, we proposed to require that requests for hearing on sample claims that are part of a statistical sample and/or extrapolation that the appellant also wishes to challenge would be filed together, which may be more than 60 calendar days after the appellant receives the first QIC reconsideration of one of the sample claims. In addition, we proposed to revise the statement that a request must be “submitted” in current §423.2014(c)(1), with a request must be “filed” in §423.2014(d)(1), for consistency with §§405.1014 and 422.602, both of which use the term “filed.” We also proposed in §§405.1014(c)(2) and 423.2014(d)(2) to replace references to sending requests to the “entity” specified in the QIC’s or IRE’s reconsideration in current §§405.1014(b)(2) and 423.2014(c)(2), with sending requests to the “office” specified in the QIC’s or IRE’s reconsideration or dismissal, respectively, so they are properly routed. As discussed in sections III.A.3.b and III.A.3.c of the proposed rule (and discussed in sections II.B.3.b and II.B.3.c above), regarding proposed §§405.1002 and 405.1004, and 423.2002 and 423.2004, replacing “entity” with

“office” in §§405.1014, 423.1972, and 423.2014 would help ensure appellants are aware that a request for hearing or request for a review of a QIC or IRE dismissal must be filed with the office indicated in the QIC’s or IRE’s reconsideration or dismissal and avoid delays. However, we again noted that for the few requests for hearing that are misrouted by a party, a notice would be sent to the appellant when the request for hearing is received in the correct office and the date the timely request was received by the incorrect office would be used to determine the timeliness of the request, in accordance with proposed §§405.1014(c)(2) and 423.2014(d)(2)(i), which would incorporate the misrouted request provisions from current §§405.1014(b)(2) and 423.2014(c)(2)(i). We also proposed in §§405.1014(c)(2) and 423.2014(d)(2)(i) that the adjudication time frame is only affected if there is an applicable adjudication time frame for the appeal.

Current §423.1972(b) states that an enrollee must file a request for a hearing within 60 calendar days of the date of the notice of the IRE reconsideration determination. This requirement differs from §423.2002(a)(1), which states that a request for hearing must be filed within 60 calendar days after receipt of the IRE’s reconsideration (this is also the standard for filing Part A and Part B requests for hearing after receipt of QIC reconsiderations, at §405.1002(a)(1)). Thus, we proposed to revise §423.1972(b)(1) to state that a request for hearing must be filed within 60 calendar days after receipt of the IRE’s reconsideration. We also proposed to add new §423.1972(b)(2), to incorporate current §423.2002(d), which provides the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration unless there is evidence to the contrary (this is also a presumption for receipt of QIC reconsiderations in Part A and Part B appeals, at §405.1002). These changes

would align proposed §423.1972(b) with current §423.2002, and remove potential enrollee confusion on when a request for an ALJ hearing must be filed.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter asked whether the same requirements would apply when a request for hearing is misrouted because the CMS contractor provided the appellant with an incorrect address, for example, if the contractor moved or changed jurisdictions after the address was provided.

Response: We assume the requirements to which the commenter is referring are the provisions of current §§405.1014(b)(2) and 423.2014(c)(2)(ii), which we proposed to incorporate into proposed §§405.1014(c)(2) and 423.2014(d)(2)(ii) as a requirement for OMHA to notify the appellant of the date a misrouted request for hearing is received in the correct office and the commencement of any applicable adjudication time frame. We also stated in the proposed rule that the date a timely request was received by an incorrect office would be used to determine the timeliness of the request (as set forth in proposed §§405.1014(c)(2) and 423.2014(d)(2)(i)). For most appeals, the notice of reconsideration or dismissal of a request for reconsideration instructs appellants to file their requests for hearing or review of a dismissal with the OMHA central docketing office, and we do not anticipate that changes in CMS contractors or changes to a CMS contractor's address will affect the accuracy of the filing address that is provided in the QIC's or IRE's reconsideration or dismissal. However, for a small segment of cases, such as Part C appeals, the notice of reconsideration instructs appellants to file their requests for hearing or review of a dismissal with the entity that conducted the reconsideration, which then forwards the request, along with the case file, to the OMHA central docketing office. In the event that the

entity that conducted the reconsideration changes the address to file a request for hearing or review, due to operational changes or a change in the contractor, there would be a transition plan to address providing a new address in filing instructions and a process for forwarding requests sent to the previous address. Regardless, if a timely request for hearing or review of a dismissal is mistakenly sent to another CMS contractor, to an incorrect or outdated address, or to an OMHA field office, the request is not treated as untimely or otherwise rejected. In accordance with §§405.1014(c)(2) and 423.2014(d)(2)(i) as finalized in this rule, the date the request was received by the incorrect office would be used to determine the timeliness of the request, and OMHA would notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame in accordance with §§405.1014(c)(2) and 423.2014(d)(2)(ii) as finalized.

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing §423.1972(b) as proposed without modification. In addition, we are finalizing §§405.1014(c) and 423.2014(d) with the following modifications. As discussed in section II.B.3.b above, we are adding language to §§405.1014(c)(2) and 423.2014(d)(2)(i) to clarify that a request for an ALJ hearing that is timely filed with an office other than the office specified in the QIC's or IRE's reconsideration is not treated as untimely. We are also removing the term "entity office," which was a drafting error, from proposed §405.1014(c)(2) and adding "office" in its place.

v. Sending copies of a request for hearing and other evidence to other parties to the appeal

We proposed to incorporate the portion of current §405.1014(b)(2) that states that the appellant must also send a copy of the request for hearing to the other parties and failure to do so will toll the ALJ's 90 calendar day adjudication deadline until all parties to the QIC

reconsideration receive notice of the requested ALJ hearing in proposed §405.1014(d) with changes discussed below. Current §405.1014(b)(2) has been another source of considerable confusion, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. Current §405.1014(b)(2) requires an appellant to send a copy of the request for hearing to the other parties. Other parties consist of all of the parties specified in §405.906(b) as parties to the reconsideration, including beneficiaries in overpayment cases that involve multiple beneficiaries who have no liability, in which case the QIC may elect to only send a notice of reconsideration to the appellant, in accordance with §405.976(a)(2). We proposed in §405.1014(d)(1) to amend the current copy requirement by only requiring an appellant to send a copy of a request for an ALJ hearing or review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. We stated in the proposed rule that this change would make the standard consistent with requests for Council review, a copy of which must be sent by the appellant to the other parties who received a copy of an ALJ's decision or dismissal, in accordance with current §405.1106(a). We also stated that this change would also extend the requirement to requests for review of a QIC dismissal to provide the other parties who received notice of the QIC's dismissal action with notice of the appellant's appeal of that action.

We also proposed in §405.1014(d)(1) to address whether copies of materials that an appellant submits with a request for hearing or request for review of a QIC dismissal must be sent to other parties. Currently some ALJs consider the materials to be part of the request and require an appellant to send copies of all materials submitted with a request, while other ALJs do not consider the materials to be part of the request. We proposed in §405.1014(d)(1) that if additional materials submitted with a request are necessary to provide the information required

for a complete request in accordance with proposed §405.1014(b), copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). We also proposed that if additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence). For example, if a complete request includes a position paper or brief that explains the reasons the appellant disagrees with the QIC's reconsideration, in accordance with proposed §405.1014(a)(1)(v), a copy of the position paper or brief would be sent to the other parties, subject to any authorities that apply to disclosing the personal information of other parties. However, we stated that additional evidence such as medical records, is generally not required for a complete request, and therefore copies would not have to be sent, but could instead be summarized and provided to the other parties at their request, again subject to any authorities that apply to disclosing the personal information of other parties. We stated that this approach would balance the objectives of ensuring that parties to a claim and an appeal of that claim remain informed of the proceedings that are occurring on the claim, with the burdens on appellants to keep their co-parties so informed. We also noted that in sending a copy of the request for hearing and associated materials, appellants are free to include cover letters to explain the request, but we noted that such letters on their own do not satisfy the copy requirement in its current or proposed form. No corresponding changes were proposed in §423.2014 because the enrollee is the only party to the appeal.

Current §405.1014 does not contain standards for what constitutes evidence that a copy of the request for hearing or review, or copy of the evidence or a summary thereof, was sent to

the other parties, which has led to confusion and inconsistent practices. Therefore, we proposed in §405.1014(d)(2) to address this issue by establishing standards that an appellant would follow to satisfy the requirement. We proposed in §405.1014(d)(2) that evidence that a copy of the request for hearing or review, or a copy of submitted evidence or a summary thereof, was sent includes: (1) certifications that a copy of the request for hearing or request for review of a QIC dismissal is being sent to the other parties on the standard form for requesting a hearing or review of a QIC dismissal; (2) an indication, such as a copy or “cc” line on a request for hearing or review, that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipients; (3) an affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or (4) a mailing or shipping receipt that identifies the name and address of the recipient and what was sent to the recipient. We stated in the proposed rule that we believed these options would provide an appellant with flexibility to document the copy requirement was satisfied and bring consistency to the process.

Beyond stating that an adjudication time frame is tolled if a party does not satisfy the copy requirement, current §405.1014 does not address the consequence of not satisfying the requirement, and adjudicators are faced with an appeal being indefinitely tolled because an appellant refuses to comply with the requirement. OMHA ALJs have addressed this issue by providing appellants with an opportunity to send the required copy of the request for hearing, and by informing the appellant that if the copy is not sent, its request will be dismissed. This allows OMHA ALJs to remove requests that do not satisfy the requirement from their active dockets so time and resources can be focused on appeals of those who comply with the rules. We proposed in §405.1014(d)(3) that, if the appellant fails to send a copy of the request for hearing or request

for review of a QIC dismissal, any additional materials, or a copy of the submitted evidence or a summary thereof, the appellant would be provided with an opportunity to cure the defects by sending the request, materials, and/or evidence or summary thereof described in proposed subsection (d)(1). Further, we proposed in §405.1014(d)(3) that if an adjudication time frame applies, it does not begin until evidence that the request, materials, and/or evidence or summary thereof were sent is received. We also proposed in §405.1014(d)(3) that if an appellant does not provide evidence within the time frame provided to demonstrate that the request, materials, and/or evidence or summary thereof were sent to other parties, the appellant's request for hearing or review would be dismissed.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received three comments on the proposal clarifying an appellant's obligation to furnish supporting documentation filed with a request for hearing or review of a QIC dismissal to the other parties, which the commenters opposed on the grounds that it would increase the amount of paperwork involved in filing an appeal. The commenters stated it would be costly and burdensome for appellants to produce and send the extra copies; would cause delays and increased time spent on appeals; and would be confusing for beneficiaries who are otherwise uninvolved in the appeal to receive additional paperwork.

Response: We do not agree that this proposal increases the amount of paperwork that an appellant is required to send to the other parties. Proposed §405.1014(d)(1) incorporates the requirement to send a copy of the request for hearing to the other parties from current §405.1014(b)(2). As noted above, there has been considerable confusion under the current rule as to whether materials submitted with a request for hearing are considered part of that request and,

therefore, whether copies of that material must be sent to the other parties. Currently some ALJs consider any materials sent with the request for hearing to be part of the request and require an appellant to send copies of all the materials submitted with a request to the other parties. The proposed clarification will standardize how this requirement is applied and bring uniformity to the filing process by limiting the materials that must be sent to the other parties to those materials that provide the information that is required for a complete request in accordance with proposed §405.1014(b). Any evidence that is not required for a complete request can be simply summarized and provided to the other parties at their request, subject to any authorities that apply to disclosing the personal information of other parties. For example, if new evidence is submitted in the form of medical records, a brief description explaining that medical records were submitted and how to contact the appellant for a copy of those medical records can be provided to the other parties, rather than sending copies of the medical records with the copy of the request for hearing. In contrast, if a copy of the QIC reconsideration is included for the purpose of providing the Medicare appeal number or claim-specific information that is required for a complete request for hearing (that is, the information is not contained on a request for hearing form or letter sent from the appellant requesting the appeal), then a copy of the QIC reconsideration would have to be sent to the other parties because the appellant is relying on it to provide information required for a complete request for hearing.

We further note that §405.1014(d)(1) as finalized actually reduces the number of recipients to whom an appellant is required to send a copy of the request and other materials. Instead of all of the parties to the reconsideration, which potentially includes beneficiaries who are not liable in overpayment cases that involve multiple beneficiaries, and therefore did not receive the notice of reconsideration in accordance with §405.976(a)(2), §405.1014(d)(1) as

finalized only requires an appellant to send a copy to those parties who received a copy of the QIC's reconsideration or dismissal. This change will reduce the time and expense for an appellant to produce and send the required copies, and will reduce the amount of paperwork sent to beneficiaries who are otherwise uninvolved in the appeal.

Comment: One commenter recommended, as an alternative approach, only requiring providers to notify the beneficiary of the outcome of an appeal, and only in cases where the claims remain denied.

Response: We do not believe that notifying beneficiaries solely of the outcome of the appeal when a claim remains denied would be sufficient in cases where the beneficiary received notice of the QIC's reconsideration or dismissal. Providing a complete copy of the request for hearing or review of a dismissal to the other parties is necessary to ensure that beneficiaries remain informed of the proceedings related to items or services furnished to them and can provide information or make inquiries about the appeal if they wish to do so. However, we also emphasize that, under the final rule, appellants are not required to send a copy of the request for hearing or review of a dismissal to any party that did not receive notice of the QIC's reconsideration or dismissal. This aligns the standard with current §405.1106(a), which requires appellants to send a copy of a request for Council review to the other parties who received a copy of an ALJ's decision or dismissal.

Comment: Another commenter asserted that requiring an appellant to send copies of additional materials sent with a request for hearing or review of dismissal to the beneficiaries would discourage filing requests for claims involving multiple beneficiaries together due to confidentiality issues, and would result in more individual appeals and increased delays.

Response: We do not agree that requiring appellants to send the other parties a copy of the complete request, including any additional materials that are necessary to complete the request, will discourage appellants from filing requests for claims involving multiple beneficiaries together. While appellants must comply with any authorities that apply to disclosing the personal information of other parties, if an appeal involves multiple beneficiaries, we believe the minor inconvenience of redacting a party's personal information from a brief or position paper when sending a copy to the other parties will be outweighed by the added efficiency of appealing multiple claims together in one request. We also note that in overpayment appeals that involve multiple beneficiaries who have no liability, the QIC generally does not send a copy of the reconsideration to the beneficiaries in accordance with §405.976(a)(2), and under §405.1014(d)(1) as finalized, a copy of the request for hearing or review of a dismissal is only sent to the parties who received a copy of the reconsideration. In addition, we note that the current requirement to send a copy of the request for hearing to all parties to the QIC reconsideration, regardless of whether the parties were sent a copy of that reconsideration, which has been in place since part 405, subpart I was promulgated in 2005, has not appeared to discourage appellants from filing appeals of QIC reconsiderations individually or together. Thus, for the reasons discussed above, we do not believe that §405.1014(d) as finalized in this rule will discourage filing requests for hearing for multiple beneficiaries together, or result in more individual appeals or increased delays.

Comment: One commenter expressed concern that unrepresented beneficiaries may have difficulty identifying where to send the required copies, determining which materials need to be copied, or summarizing other evidence. The commenter suggested that unrepresented beneficiaries should be afforded leniency or assisted with meeting the copy requirement, and

suggested that QIC reconsiderations and dismissals should include the full names and mailing addresses of the parties so that appellants can easily find the information.

Response: We thank the commenter for its suggestions. We agree that unrepresented beneficiaries may have difficulty determining where to send copies of a request, or what materials to provide to the other parties. Historically, if it is not apparent that an unrepresented beneficiary sent a copy of his or her request to the other parties, it has been the informal practice of both OMHA and the Council to send notice of the request to the other parties on the beneficiary's behalf. In response to the commenter's concerns, we agree that requests filed by unrepresented beneficiaries should not be subject to dismissal for failing to meet this requirement. Accordingly, we are amending §405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the consequences of failing to send a copy of the request, materials, and/or evidence or summary thereof to the other parties. We are also amending §405.1052(a)(7) and (b)(4) to reflect this exemption, as discussed in section II.B.3.x below.

With respect to including the full names and mailing addresses of the parties in a QIC reconsideration or dismissal, we thank the commenter for its suggestion and will share this recommendation with the QICs. However, at this time we do not believe that it would be appropriate to add the parties' contact information as a content requirement for QIC reconsiderations and dismissals in this final rule. Instead, OMHA will continue its current practice of assisting unrepresented beneficiaries with meeting the copy requirement by mailing copies of the request, materials, and/or evidence or summary thereof to the other parties if it is not apparent that copies were sent by the beneficiary.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals to revise §405.1014(d) with

modification. We are amending §405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the consequences of failing to send a copy of the request for hearing, any additional materials, and/or a copy of submitted evidence or summary thereof, as described in §405.1014(d)(1), to the other parties.

vi. Extending time to file a request for hearing or review of a QIC or an IRE dismissal

We proposed that the provisions of current §§405.1014(c) and 423.2014(d) for extensions of time to file a request for hearing would be incorporated in proposed §§405.1014(e) and 423.2014(e) with changes, and would extend to requests for reviews of QIC and IRE dismissals. On occasion, OMHA is asked whether a request for an extension should be filed without a request for hearing, for a determination on the request for extension before the request for hearing is filed. We stated that in those instances, we ask the filer to file both the request for hearing and request for extension at the same time because an independent adjudication of the extension request would be inefficient and any adjudication time frame begins on the date that the ALJ grants the extension request, in accordance with current §§405.1014(c)(4) and 423.2014(d)(5). We proposed in §§405.1014(e)(2) and 423.2014(e)(3) to require a request for an extension be filed with the request for hearing or request for review of a QIC or IRE dismissal, with the office specified in the notice of reconsideration or dismissal. We stated that the revisions we proposed in §§405.1014(e)(2) and 423.2014(e)(3) would also align the provisions with proposed §§405.1014(c) and 423.2014(d) by specifying that a request for an extension must be filed with the “office,” rather than the “entity,” specified in the notice of reconsideration. We proposed in §§405.1014(e)(3) and 423.2014(e)(4) that an ALJ or attorney adjudicator may find good cause to extend the deadline to file a request for an ALJ hearing or a request for a review of a QIC or IRE dismissal, or there is no good cause for missing the deadline to file a request for a

review of a QIC or IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. As we stated in the proposed rule, because only an ALJ may dismiss a request for an ALJ hearing for an untimely filing in accordance with proposed §§405.1052 and 423.2052, an attorney adjudicator could not make a determination on a request for an extension that would result in a dismissal of a request for hearing. We also proposed to incorporate current §§405.1014(c)(4) and 423.2014(d)(5) into proposed §§405.1014(e)(4) and 423.2014(e)(5), but indicate that the adjudication time frame begins on the date the ALJ or attorney adjudicator grants the request to extend the filing deadline only if there is an applicable adjudication period. Finally, we proposed in §§405.1014(e)(5) and 423.2014(e)(6) to add a new provision to provide finality for the appellant with regard to a determination to grant an extension of the filing deadline. We proposed that if an ALJ or attorney adjudicator were to make a determination to grant the extension, the determination is not subject to further review. However, we did not propose to preclude review of a determination to deny an extension because such a denial would result in a dismissal for an untimely filing, and the dismissal and determination on the request for an extension would be subject to review by the Council.

We received no comments on these proposals, other than comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing our proposals, as discussed above, without modification to revise §§405.1014(e) and 423.2014(e).

h. Time frames for deciding an appeal of a QIC or an IRE reconsideration or an escalated request for a QIC reconsideration, and request for Council review when an ALJ does not issue a decision timely (§§405.1016, 405.1104 and 423.2016)

i. Section 405.1016: Time frames for deciding an appeal of a QIC reconsideration or an escalated request for a QIC reconsideration

As discussed below, we proposed changes to §405.1016, which addresses the adjudication time frames for requests for hearing filed after a QIC has issued its reconsideration, in accordance with section 1869(d)(1)(A) of the Act, and escalations of requests for a QIC reconsideration when the QIC does not issue its reconsideration within its adjudication time frame, which is permitted by section 1869(c)(3)(C)(ii) of the Act. 81 FR 43790, 43820–43821

We proposed to revise the title of §405.1016 from “Time frames for deciding an appeal before an ALJ” to “Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration” because the section specifically applies to appeals of QIC reconsiderations and escalated requests for QIC reconsiderations (as specified in current and proposed §405.1016(a) and (c)). This revision would also allow for application of this section to requests for hearing adjudicated by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to replace each instance of the term “the ALJ” with “the ALJ or attorney adjudicator” throughout proposed §405.1016 to assist appellants in understanding that an adjudication time frame, and the option to escalate, also would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We did not propose to change the reference to “a request for an ALJ hearing” because, as explained in section II.B of the proposed rule and II.A.2 above,

even if an appellant waives its right to hearing, the case would remain subject to a potential oral hearing before an ALJ, and we believe the request is therefore properly characterized as a request for an ALJ hearing.

We proposed to add titles to proposed §405.1016(a) to indicate that this paragraph discusses the adjudication period for appeals of QIC reconsiderations, and proposed §405.1016(c) to indicate that this paragraph discusses the adjudication period for escalated requests for QIC reconsiderations. In addition, we proposed at §405.1016(a) and (c) to remove “must,” in providing that when a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration. While the statute envisions that appeals will be adjudicated within the statutory time frame, the statute also provides for instances in which the adjudication time frame is not met by allowing an appellant to escalate his or her appeal to the next level of appeal. We believe “must” should be reserved for absolute requirements, and in the context of adjudication time frames, the statute provides the option for an appellant to escalate an appeal if the adjudication time frame is not met.

We proposed to add a title to proposed §405.1016(b) to indicate that the paragraph discusses when an adjudication period begins. We also proposed to re-designate current §405.1016(b), which explains that the adjudication period for an appeal of a QIC reconsideration begins on the date that a timely filed request for hearing is received unless otherwise specified in the subpart, as §405.1016(b)(1). We proposed in §405.1016(b)(2) that if the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c), the

remanded appeal would be subject to the adjudication time frame of §405.1016(a) beginning on the date that OMHA receives the Council remand. Currently the regulations do not address whether an adjudication time frame applies to appeals that are remanded from the Council, and whether escalation is an option for these appeals. To provide appellants with an adjudication time frame for remanded appeals that were subject to an adjudication time frame when they were originally appealed to OMHA, we proposed in §405.1016(b)(2) to apply the adjudication time frame under §405.1016(a) to a remanded appeal that was subject to an adjudication time frame under paragraph (a) or (c). For example, if an ALJ decision reviewed by the Council involved a QIC reconsideration and was remanded by the Council, a 90 calendar day time frame would apply from the date that OMHA received the remand order. If the adjudication time frame is not met under proposed §405.1016(b)(2), the appeal would be subject to escalation, in accordance with proposed §405.1016(e).

In addition, we proposed in §405.1016(a) and (b) to align the paragraphs with proposed §405.1014(c) by specifying that a request for hearing is received by the “office,” rather than the “entity,” specified in the QIC’s notice of reconsideration.

We proposed to add a title to proposed §405.1016(d) to indicate that the paragraph discusses waivers and extensions of the adjudication period. We proposed in §405.1016(d)(1) to incorporate the adjudication period waiver provision in current §405.1036(d), which states that, at any time during the hearing process, the appellant may waive the adjudication deadline specified in §405.1016 for issuing a hearing decision, and that the waiver may be for a specific period of time agreed upon by the ALJ and the appellant. We proposed to move the provision because, as we stated in the proposed rule, we believe it is more appropriately addressed in §405.1016, as it is directly related to the adjudication period. We also proposed in §405.1016(d)

to revise the language in current §405.1036(d) to reference an attorney adjudicator consistent with our proposals in section II.B of the proposed rule and as discussed in section II.A.2 above; to reference the “adjudication” process rather than the “hearing process” to account for appeals that may not involve a hearing; to consistently reference an adjudication “period” for internal consistency; and to replace the reference to §405.1016 with internal paragraph references.

Current §405.1016 does not address delays that result from stays ordered by U.S. Courts. In addition, we have had instances in which an appellant requests a stay of action on his or her appeals while related matters are addressed by another court or tribunal, or by investigators. To address these circumstances, we proposed in §405.1016(d)(2) that the adjudication periods specified in paragraphs (a) and (c) are extended as otherwise specified in subpart I, and for the duration of any stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction, or the duration of any stay of proceedings granted by an ALJ or attorney adjudicator on the motion of the appellant, provided no other party also filed a request for hearing on the same claim at issue.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received fifteen comments opposing our proposal to remove “must” from §405.1016(a) and (c). Commenters opposed the proposal on the grounds that the 90-day adjudication time frame is a statutory requirement under section 1869 of the Act, and removing “must” undermines the duty owed to appellants by OMHA adjudicators and would only serve to increase delays in the appeals process. Several commenters cited a recent decision by the Court of Appeals for the District of Columbia Circuit that held that the statute mandated a decision within ninety days. The commenters stated that the ability to escalate an appeal to the Council is

a remedy for when the statutory deadline is not met, as opposed to an alternative to the timely adjudication of an appeal, and the existence of that remedy does not negate the mandatory nature of the statutory time frame. One commenter opposed the proposal with respect to appeals filed by beneficiaries and Medicaid State agencies, asserting that escalation is an inadequate remedy for those appellants because it means forgoing a level of administrative review where beneficiaries have historically had the greatest likelihood of success, and facing similar delays at the Council. Another commenter stated that it was particularly important not to weaken the statutory right to a timely decision for low-income beneficiaries. One commenter interpreted the proposal as eliminating the option to escalate an appeal if the adjudication time limit is exceeded.

Response: We do not agree that removing “must” from §405.1016(a) and (c) would undermine or weaken the adjudication time frame set forth in section 1869(d)(1)(A) of the Act. We recognize that one court of appeals has held that the statutory timeframe is mandatory, while another court of appeals has not. Compare *Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016) (holding that the Act does not provide a clear and indisputable right to adjudication of appeals before an ALJ within 90 days) with *American Hospital Association, et al. v. Burwell*, 812 F.3d 183, 192 (D.C. Cir. 2016) (holding that the Act imposes a clear duty on the Secretary to comply with the statutory time frame). We respectfully disagree that the statute mandates that all ALJ decisions reviewing QIC reconsiderations be issued within 90 days. Section 1869(d)(3)(A) of the Act, which provides for the consequences of failing to meet the adjudication time frame to render a decision in an appeal of QIC reconsideration decision made under section 1869(c) of the Act, contemplates that the adjudication time frame for an ALJ to render such a decision will not always be met, and provides the option for an appellant to request a review by the Council if the ALJ adjudication

time frame is not met. Consistent with this section, §405.1016(f), as finalized in this rule, provides for escalating an appeal of a QIC reconsideration to the Council when a decision, dismissal, or remand is not issued by an ALJ or attorney adjudicator within the adjudication time frame. Removing “must” does not abrogate the general expectation that a decision, dismissal, or remand will be issued within an applicable adjudication time frame, such as the 90 day time frame provided for at section 1869(d)(1)(A) of the Act to render a decision in an appeal of QIC reconsideration decision made under section 1869(c) of the Act. As we conveyed in the proposed rule, removing “must” only has the effect of more appropriately setting expectations with regard to whether there is an absolute and unqualified requirement to issue a decision, dismissal, or remand within the adjudication time frame. Removing the word “must” from §405.1016(a) and (c) also does not change the amount of time that an ALJ or attorney adjudicator has to issue a decision, dismissal, or remand before an appellant may choose to escalate his or her appeal to the Council. Moreover, removing “must” will have no effect on ALJs (and attorney adjudicators) issuing a decision, dismissal, or remand as quickly as possible, thus the change will not result in increased delays in obtaining a decision, dismissal, or remand. The Department has publicly committed itself to resolving the appeals backlog as quickly as possible while acting within statutory constraints. In particular, appeals brought by beneficiaries are prioritized under current OMHA policy and are generally decided within the applicable adjudication time frame.

Comment: One commenter pointed out that we did not propose to remove “must” from other sections of the regulations where it appears, such as current §405.1014(b)(1), which states that a request for an ALJ hearing after a QIC reconsideration must be filed within 60 days from the date the party receives notice of the reconsideration. Two commenters stated that if filing

deadlines and other regulatory time frames are mandatory for the parties, they should be mandatory for the government, too.

Response: Although we recognize that there are other uses of “must” in the regulations that we did not propose to revise, those are distinguishable. As we stated in the proposed rule, we believe “must” should be reserved for absolute requirements. In those instances, the result of not meeting the requirement does not trigger another option. As the commenter identified, current §405.1014(b)(1) provides that a request for hearing after a QIC reconsideration must be filed within 60 calendar days from the date the party receives notice of the reconsideration. However, we also note that current §405.1014(c) provides for extensions of that time frame in certain circumstances. Current §405.1014(b)(1) implements section 1869(b)(1)(D)(ii) of the Act, which provides that “[t]he Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 205 and 206” of the Act. Section 205(b)(1) of the Act in turn provides that a request for hearing “must be filed within [60] days after notice of [the decision being appealed] is received by the individual making such request.” Thus the statute establishes a clear duty for the appealing party to request a hearing within a specific time period after receiving a decision that the party wishes to appeal. If the party does not act, the party does not have a right to a hearing. However, we again note that when the time limit for filing a request for hearing is not met, the Secretary provides a mechanism for a party to request an extension for good cause in current §405.1014(c).

In contrast to the time limit for filing a request for hearing, §405.1016(a) and (c) set forth time frames to obtain a decision, dismissal, or remand, which, consistent with section 1869(d)(3)(A) of the Act, if not met results in the appellant having the option to escalate the appeal to the Council. Whereas the consequence of not meeting the time limit for filing a request

for hearing is that an adjudicator is precluded from reviewing the decision being appealed, the consequence of exceeding the adjudication time frames is the appellant then has the option to escalate the appeal to the next level. If the appellant at the hearing level chooses not to escalate his or her appeal to the Council, the appeal remains pending with OMHA in accordance with §405.1016(e) as finalized, which replaces current §405.1104(c) explaining the same.

Comment: One commenter stated that a decision should be issued in the provider's favor if the 90-day time frame cannot be met. Another commenter stated that if the government cannot meet its deadlines, the claim should be forfeited.

Response: We interpret the commenters' statements as suggesting that Medicare should pay every denied claim that is the subject of an appeal of a QIC reconsideration for an ALJ hearing if a decision, dismissal, or remand is not issued within the adjudication time frame applicable to the appeal, which could include time in addition to the 90 days based on certain regulatory provisions that allow for the extension of that time for certain actions or events (for example, §405.1016(d)). We believe such a provision would be inappropriate because Medicare may only pay a claim if the item or service is a covered benefit and coverage is not excluded by statute, and any applicable conditions of payment are met, unless specific statutory criteria are met for limiting liability on denied claims under section 1879 of the Act or waiving an overpayment under section 1870 of the Act. Medicare cannot make payment on a claim when a QIC has issued a reconsideration that determined that the item or service is not covered by Medicare or payment may not be made, and if applicable, that the provisions for limiting liability or waiving an overpayment are not met. Further, there is no statutory limitation on liability or overpayment waiver provision that permits payment to be made if an adjudication time frame is not met. Rather, the statute provides that when an ALJ's adjudication time frame is not met for

an appeal of a QIC reconsideration, the appellant has the option to request a review by the DAB, which is implemented in §405.1016(f), as finalized in this rule, which provides for escalating an appeal of a QIC reconsideration to the Council when a decision, dismissal, or remand is not issued by an ALJ or attorney adjudicator within the adjudication time frame. Moreover, we believe requiring payment to be made on a claim only because an adjudication time frame for an appeal of a denial is not met could increase the appeals workload and raise significant program integrity risks by creating an incentive for providers and suppliers to overwhelm the appeals process with appeals in an effort to obtain payment on claims that may not meet coverage requirements or conditions of payment.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §405.1016 as proposed without modification.

ii. Incorporation of the provisions of section 405.1104 (Request for Council review when an ALJ does not issue a decision timely) into section 405.1016(f)

Section 405.1104 addresses how to request escalation from an ALJ to the Council, when an ALJ has not issued a decision, dismissal or remand on a QIC reconsideration within an applicable adjudication time frame, in accordance with section 1869(d)(3)(A) of the Act in paragraph (a); the procedures for escalating an appeal in paragraph (b); and the status of an appeal for which the adjudication time frame has expired but the appellant has not requested escalation in paragraph (c). We proposed to remove and reserve §405.1104 and incorporate the current §405.1104 providing for escalating a request for an ALJ hearing to the Council into proposed §405.1016(e) and (f) with revisions, as its current placement in the Council portion of part 405, subpart I has caused confusion. We also proposed to insert “or attorney adjudicator”

after “ALJ” in proposed §405.1016(e) and (f) to assist appellants in understanding that the effect of exceeding the adjudication period and the option to escalate would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B of the proposed rule and II.A.2 above.

Section 405.1104(c) is titled “No escalation” and states that if the ALJ’s adjudication period set forth in §405.1016 expires, the case remains pending with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the Council. We proposed in §405.1016(e) to incorporate §405.1104(c) with changes. We proposed to revise the paragraph title for proposed §405.1016(e) to indicate that the paragraph discusses the effect of exceeding the adjudication period. Proposed §405.1016(e) would provide that if an ALJ or an attorney adjudicator assigned to a request for hearing (as proposed in section II.B of the proposed rule and discussed in section II.A.2 of this final rule above) does not issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in the section, the party that filed the request for hearing may escalate the appeal when the adjudication period expires. However, if the adjudication period expires and the party that filed the request for hearing does not exercise the option to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand. We proposed to indicate that the appeal remains pending with OMHA to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned.

Section 405.1104(a) describes how to request an escalation and states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period may request Council review if the appellant files a written request with the ALJ to escalate the appeal to the Council after the

adjudication period has expired, and the ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in §405.1016. We proposed in §405.1016(f)(1) to remove the requirement to request Council review in the course of requesting an escalation and to describe when and how to request escalation. Specifically, we proposed to revise the current procedures at §405.1104(a) and (a)(1), to provide that an appellant who files a timely request for a hearing with OMHA and whose appeal continues to be pending at the end of an applicable adjudication period may exercise the option to escalate the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council, which would simplify the process for appellants and adjudicators by only requiring appellants to file a single request for escalation with OMHA. We proposed to replace the reference to an appeal that “continues to be pending before the ALJ” in §405.1104(a) with an appeal that “continues to be pending with OMHA” in proposed §405.1016(f)(1) to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned. We also proposed that a written request to escalate an appeal to the Council would be filed with OMHA to allow OMHA to provide a central filing option for escalation requests. Section 405.1106(b) requires that the appellant send a copy of the escalation request to the other parties and failing to do so tolls the Council’s adjudication deadline set forth in §405.1100 until the other parties to the hearing have received notice. As discussed in section III.A.5.c of the proposed rule and II.B.5.c of this final rule below, we proposed to revise §405.1106(b) to require that the request for escalation be sent to other parties who were sent a copy of the QIC reconsideration. Therefore, we also proposed at §405.1016(f)(1) that the appellant would send a copy of the escalation request to the other parties

who were sent a copy of the QIC reconsideration so appellants would be aware of the requirement and which parties must be sent a copy of the escalation request.

Section 405.1104(b) describes the escalation process and states if the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set for in paragraph (a)(2) of the section (later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in §405.1016), he or she sends notice to the appellant acknowledging receipt of the request for escalation and confirming that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory time frame. Section 405.1104(b)(3) states that if the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of the section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to Council review consistent with §405.1102(a). We stated in the proposed rule that this process has caused confusion for both appellants and adjudicators because an initial escalation request must be filed with the ALJ, and if the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request or within 5 calendar days from the end of the applicable adjudication period, the appellant must file a request with the Council to move the appeal to the Council level. We also stated that some appellants neglect to take this second step of filing an escalation request with the Council. This leaves it unclear to the ALJ and support staff whether to continue adjudicating the appeal after issuing a notice that the ALJ is unable to issue a decision, dismissal or remand within the later of 5 calendar days of receiving the escalation request or 5 calendar days from the end of the applicable adjudication period. We proposed in §405.1016(f)(2) to revise the escalation process. Specifically, we proposed that if an escalation request meets the requirements of proposed §405.1016(f)(1), and an ALJ or attorney adjudicator is not able to issue

a decision, dismissal order, or remand within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period, OMHA (to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned) would send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of §405.1016. We also proposed that the notice would state that the QIC reconsideration would be the decision that is subject to Council review consistent with §405.1102(a); and the appeal would then be automatically escalated to the Council in accordance with §405.1108. We proposed that OMHA would then forward the case file, which would include the file received from the QIC and the request for escalation and all other materials filed with OMHA, to the Council. We stated in the proposed rule that we believed that this proposed process would help alleviate the current confusion, and would simplify the escalation process for appellants because appellants would not have to file a separate request for Council review after filing an escalation request with OMHA.

Currently, invalid escalation requests are not addressed in the regulations. We proposed in §405.1016(f)(3) to address invalid escalation requests. We proposed that if an ALJ or attorney adjudicator determines an escalation request does not meet the requirements of proposed §405.1016(f)(1), OMHA would send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation. For example, we stated in the proposed rule that an escalation request would be deemed invalid if escalation is not available for the appeal, such as appeals of SSA reconsiderations; the escalation request is premature because the adjudication period has not expired; or the party that filed the escalation request did not file the request for hearing. We stated in the proposed rule that if an ALJ or

attorney adjudicator were to determine the request for escalation was invalid for a reason that could be corrected (for example, if the request was premature), the appellant could file a new escalation request when the adjudication period expires.

We received no comments on our proposals to revise and incorporate the provisions of §405.1104 into §405.1016(e) and (f), other than: (1) comments discussed in section II.A.2 above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the proposals without modification.

iii. Section 423.2016: Time frames for deciding an appeal of an IRE reconsideration

As discussed below, we proposed changes to §423.2016, which addresses the adjudication time frames for requests for hearing filed after an IRE has issued its reconsideration. 81 FR 43790, 43823. The title of current §423.2016 states, “Timeframes for deciding an Appeal before an ALJ.” We proposed to revise the title of §423.2016 to read “Time frames for deciding an appeal of an IRE reconsideration” in order to state that the section addresses adjudication time frames related to appeals of IRE reconsiderations and to accommodate the application of this section to attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and as discussed earlier. We also proposed to insert “or attorney adjudicator” after “ALJ” throughout proposed §423.2016 so that an adjudication time frame

would apply to a request for an ALJ hearing following an IRE reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B of the proposed rule and II.A.2 above.

Current §423.2016(a) and (b) explain the adjudication time frames for standard and expedited appeals of IRE reconsiderations, respectively. However, the current paragraph titles refer to hearings and expedited hearings. We proposed at §423.2016(a) and (b) to retitle the paragraphs to refer to standard appeals and expedited appeals because the time frames apply to issuing a decision, dismissal, or remand, and are not limited to appeals in which a hearing is conducted. We proposed at §423.2016(a) and (b) to remove “must” in providing when an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the IRE, as appropriate, after the request for hearing is received by the office specified in the IRE's notice of reconsideration because there may be instances in which a decision, dismissal, or remand cannot be issued within the adjudication time frame, though we stated that we expect those instances to be rare because beneficiary and enrollee appeals are generally prioritized by OMHA. In addition, we proposed in §423.2016(a) and (b) to replace references to sending a request to the “entity” specified in the IRE’s reconsideration, with the “office” specified in the IRE’s reconsideration notice, to minimize confusion and delays in filing requests with OMHA. Similar to proposed §405.1016(b)(2), we proposed at §423.2016(a)(3) and (b)(6) to adopt adjudication time frames for appeals that are remanded by the Council. Specifically, we proposed in §423.2016(a)(3) that if the Council remands a case and the case was subject to an adjudication time frame, the remanded appeal would be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand to provide enrollees with an adjudication time frame for remanded appeals. In §423.2016(b)(6), we proposed to require that if the standards for an

expedited appeal continue to be met after the appeal is remanded from the Council, the 10-day expedited time frame would apply to an appeal remanded by the Council. If the standards for an expedited appeal are no longer met, the adjudication time frame for standard appeals would apply because the criteria for an expedited hearing are no longer present. Finally, we proposed at §423.2016(b) to revise the expedited appeal request process to permit an ALJ or attorney adjudicator to review a request for an expedited hearing, but not require the same ALJ or attorney adjudicator to adjudicate the expedited appeal, to provide OMHA with greater flexibility to review and assign requests for expedited hearings, and help ensure the 10-day adjudication process is completed as quickly as the enrollee's health requires. For example, if an attorney adjudicator were to review a request for an expedited hearing and determine that the standards for an expedited hearing were met, but did not believe a decision could be issued without a hearing, the attorney adjudicator could provide the enrollee with notice that the appeal would be expedited and transfer the appeal to an ALJ for an expedited hearing and decision.

As described in section III.A.3.q of the proposed rule and II.B.3.q below, we proposed to move the provision for waiving the adjudication period from current §423.2036(d) to proposed §423.2016(c) because proposed §423.2016 addresses adjudication time frames and, as we stated in the proposed rule, we believed the section is a better place for discussing adjudication time frame waivers.

We proposed that the provisions of proposed §405.1016(d) also be adopted in proposed §423.2016(c) for adjudication period waivers and stays of the proceedings ordered by a court or granted by an ALJ or attorney adjudicator on motion by an enrollee.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: Two commenters opposed the proposal to remove “must” from §423.2016(a) and (b), stating that it would be detrimental to beneficiaries given the current state of the appeals system. One commenter added that if beneficiary and enrollee appeals are prioritized by OMHA, there is no compelling reason to alter the time frame requirement.

Response: We disagree that the proposal will be detrimental to beneficiaries. As discussed in section II.B.3.h.i above in response to similar comments about our proposal to remove “must” from §405.1016(a) and (c), removing “must” does not alter the applicable adjudication time frames, and so does not abrogate the general expectation that a decision, dismissal, or remand will be issued within those time frames. Nor will removing “must” have an effect on ALJs and attorney adjudicators issuing a decision, dismissal, or remand as quickly as possible, so the change will not result in delays in obtaining a decision, dismissal, or remand. Moreover, appeals brought by beneficiaries, including appeals by Part D enrollees, are prioritized under current OMHA policy and are generally decided within the applicable adjudication time frame.

We also disagree that the proposal is unnecessary. As we explained in the proposed rule, there may be times in which it is not possible to issue a decision, dismissal, or remand within the applicable adjudication time frame. 81 FR 43790, 43823. Removing “must” from §423.2016(a) and (b) more accurately reflects that the time frames in those sections will not always be met.

Comment: One commenter supported the proposal to adopt adjudication time frames for appeals that are remanded by the Council. The commenter requested clarification regarding how an appellant will know when OMHA receives a remand, starting the adjudication time frame for cases that are subject to an adjudication time frame.

Response: We thank the commenter for its support. We note that when the Council remands an appeal to OMHA, notice of the remand is also sent to the appellant and other parties consistent with §405.1128. This notice shows the date that a remand was issued by the Council, giving the appellant a general idea of when a remand would have been received by OMHA. If an appellant would like to know the exact date that a remand was received by OMHA for purposes of calculating any applicable adjudication time frame, the appellant can contact OMHA directly or check the status of a specific appeal using AASIS, which provides public access to appeal status information and can be accessed through the OMHA website (www.hhs.gov/omha). Currently, for appeals that have been remanded by the Council, the original ALJ appeal number assigned to the case will display in AASIS with a status indicator of “Reopened,” along with the new ALJ appeal number assigned to the remanded appeal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §423.2016 as proposed without modification.

i. Submitting evidence (§§405.1018 and 423.2018)

As described below, we proposed a number of changes to current §§405.1018 and 423.2018, which address submitting evidence before an ALJ hearing is conducted. 81 FR 43790, 43823–43824. We proposed to retitle the sections from “Submitting evidence before the ALJ hearing” to “Submitting evidence” because evidence may be submitted and considered in appeals for which no hearing is conducted by an ALJ, and we believe an attorney adjudicator should be able to consider submitted evidence in deciding appeals as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). For the same reason, we proposed in §423.2018 to replace the references to “hearings” in the heading to paragraph (a) and in the

introductory text to paragraphs (b) and (c), with “appeals.” We also proposed to add headings to paragraphs that do not currently have headings, for clarity of the matters addressed in the paragraphs.

Current §405.1018(a) states that, except as provided in this section, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 calendar days of receiving the notice of hearing). We proposed in §405.1018(a) to provide for the submission of other evidence, in addition to written evidence, that the parties wish to have considered. Other evidence could be images or data submitted on electronic media. We proposed to also adopt this revision in §405.1018(b) and §423.2018(a), (b), and (c). We also proposed in §405.1018(a) to remove “at the hearing” so that parties would submit all written or other evidence they wish to have considered, and consideration of the evidence would not be limited to the hearing. We proposed a corresponding change to §423.2018(a).

Current §405.1018(a) states that evidence must be submitted with the request for hearing, or within 10 calendar days of receiving the notice of hearing. This provision has caused confusion as to when evidence is required to have been submitted because current §405.1014(a)(7) allows an appellant to state in the request for hearing that additional evidence will be submitted and the date it will be submitted. To reconcile the provisions, we proposed in §405.1018(a) to provide that parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with proposed §405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. We proposed to also adopt these revisions in §423.2018(b) and (c).

Current §405.1018(b) addresses how the submission of evidence impacts the adjudication period, and provides that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, the period between when the evidence “was required to have been submitted” and the time it is received does not count towards an adjudication period. To simplify the provision, we proposed at §405.1018(b) that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received. We also proposed to adopt this provision in §423.2018(b)(2) and (c)(2), except that in (c)(2), the adjudication time frame is affected if the evidence is submitted later than 2 calendar days after receipt of the notice of expedited hearing because 2 calendar days is the equivalent time frame to submit evidence for expedited appeals before the adjudication period is affected under current §423.2018.

Current §405.1018(c) addresses new evidence, and is part of the implementation of section 1869(b)(3) of the Act, which precludes a provider or supplier from introducing evidence after the QIC reconsideration unless there is good cause that prevented the evidence from being introduced at or before the QIC’s reconsideration. These provisions, which provide for the early submission of evidence, help adjudicators to obtain evidence necessary to reach the correct decision as early in the appeals process as possible. We proposed to incorporate current §405.1018(c), which requires a provider, supplier, or beneficiary represented by a provider or supplier that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker, in proposed §405.1018(c)(1). However, current §405.1018 does not address the consequences of not submitting the statement. The statute sets a bar to introducing new evidence, and the submitting

party must establish good cause by explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. However, when a provider or supplier, or beneficiary represented by a provider or supplier, fails to include the required statement, OMHA ALJs and staff spend time seeking out the explanation and following up with parties to fulfill their obligation. Thus, we proposed to revise §405.1018(c)(2) to state that if the provider or supplier, or beneficiary represented by a provider or supplier fails to include the statement explaining why the evidence was not previously submitted, the evidence will not be considered. Because only the enrollee is a party to a Part D appeal, we did not propose a corresponding revision to §423.2018.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter questioned whether directing parties to submit all evidence with the request for hearing is incompatible with the appeal instructions currently sent by QICs, which instruct appellants not to attach evidence to the hearing request and instead submit the evidence directly to the ALJ when the case is assigned.

Response: We do not agree that proposed §405.1018(a) requires an appellant to submit all evidence with the request for hearing, or that the proposals are incompatible with appeal instructions currently sent by QICs. Under current §405.1018(a), appellants may submit evidence with the request for hearing or within 10 calendar days of receiving the notice of hearing. However, current §405.1014(a)(7) also provides that in a request for hearing, an appellant could provide a statement of any additional evidence to be submitted and the date it will be submitted. Due to the significant increase in appeals to OMHA in recent years, OMHA requested that the QICs include language encouraging appellants to use current §405.1014(a)(7) to submit evidence

directly to the ALJ after the appeal was assigned, to help OMHA process requests for hearing more efficiently.

Under proposed §405.1018(a), we proposed to add an explicit reference to the §405.1014(a)(7) provision (re-designated as proposed §405.1014(a)(2)) to more fully specify in proposed §405.1018(a) when evidence may be submitted. Under proposed §405.1018(a), evidence can be submitted after a request for hearing is submitted and, therefore, an appellant would not be precluded from submitting the evidence at a later time. For example, an appellant could indicate in the request for hearing that it has additional evidence to submit and will submit it when the appeal is assigned to an adjudicator. However, there may be times when the appellant wishes to submit new evidence with the request for hearing, such as when the appellant waives his or her right to appear at a hearing before an ALJ and requests that a decision be made on the record, or the appellant believes the evidence addresses the issues identified in the reconsideration and including the evidence may increase the likelihood that a decision that is fully favorable could be issued based on the record alone in accordance with proposed §405.1038(a). The current appeal instructions do not preclude an appellant from submitting evidence with the request for hearing, but rather request that appellants consider submitting it at a later time. Therefore, we believe that by allowing for the submission of evidence with the request for hearing or after the request is submitted, by the date specified in the request for hearing in accordance with §405.1014(a)(2) or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing, proposed §405.1018(a) is not incompatible with appeal instructions currently sent by QICs. However, we will review the appeal instructions being issued by QICs to determine if clarification may be appropriate to reduce potential confusion.

Comment: Two commenters recommended adding language to specifically state that Medicaid State agencies are exempt from the requirement of current §405.1018(c) to provide a statement of good cause explaining why evidence was submitted for the first time at the OMHA level.

Response: As discussed above, current §405.1018(c) is part of the implementation of section 1869(b)(3) of the Act (42 U.S.C. 1395ff(b)(3)), which precludes a provider or supplier from introducing evidence after the QIC reconsideration without a showing of good cause. Considering the language of the statute, which expressly states that this limitation applies to providers and suppliers, we agree that the requirement under §405.1018(c) to support the introduction of new evidence with a statement of good cause does not apply to Medicaid State agencies. Further, we note that the provision would not apply to other parties or potential parties such as unrepresented beneficiaries, applicable plans, CMS and its contractors, or beneficiaries represented by someone other than a provider or supplier. To address the comment and more broadly clarify the application of the requirements under proposed §405.1018, we are redesignating proposed §405.1018(d) as (d)(1) and clarifying that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing, or to evidence submitted by unrepresented beneficiaries, as is the case under current §405.1018(d). Because current §405.1018(c) applies only to providers, suppliers, and beneficiaries represented by a provider or supplier, we are also adding paragraph (d)(2) to clarify that the requirements in paragraph (c) to show good cause for the submission of new evidence do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, Medicaid State agencies, applicable plans, CMS and its contractors, or beneficiaries represented by someone other than a provider or supplier.

Comment: One commenter stated that any limitation on new evidence prevents a fair hearing because OMHA does not always receive evidence that was submitted earlier in the appeal process. Another commenter suggested that §405.1018(c)(2) should be amended to provide flexibility for an ALJ or attorney adjudicator to review evidence that was not timely submitted, in his or her discretion, even without an explanation of good cause.

Response: We disagree with the commenter that any limitation on new evidence prevents a fair hearing because OMHA does not always receive evidence that was submitted earlier in the appeal process. There are ample opportunities to submit evidence at the redetermination and reconsideration levels of appeal, and section 1869(b)(3) of the Act expressly states that providers and suppliers may not introduce new evidence in any appeal that was not presented at the reconsideration, unless there is good cause which precluded the introduction of such evidence at or before the reconsideration. This statutory provision was added to promote an efficient appeals process in which adjudicators receive evidence as early in the appeals process as possible, but also allow new evidence to be introduced after the reconsideration when there is good cause. OMHA receives evidence from the contractors and, in the vast majority of cases, there is no question regarding missing evidence that was submitted at prior levels of appeal; but in the few cases in which that is a question, good cause could be found to admit the evidence in accordance with proposed §405.1028(a)(2)(iv). We also disagree with the commenter who suggested allowing additional flexibility for an ALJ or attorney adjudicator to consider evidence that was not timely submitted in accordance with section 1869(b)(3) of the Act without a statement of good cause, because doing so would be contrary to section 1869(b)(3) of the Act.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1018 and 423.2018 as

proposed with the following modifications. We are revising §405.1018(d) to provide in paragraph (d)(1) that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, and in (d)(2) that the requirement in paragraph (c) to support new evidence with a statement of good cause does not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier. We are also correcting a drafting error and adding a missing comma to §423.2018(b)(1) and (c)(1) for consistency with §405.1018(a) and to clarify that there are three time frames when a represented enrollee may submit written or other evidence he or she wishes to have considered with the request for hearing: (1) with the request for hearing; (2) by the date specified in the request for hearing in accordance with §423.2014(a)(2); or (3) if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

j. Time and place for a hearing before an ALJ (§§405.1020 and 423.2020)

As described below, we proposed a number of changes to provisions concerning the time and place for a hearing before an ALJ in §§405.1020 and 423.2020. 81 FR 43790, 43824-43827. As the ALJ hearing function transitioned from SSA, where hearings could be held at over 140 hearing sites nation-wide, to OMHA with four field offices, OMHA became one of the first agencies to use video-teleconferencing (VTC) as the default mode of administrative hearings. The effective use of VTC mitigated OMHA's reduced geographic presence, and allowed OMHA to operate more efficiently and at lower cost to the American taxpayers. However, the preference of most appellants quickly turned to hearings conducted by telephone. We stated in the proposed rule that, in FY 2015, over 98% of hearings before OMHA ALJs were conducted by telephone.

Telephone hearings provide parties and their representatives and witnesses with the opportunity to participate in the hearing process with minimal disruption to their day, and require less administrative burden at even lower cost to the American taxpayers than hearings conducted by VTC. OMHA ALJs also prefer telephone hearings in most instances, because they allow more hearings to be conducted without compromising the integrity of the hearing. However, even if a telephone hearing is being conducted, when the ALJ conducting the hearing believes visual interaction is necessary for a hearing, he or she may conduct a VTC hearing, and when special circumstances are presented, ALJs may conduct in-person hearings.

Despite the shift in preferences for most appellants to telephone hearings, current §405.1020 still makes VTC the default mode of hearing, with the option to offer a telephone hearing to appellants. In fact, some appellants have required the more expensive VTC hearing even when their representative is presenting only argument and no testimony is being offered. We stated in the proposed rule that we believe this is inefficient and results in wasted time and resources that could be invested in adjudicating additional appeals, and unnecessarily increases the administrative burdens and costs on the government for conducting a hearing with little to no discernable benefit to the parties in adjudicating denials of items or services that have already been furnished. Based on these considerations, we proposed that a telephone hearing be the default method, unless the appellant is an unrepresented beneficiary. We stated in the proposed rule that we believed that this proposal balances the costs and administrative burdens with the interests of the parties, recognizing that unrepresented beneficiaries may have an increased need and desire to visually interact with the ALJ.

We proposed in §405.1020(b) to provide two standards for determining how appearances are made, depending on whether appearances are by unrepresented beneficiaries or by

individuals other than unrepresented beneficiaries. We proposed to incorporate the provisions of current §405.1020(b) into proposed §405.1020(b)(1), and revise them to specify that they are applicable to an appearance by an unrepresented beneficiary who files a request for hearing. We proposed in subsection (b)(1) that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by VTC if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance. As in the current rule, we also proposed in §405.1020(b)(1) to allow the ALJ to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary. The current standard for determining whether an in-person hearing should be conducted involves a finding that VTC technology is not available or special or extraordinary circumstances exist. Because, absent special or extraordinary circumstances, a hearing could still be conducted by telephone if VTC technology were unavailable, we proposed that the standard for an in-person hearing be revised to state that VTC or telephone technology is not available or special or extraordinary circumstances exist, and the determination would be characterized as finding good cause for an in-person hearing, to align with current §405.1020(i)(5), which provides for granting a request for an in-person hearing on a finding of good cause. We also proposed in §§405.1020(b)(1) and 405.1020(i)(5) to replace the reference to obtaining the concurrence of the “Managing Field Office ALJ” with the “Chief ALJ or designee.” We stated in the proposed rule that the position of the Managing Field Office ALJ became what is now an Associate Chief ALJ, see 80 FR 2708, and using “Chief ALJ or designee” would provide OMHA with the flexibility to designate the appropriate individual regardless of future organizational changes. We proposed to adopt these revisions in proposed §423.2020(b)(1) for appearances by unrepresented enrollees

and §423.2020(i)(5), for when an ALJ may grant a request for an in-person hearing. We also proposed in §405.1020(b)(1) to replace “videoteleconferencing,” with “video-teleconferencing,” for consistency with terminology used in §§405.1000, 405.1036, 423.2000, 423.2020 and 423.2036.

Section 405.1020(b)(2), as proposed, addresses appearances by an individual other than an unrepresented beneficiary who files a request for hearing. We proposed in §405.1020(b)(2) that the ALJ would direct that those individuals appear by telephone, unless the ALJ finds good cause for an appearance by other means. Further, we proposed in §405.1020(b)(2) that the ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal. Also, we proposed that the ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if VTC and telephone technology are not available, or special or extraordinary circumstances exist. We proposed to adopt these revisions in §423.2020(b)(2) for appearances by represented enrollees, which is more specific than proposed §405.1020(b)(2) because only enrollees are parties to appeals under part 423, subpart U, and the provisions of subsection (b)(2) would apply only to appearances by represented enrollees.

Current §405.1020(c)(1) states that the ALJ sends a notice of hearing. This has caused confusion as to whether the ALJ must personally sign the notice, or whether it can be sent at the direction of the ALJ. We believe that the notice may be sent at the direction of the ALJ, and requiring an ALJ signature adds an unnecessary step in the process of issuing the notice. Therefore, we proposed in §405.1020(c)(1) that a notice of hearing be sent without further qualification, and to let other provisions indicate the direction that is necessary from the ALJ in

order to send the notice, such as §405.1022(c)(1), which provides that the ALJ sets the time and place of the hearing. We proposed to adopt these provisions in §423.2020(a)(1).

Current §405.1020(c)(1) also requires that the notice of hearing be sent to the parties who filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration. However, there are instances in which a party who does not meet the criteria may face liability because the ALJ may consider a new issue based on a review of the record. To address this, we proposed in §405.1020(c)(1) to add that a party that may be found liable based on a review of the record must be sent a notice of hearing. In addition, current §405.1020 does not address notices of hearing sent to CMS or a non-QIC contractor. We stated in the proposed rule that, currently, ALJs may also send a notice of hearing to CMS or a contractor when the ALJ believes their input as a participant or party may be beneficial. We proposed in §405.1020(c)(1) that the notice of hearing also be sent to CMS or a contractor that the ALJ believes would be beneficial to the hearing. We did not propose any corresponding revisions to current §423.2020(c)(1) because only enrollees are parties to appeals under part 423, subpart U.

OMHA ALJs have expressed concern that parties and representatives who appear at a hearing with multiple individuals and witnesses who were not previously identified, complicate and slow the hearing process. We stated that while a party or representative has considerable leeway in determining who will attend the hearing or be called as a witness, prior notice of those individuals is necessary for the ALJs to schedule adequate hearing time, manage their dockets, and conduct the hearing. To address these concerns, we proposed at §405.1020(c)(2)(ii) to add a requirement to specify the individuals from the entity or organization who plan to attend the hearing if the party or representative is an entity or organization, and at subsection (c)(2)(iii) to

add a requirement to list the witnesses who will be providing testimony at the hearing, in the response to the notice of hearing. We also proposed to consolidate the provisions in current §405.1020(c)(2)(i) and (c)(2)(ii) in proposed §405.1020(c)(2)(i) to simplify the provisions related to the current requirements for replying to the notice of hearing. Thus, subsection (c)(2)(i) would require all parties to the ALJ hearing to reply to the notice by acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing. We proposed at §423.2020(c)(2) to adopt corresponding revisions for an enrollee's reply to the notice of hearing.

We also proposed in §405.1020(c)(2) to remove the provision for CMS or a contractor that wishes to participate in the hearing to reply to the notice of hearing in the same manner as a party because a non-party may not object to the proposed time and place of the hearing, or present witnesses. Instead, we proposed in §405.1020(c)(3) to require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice of hearing by acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing, and specifying who from the entity plans to attend the hearing. We proposed at §423.2020(c)(3) to adopt corresponding revisions for CMS's, the IRE's, or the Part D plan sponsor's reply to the notice of hearing when the entity requests to attend the hearing as a participant.

In discussing a party's right to waive a hearing, current §405.1020(d) states that a party may waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. In light of proposed §405.1038(b), which would allow attorney adjudicators to issue decisions in appeals that do not require hearings on the record without an ALJ conducting a hearing in certain situations, we proposed in §405.1020(d) to state that a party also may waive the right to a hearing and request a decision based on the written evidence in the

record in accordance with §405.1038(b), but an ALJ may require the parties to attend a hearing if it is necessary to decide the case. We proposed at §423.2020(d) to adopt corresponding revisions for an enrollee to waive his or her right to a hearing and request a decision based on the written evidence in the record in accordance with §423.2038(b), but an ALJ could require the enrollee to attend a hearing if it is necessary to decide the case. We stated in the proposed rule that these references would direct readers to the section that provides the authority for a decision based on the written record, which would provide them with a complete explanation of when the authority may be used and notify them that an ALJ or attorney adjudicator may issue the decision.

In addressing the ALJ's authority to change the time or place of the hearing if the party has good cause to object, current §405.1020(e) requires a party to make the request to change the time or place of the hearing in writing. However, we stated that on occasion, a party may need to request a change on the day prior to, or the day of, a hearing due to an emergency, such as a sudden illness or injury, or inability to get to a site for the hearing. In this circumstance, we stated in the proposed rule that we believed an oral request should be permitted. Therefore, we proposed in §405.1020(e)(3) that the request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing, and the ALJ must document the oral request in the administrative record. We proposed at §423.2020(e)(3) to adopt a corresponding provision for an enrollee to orally request a rescheduled standard hearing, and to modify the documentation requirement, which is currently limited to documenting oral requests made for expedited hearings, to include all oral objections.

In addition, current §§405.1020(e)(4) and 423.2020(e)(4), which explain the ALJ may change the time or place of the hearing if the party has good cause, contain a parenthetical that references the procedures that an ALJ follows when a party does not respond to a notice of

hearing and fails to appear at the time and place of the hearing. The parenthetical does not appear to address or assist in understanding the circumstances covered by current §§405.1020(e)(4) and 423.2020(e)(4), and we, therefore, proposed to remove the parenthetical from the respective sections.

Current §§405.1020(g)(3) and 423.2020(g)(3) provide a list of examples of circumstances a party might give for requesting a change in the time or place of the hearing. We stated in the proposed rule that we have heard from ALJs and stakeholders that it would be helpful to also include the following two additional examples: (1) the party or representative has a prior commitment that cannot be changed without significant expense, in order to account for circumstances in which travel or other costly events may conflict with the time and place of a hearing, which the ALJ may determine warrants good cause for changing the time or place of the hearing; and (2) the party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place, which the ALJ may determine warrants good cause for changing the time or place of the hearing. We proposed in §§405.1020(g)(3)(vii) and (viii), and 423.2020(g)(3)(vii) and (viii) to add these two examples to address these circumstances. We believe these additional examples will provide greater flexibility in the appeals process and better accommodate the needs of appellants.

We proposed in §§405.1020(h) and 423.2020(h) to revise the references to the adjudication “deadline” with references to the adjudication “period,” for consistency in terminology with the specified cross-references.

We proposed revisions to §405.1020(i) to align the provision with proposed §405.1020(b). We proposed in §405.1020(i) that if an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ’s offer to conduct a hearing by

telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The party would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held, and the request must be in writing. We proposed in §405.1020(i)(4) to incorporate the current §405.1020(i)(4) provision that requires the appeal to be adjudicated within the time frame specified in §405.1016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. However, we proposed at §405.1020(i)(4) to revise the language to more accurately state that the ALJ issues a “decision, dismissal, or remand to the QIC,” rather than just a “decision,” within the adjudication time frame specified in §405.1016. We proposed revisions to §423.2020(i) to align the provision with proposed §423.2020(b). We proposed in §423.2020(i) that if an unrepresented enrollee who filed the request for hearing objects to a VTC hearing or to the ALJ’s offer to conduct a hearing by telephone, or if a represented enrollee who filed the request for hearing objects to a telephone or VTC hearing, the enrollee or representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or in-person hearing. The enrollee would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held. We proposed in §423.2020(i)(4) to incorporate the current §423.2020(i)(4) provision with some modifications so that the appeal would be adjudicated within the time frame specified in §423.2016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. We proposed at §423.2020(i)(4) to revise the language to more accurately state that the ALJ issues a “decision, dismissal, or remand to the IRE,” rather than just a “decision,” within the adjudication time

frame specified in §423.2016 and to include requests for VTC hearings as well as requests for in-person hearings. In addition, we proposed at §§405.1020(i)(5) and 423.2020(i)(5) to provide that upon a finding of good cause, a hearing would be rescheduled at a time and place when the party may appear in person or by VTC, to account for objections to VTC hearings as well as objections to telephone hearings or offers to conduct a hearing via telephone. We also proposed to replace “concurrence of the Managing Field Office ALJ” with “concurrence of the Chief ALJ or a designee” because the position of Managing Field Office ALJ was replaced by the position of Associate Chief ALJ (80 FR 2708) and providing a more general reference would provide greater flexibility in the future as position titles change.

Current §§405.1020 and 423.2020 do not address what occurs when the ALJ changes the time or place of the hearing. We proposed at §405.1020(j) to add a provision titled “Amended notice of hearing” to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing, in accordance with the procedures of §405.1022(a), which addresses issuing a notice of hearing. We proposed at §423.2020(j) to add a provision to clarify that, if the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with the procedures of §423.2022(a), which addresses issuing a notice of hearing. We stated that these revisions would help ensure that if changes are made to the time or place of the hearing, a new notice is issued or waivers are obtained in a consistent manner.

Provided below are summaries of the specific comments received and responses to these comments:

We received ten comments on the proposed changes to time and place for a hearing before an ALJ. We received five comments on the proposal to make telephone the default method for conducting hearings, except when the appellant is an unrepresented beneficiary, unless an ALJ finds good cause for conducting a hearing by VTC or an in-person hearing. The remaining comments addressed other aspects of the time and place for hearing before an ALJ and are discussed in further detail below.

Comment: Three commenters on behalf of advocacy organizations and one individual commenter, opposed making telephone the default method for conducting hearings for appellants who are not unrepresented beneficiaries. Commenters generally argued that conducting a hearing by telephone reduces due process, but they appreciated the proposal to maintain VTC as the default method for conducting hearings for unrepresented beneficiaries. By contrast, one commenter supported the proposal.

Response: We thank the commenter who supports the proposal. We disagree with opposing commenters that telephone hearings reduce due process. We believe that all ALJ hearings currently conducted by OMHA fully protect appellants' rights to procedural due process, and that our proposed changes do not compromise those rights. Furthermore, section 1869(b)(1)(A) of the Act does not specify the manner in which hearings must be held, and in legislation that led to the establishment of OMHA to administer the ALJ hearing program, Congress instructed HHS to explore the possibility of providing hearings using formats other than in-person hearings. Specifically, the MMA instructed HHS to consider the feasibility of conducting Medicare hearings "using tele- or videoconference technologies." See section 931(a)(2)(G) of the MMA.

Under both the current regulations and our proposed changes, procedural safeguards are in place that meet the due process requirements for administrative hearings such as the right to proper notice that a hearing has been scheduled, the right of a party to appear before the ALJ to present evidence and to state his or her position, the right to have a representative present at the hearing, the right to present witnesses and testimony, the right to cross examine witnesses, the right to object to the issues in the notice and/or the hearing method, the right to request and receive a copy of all or part of the record from OMHA (including the hearing audio), and the right to appeal the ALJ's decision. Parties also have the same access to the audio hearing record when appearing by telephone as they would have if appearing by VTC or in-person. In addition, the proposal includes mechanisms in §405.1020(b) that permit a VTC or in-person hearing if there is a finding of good cause in a given appeal. Given the procedural safeguards existing in the regulations, we do not believe changing the default method of conducting hearings to telephone hearings for appellants other than unrepresented beneficiaries would compromise an appellant's due process or right to a hearing.

However, while we do not believe that due process requires a hearing that includes a visual component as a matter of right in all cases, we acknowledge that those who are most unfamiliar with legal proceedings, specifically unrepresented beneficiaries, may benefit from the interaction with the ALJ and be more comfortable with a visual component. Thus, the proposal provides two standards for determining how hearings would be conducted, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. We have retained VTC as the default hearing method for unrepresented beneficiaries under §405.1020(b)(1), unless the ALJ finds good cause for an in-person hearing (note that the ALJ also may offer a telephone hearing in certain circumstances).

Under §405.1020(b)(2) (as discussed below), in appearances by individuals other than unrepresented beneficiaries, telephone hearings are the default hearing method, though the parties may obtain a VTC or in-person hearing if the ALJ finds good cause.

Comment: One commenter indicated telephone hearings do not take appreciably less time than VTC hearings, and also OMHA is budgeted to provide VTC hearings and there is no evidence that the volume of VTC hearings in past years has exceeded this line item on OMHA's operational budget.

Response: We disagree with the commenter's assertions.

As we stated in the proposed rule (81 FR 43824), in FY2015 alone, over 98% of hearings before OMHA ALJs were conducted by telephone, and in FY2016 over 99% of hearings before OMHA ALJs were conducted by telephone. Contrary to the commenter's assertion, we have learned over eleven years of operation that telephone hearings take less time and are less costly for parties, representatives, and witnesses because telephone hearings do not require travel time or travel expenses for parties to a VTC site. Telephone hearings also provide parties with the opportunity to participate in the hearing process with minimal disruption to the day. Further, telephone hearings take less time for OMHA to schedule and conduct. When a VTC hearing room is reserved or unavailable, scheduling of the hearing is delayed. Support staff must also remain present during the entire duration of a VTC hearing to assist the ALJ in case the equipment does not operate properly. We believe this is inefficient and can result in wasted staff time and resources that could be redirected to scheduling additional appeals.

Although we acknowledge the volume of VTC hearings in past years has not exceeded OMHA's operational budget, due in part to the fact that a majority of hearings were conducted by telephone, telephone hearings cost less to conduct, and would result in significant savings to

the agency and ultimately to the taxpayers. We also believe the money budgeted to provide for the more expensive VTC hearings could instead be reallocated to hire additional support staff and resources to address the backlog. On balance, telephone hearings require less administrative burden to parties and OMHA, at a lower cost to taxpayers.

Comment: Commenters who opposed the proposal to make telephone hearing the default method of conducting a hearing for individuals other than unrepresented beneficiaries and supported maintaining VTC as the default method of conducting a hearing argued: (1) VTC is beneficial to ALJs in lengthy hearing sessions “due to the volume of appeals, issues, documentation, and complexity of the arguments being conveyed”; (2) VTC allows a party to show and discuss images of injuries, wounds, and other visual evidence; (3) it is unreasonable to require an appellant to make their case by telephone “where millions of dollars are at stake, or perhaps the very existence of an appellant”; (4) VTC is beneficial where reference to the medical documentation can be cumbersome; and (5) VTC can be particularly valuable in facilitating communication when representatives of appellants have limited familiarity with the OMHA appeals process.

Response: Although telephone hearings are the default hearing method under proposed §405.1020(b)(2), (which we are finalizing in this rule), parties still have the opportunity under that section for a VTC or in-person hearing in certain circumstances. Sections 405.1020(b)(2) and 423.2020(b)(2), as finalized, state the ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone unless the ALJ finds good cause for an appearance by other means. Specifically, the ALJ may find good cause for an appearance by VTC if the ALJ determines VTC is necessary to examine the facts or issues in an appeal. In addition, the ALJ, with the concurrence of the Chief

ALJ or designee, may find good cause for an in-person hearing if VTC and phone technology are not available or special or extraordinary circumstances exist. We believe the situations raised by the commenters who opposed the proposal could be examples where “the ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal,” depending on the facts of a particular appeal. See §§405.1020(b)(2)(i) and 423.2020(b)(2)(i). For example, under §405.1020(b)(2)(i) and 423.2020(b)(2)(i), an ALJ could find that visual interaction is necessary and that there is good cause for a VTC hearing where: (1) the ALJ or appellant raises an issue with an individual’s credibility; (2) a party presents multiple witnesses to provide testimony; or (3) a party wishes to present video/visual evidence. An ALJ may also find good cause where the case presents complex, challenging, or novel issues, such as in appeals with a high volume of claims and a high dollar or overpayment amount. We believe our decision not to provide an exhaustive description of the good cause standard in the regulations would benefit parties by affording an ALJ the flexibility to grant a VTC or an in-person hearing based on factors or circumstances that may be relevant in a particular case, yet unforeseen at this time.

Comment: Commenters who opposed the proposal to make telephone hearing the default method of conducting a hearing and supported maintaining VTC as the default method of conducting a hearing argued: (1) the face-to-face aspect of VTC hearings afford greater assurance that ALJs will hear and understand the testimony and arguments being presented; (2) VTC hearings assure ALJs fulfill the duty to provide a fair hearing; and (3) VTC hearings allow an appellant to observe if the ALJ is tired, disinterested, talking to someone else in the room, thumbing through the file, or not referring to the file at all, which cannot be readily observed on a telephone call.

Response: A primary function of the ALJ hearing is to allow the parties to present arguments and testimony, and to allow the ALJ to ask questions in order to provide the ALJ with the necessary information to make the findings of fact and conclusions of law in rendering a decision consistent with the applicable authorities. We do not agree that the face-to-face aspect of VTC hearings afford greater assurance that ALJs will hear and understand the testimony and arguments being presented. While the commenters may prefer to see the ALJ during the hearing, we do not believe a visual connection with the ALJ is necessary in most cases, and in the circumstances in which it may be necessary, the rules being finalized provide for a mechanism to request a VTC or in-person hearing in §§405.1020(i) and 423.2020(i). Regardless of how the hearing is conducted, ALJs have a responsibility pursuant to §§405.1030(b) and 423.2030(b) to fully examine the issues on appeal and question the parties and other witnesses, ensuring that all necessary testimony is considered, which would continue under these rules as finalized. An appellant can also ascertain whether the ALJ understands the testimony and arguments being presented over telephone, by gauging the ALJ's reaction to the testimony and arguments, the ALJ's follow-up questions, and whether the ALJ has lingering questions. The appellant can then provide the ALJ with the necessary clarification to enable the ALJ to make the findings of fact and conclusions of law. Further, the written decision will reflect the testimony and arguments presented at the hearing, and if a party is dissatisfied with the ALJ's decision, the party may request a review by the Council and, if applicable, indicate what testimony or arguments presented at the hearing were not fully considered.

In addition, we do not believe that visual interaction is necessary to assure appellants that ALJs are fulfilling their duty to provide a fair hearing. OMHA ALJs have a responsibility to ensure both a fully examined and fairly administered hearing, and must fulfill their duties with

fairness and impartiality in accordance with section 205(b) of the Act. As discussed above, we believe that all ALJ hearings currently conducted by OMHA fully protect appellants' rights to procedural due process, including the right to a fair hearing, and that the changes we are finalizing do not compromise those rights. Further, we do not agree that visual interaction is necessary to observe whether the ALJ is tired, disinterested, or talking to someone else in the room, because an appellant can readily observe how the ALJ is acting during a telephone hearing by noting the ALJ's tone of voice, pauses, and reaction to arguments or responses to questions. Moreover, we note the visual component of the hearing is not recorded or subject to review. However, parties have the same access to the audio hearing record when appearing by telephone as they would have if appearing by VTC or in person. The ALJ and his or her staff may also review the audio hearing record after the hearing is conducted, which becomes part of the administrative record for other reviewers. Based on the foregoing, we believe that telephone hearings provide sufficient assurances addressed by the commenters.

Comment: One commenter suggested that giving ALJs the discretion to find good cause for an appearance by VTC would almost never result in a VTC hearing, and in the commenter's opinion, the good cause provisions for VTC or in-person hearings is "almost meaningless."

Response: We disagree with the commenter's assertion that the good cause provision for VTC or in-person hearings is "almost meaningless." We believe the good cause provisions are meaningful because, as discussed above, an ALJ could find that visual interaction is necessary and that there is good cause for a VTC hearing where the ALJ or appellant raises an issue with an individual's credibility, a party presents multiple witnesses to provide testimony, or a party wishes to present video/visual evidence. An ALJ may also find good cause where the case presents complex, challenging, or novel issues, such as in appeals with a high volume of claims

and a high dollar or overpayment amount. Given the volume of hearing requests and adjudication timeframes imposed by statute, we believe it is reasonable to use a good cause standard to determine when it is appropriate for an ALJ to conduct a VTC hearing for all appellants except unrepresented beneficiaries. In addition, as discussed above, we believe that telephone hearings adequately protect appellants' rights to procedural due process. In proposed §§405.1020(b)(2) and 423.2020(b)(2), which we are finalizing in this rule, we provide for circumstances in which it may be appropriate for the ALJ to provide a VTC or in-person hearing on his or her own initiative, or to grant a request under §§405.1020(i) and 423.2020(i) to change the type of hearing scheduled and permit a VTC or in-person hearing. For appellants other than unrepresented beneficiaries, ALJs will evaluate VTC and in-person hearing requests using the good cause standard established in §§405.1020(b)(2) and 423.2020(b)(2), and when appropriate grant a request for a VTC or in-person hearing. If an individual appellant believes a request for a VTC or in-person hearing should have been granted and disagrees with the outcome of the appeal, the appellant can request review of the ALJ's decision by the Council and request that the Council remand the appeal for a new hearing if it believes that the method of conducting the hearing impacted the outcome of the appeal such that a new hearing using the requested format is necessary.

Comment: One commenter indicated the “availability of live testimony distinguishes the ALJ process from the prior levels of appeal, which are limited to written arguments and evidence. The ALJ hearing should not be just another Reconsideration.”

Response: We do not believe that §405.1020, as finalized in this rule, changes the ability to provide live testimony during the ALJ hearing. As discussed above, §405.1020(b)(2) provides that telephone hearings are the default hearing method for individuals other than unrepresented

beneficiaries, but that VTC or in-person hearings may be provided if the ALJ finds good cause. In telephone hearings, as with VTC and in-person hearings, parties are able to provide live testimony, present evidence, and state their positions to an ALJ, as provided in §405.1036(a)(1), and witnesses are able to provide live testimony as provided under §405.1036(a)(3). In a telephone hearing, as in a VTC or in-person hearing, there is live interaction between the ALJ and the parties and participants, which is not the case in a reconsideration, which is a decision based solely on review of the record. Further, §§405.1030(b) and 423.2030(b), as finalized in this rule, provide the ALJ will fully examine the issues on appeal and question the parties and other witnesses, ensuring that all necessary testimony is considered. We note that under §405.1020(d), a party may waive the right to a hearing and request a decision based on written evidence in the record. The decision to waive the right to appear at a hearing before an ALJ, which would entail a waiver of the ability to present live testimony, is solely at the discretion of the party. By waiving the right to appear at a hearing, the party would be requesting that the ALJ or attorney adjudicator issue a decision based on the written evidence in the record.

Comment: Three commenters requested that the final rule contain a provision to allow an appellant to request rescheduling of the ALJ hearing if the appellant's witness(es) are not available due to direct patient care duties that may conflict with the scheduled date and time.

Response: Sections 405.1020(g)(3)(iv) and 423.2020(g)(3)(iv) already provide that a party may request a change in time and place of the hearing where "a witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained." This covers the unavailability of a witness as a direct result of patient care responsibility and therefore provides flexibility to accommodate the needs of appellants.

Comment: One commenter opposed the proposed changes to §405.1020(i)(1) and (2), which provide that an unrepresented beneficiary must file their objection to the hearing method in writing and must include the reasons for their objection. The commenter suggested this could prove difficult for many beneficiaries and unrepresented beneficiaries should be afforded the convenience of being allowed to call the ALJ to orally request a change in the hearing method.

Response: We disagree with the suggestion. Section §405.1020(i)(2) and (3) indicate if a party objects to the hearing method, they “must state the reason for the objection” and the objection “must be in writing.” These provisions are not being changed in this final rule, and therefore, the requirement to include the reason for the objection and to file the objection in writing in proposed §405.1020(i)(2) and (3) would not place any additional burden on the unrepresented beneficiary. Further, OMHA sends a formatted “Response to Notice of Hearing,” to parties who are sent a notice of hearing, to facilitate their response to the notice of hearing, including making any objections. The parties may simply check the boxes in the response to notice of hearing to indicate if they will attend or if they object to the type of hearing. The response to notice of hearing also indicates the standard for changing the type of hearing, and provides examples of good cause for changing the type of hearing. We believe that using the response to hearing form that is sent with the notice of hearing makes the process of objecting to the type of hearing and providing the reasons for the objection relatively easy and convenient for an unrepresented beneficiary. In addition, a contact phone number for the ALJ’s staff is provided in the notice of hearing and OMHA maintains a dedicated beneficiary help line, if a party needs assistance. Given this process, we do not believe it is necessary to allow oral requests to change the hearing method.

Comment: One commenter suggested CMS or a contractor should be invited to an ALJ hearing “when an issue in contention involves non-adherence to or violation of a Medicare statute or policy by CMS or a contractor,” in order for CMS or the contractor “to be made aware of the appellant’s concern and to be able to answer any allegations.”

Response: Under the current regulations and the regulations as finalized in this rule, the ALJ has the discretion to make the determination of whether the appearance of CMS or a contractor would be beneficial to the hearing and to request that CMS or a contractor participate, and the ALJ will make such determination when warranted based on the facts of and the issues raised in a particular case. Under §§405.1020(c) and 423.2020(c) as finalized in this rule, a notice of hearing is sent to CMS or a contractor “that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.” In addition, under §§405.1010 and 405.1012, the ALJ can request (but not require) CMS or a contractor to participate in or be a party to any proceedings before the ALJ, including the oral hearing. Under §423.2010, the ALJ can request (but not require) CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing. In no case is the ALJ permitted to draw any adverse inference if CMS, its contractor, the IRE and/or the Part D plan sponsor decline the request.

Comment: One commenter indicated that although the proposed rule permits the ALJ to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary, nowhere does the request for hearing form elicit this information from the beneficiary. This commenter suggested OMHA should add a section or checkboxes to that effect on the hearing request form to facilitate the unrepresented beneficiary’s preference for method of hearing.

Response: Proposed §405.2010(b)(1), which we are finalizing in this rule, provides that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by VTC, or the ALJ may also offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary. We recognize that an unrepresented beneficiary may have an increased desire to visually interact with the ALJ, and therefore this section states the ALJ will direct that the appearance be conducted by VTC. However, this section also explicitly allows the ALJ to offer a telephone hearing if it may be more convenient for the beneficiary. In addition, by practice, OMHA support staff contacts an unrepresented beneficiary prior to scheduling the hearing to ask for a time, place and/or method of hearing most convenient for the unrepresented beneficiary to facilitate determination of the beneficiary's preference. And, as indicated previously, the form for responding to the notice of hearing, which is sent to parties with the notice of hearing, contains checkboxes and instructions on which boxes to check if a party plans to attend the hearing or if a party objects to the type of hearing, for example, because the proposed method of hearing is not convenient for the party. The form for responding to notice of hearing also explains the standard for changing the time, place and/or method of the hearing, and provides examples of good cause for changing the time, place and/or method of the hearing. Beneficiaries and enrollees with questions or concerns, or who require additional assistance, can call the toll free OMHA beneficiary help line at (844) 419-3358.

Comment: One commenter indicated with respect to proposed §405.1020(j) that there is no requirement that an ALJ notify the parties if they refuse to grant a request for a change in time and/or place of a hearing. The commenter suggested amending the language so that not only must a request for a change to the time and place of a hearing, or the type of hearing, be in

writing but that the ALJ be required to respond to the request in writing, even if the ALJ is refusing to change the time and place of a hearing.

Response: We believe the original notice of hearing serves as sufficient notice that the hearing will proceed as scheduled. If a party requesting a change to the time and/or place of hearing does not receive an amended notice of hearing granting the party's request, the party can contact the ALJ's staff to confirm that the hearing will proceed as scheduled in the original notice, but should presume that the ALJ did not grant the request for a change to the time and/or place of hearing. If the ALJ grants the request to change the time and/or place of the hearing, §405.1020(j), as finalized in this rule, provides "an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with §405.1022(a)," which would afford the receiving parties and participants with notice at least 20 calendar days before the rescheduled hearing date. This will help ensure that if changes are made to the time and/or place of the hearing, an amended notice is issued with sufficient time before the rescheduled hearing in a consistent manner, if waivers are not obtained.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1020 and 423.2020 as proposed, with the following modifications. For the reasons discussed in section II.B.3.f.i above, we are revising §405.1020(c)(1) to state that the notice of hearing is also sent to CMS or any contractor that has elected to participate in the proceedings in accordance with §405.1010(b). In addition, in the proposed rule (81 FR 43790, 43825), we proposed to adopt in §423.2020(b)(2) the same revisions as in §405.1020(b)(2). Section 405.1020(b)(2)(ii)(A), as finalized in this rule, states "VTC and telephone technology are not available." However, we inadvertently included in

proposed §423.2020(b)(2)(ii)(A) the following language: “video-teleconferencing or telephone technology is not available.” Consistent with our proposal to adopt the same revisions in §423.2020(b)(2) as we adopt in §405.1020(b)(2), we are revising §423.2020(b)(2)(ii)(A) to state “video-teleconferencing and telephone technology are not available.”

k. Notice of a hearing before an ALJ and objections to the issues (§§405.1022, 405.1024, 423.2022, and 423.2024)

As described below, we proposed a number of changes to §§405.1022, 405.1024, 423.2022, and 423.2024, concerning notice of a hearing before an ALJ and objections to the issues. 81 FR 43790, 43827–43828. Current §405.1022(a) provides that a notice of hearing will be mailed or personally served to the parties and other potential participants, but a notice is not sent to a party who indicates in writing that it does not wish to receive the notice. Current §423.2022(a) provides that a notice of hearing will be mailed or otherwise transmitted, or personally served, unless the enrollee or other potential participant indicates in writing that he or she does not wish to receive the notice. However, currently §405.1022(a) is limiting because it does not contemplate transmitting the notice by means other than mail or personal service even though technologies continue to develop and notice could be provided by secure e-mail or a secure portal. Also, notices must be sent in accordance with any OMHA procedures that apply, such as procedures to protect personally identifiable information. In addition, the exception in current §405.1022(a) does not contemplate a scenario in which a potential participant indicates that it does not wish to receive the notice, as is provided for in current §423.2022(a). We proposed in §§405.1022(a) and 423.2022(a) to address these issues and align the sections by providing that a notice of hearing would be mailed or otherwise transmitted in accordance with

OMHA procedures, or personally served, except to a party or other potential participant who indicates in writing that he or she does not wish to receive the notice.

Current §§405.1022(a) and 423.2022(a) provide that a notice of hearing does not have to be sent to a party who indicates in writing that it does not wish to receive the notice and that the notice is mailed or served at least 20 calendar days (for Parts A and B and for non-expedited Part D hearings), or 3 calendar days (for expedited Part D hearings) before the hearing. The provisions do not address the situation where a party wishes to receive the notice, but agrees to the notice being mailed fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing, which may be necessary to accommodate an appellant's request to conduct a hearing in fewer than 20 or 3 calendar days. We proposed to revise §§405.1022(a) and 423.2022(a) to address this situation by providing the notice is mailed, transmitted, or served at least 20 calendar days (or 3 calendar days if expedited) before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing. However, we note that like a recipient's waiver of receiving a notice of hearing, a recipient's waiver of the requirement to mail, transmit, or serve the notice at least 20 or 3 calendar days (as applicable) before the hearing would only be effective for the waiving recipient and does not affect the rights of other recipients.

Current §405.1022(b)(1) requires a notice of hearing to contain a statement of the specific issues to be decided and inform the parties that they may designate a person to represent them during the proceedings. These statements of issues take time to develop, and current §405.1032, which addresses the issues before an ALJ, provides that the issues before the ALJ are all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. Current §405.1032 also permits an ALJ to consider a new

issue at the hearing, if notice of the new issue is provided to all parties before the start of the hearing. To streamline the notice of hearing, rather than require the notice of hearing to contain a statement of the specific issues to be decided, we proposed in §405.1022(b)(1) to require the notice of hearing to include a general statement putting the parties on notice that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing. This is consistent with the standard for determining the issues before the ALJ in proposed §405.1032(a). However, we also proposed in §405.1022(b)(1) that the notice of hearing also would contain a statement of any specific new issues that the ALJ will consider in accordance with §405.1032 to help ensure the parties and potential participants are provided with notice of any new issues of which the ALJ is aware at the time the notice of hearing is sent, and can prepare for the hearing accordingly. For example, if in the request for hearing an appellant raises an issue with the methodology used to sample claims and extrapolate an overpayment, and that issue had not been brought out in the initial determination, redetermination, or reconsideration, the issue would be a new issue and the specific issue would be identified in the notice of hearing. To accommodate proposed §405.1022(b)(1), we proposed that the portion of current §405.1022(b)(1) that requires the notice of hearing to inform the parties that they may designate a person to represent them during the proceedings would be re-designated as §405.1022(b)(2), and current subsections (b)(2), (b)(3), and (b)(4) would be re-designated as subsections (b)(3), (b)(4), and (b)(5), respectively. We proposed at §423.2022(b) to adopt corresponding revisions for notice information in part 423, subpart U proceedings.

Current §405.1022(c)(1) provides that if the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not

acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation. We proposed to replace “ALJ hearing office” with “OMHA” because OMHA is the responsible entity.

Current §405.1022(c)(2) provides that if a party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her. The reference to an amended notice has caused confusion, as the original notice does not need to be amended unless the hearing is rescheduled. We proposed in §405.1022(c)(2) to remove the reference to an “amended” notice of hearing and provide that a copy of the notice of hearing is sent to the party. However, if a party cannot attend the hearing, we proposed in new §405.1022(c)(3) that the party may request that the ALJ reschedule the hearing in accordance with proposed §405.1020(e) , which discusses a party’s objection to the time and place of hearing. We proposed at §423.2022(c) to adopt corresponding revisions for providing a copy of the notice of hearing if the enrollee did not acknowledge it and states that he or she did not receive it in part 423, subpart U proceedings.

Current §405.1022(c)(2) provides that if a party did not receive the notice of hearing, a copy of the notice may be sent by certified mail or e-mail, if available. Current §423.2022(c)(2) provides an additional option to send the copy by fax. However, use of e-mail to send documents that contain a beneficiary’s or enrollee’s personally identifiable information is not currently permitted by OMHA policy, and faxes must be sent in accordance with procedures to protect personally identifiable information. We proposed in §§405.1022(c)(2) and 423.2022(c)(2) to remove the references to using e-mail and fax, and to add that a notice may be sent by certified mail or other means requested by the party and in accordance with OMHA procedures. This would provide the flexibility to develop alternate means of transmitting the request and allow OMHA to help ensure necessary protections are in place to comply with HHS information

security policies. Finally, the parenthetical in current §§405.1022(c)(2) and 423.2022(c)(2) is not applicable. We believe it was attempting to cross-reference the provision related to requesting a rescheduled hearing. Therefore, we proposed in §§405.1022(c)(2) and 423.2022(c)(2) to remove the parenthetical. As discussed above, proposed §§405.1022(c)(3) and 423.2022(c)(3) would address the option for a party to request a rescheduled hearing and contain the correct cross-reference.

Current §405.1024 sets forth the provision regarding objections by a party to the issues described in the notice of hearing. Current §405.1024(b) requires a party to send a copy of its objection to the issues to all other parties to the appeal. We proposed to revise §405.1024(b) to provide that the copy is only sent to the parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing, because we believe sending a copy of the objection to additional parties is unnecessary and causes confusion for parties who were not sent a copy of the notice of hearing. No corresponding change was proposed in §423.2024 because only the enrollee is a party.

Current §405.1024(c) states that an ALJ makes a decision on the objection to the issues either in writing or at the hearing. We proposed to revise §405.1024(c) to add the option for an ALJ to make a decision on the objections at a prehearing conference, which is conducted to facilitate the hearing, as well as at the hearing. We believe this added flexibility would allow ALJs to discuss the objections with the parties and make a decision on the record before the hearing at the prehearing conference. However, we noted that the ALJ's decision on an objection to the issues at a prehearing conference pursuant to proposed §405.1024(c) would not be subject to the objection process for a prehearing conference order under §405.1040(d). We stated in the proposed rule that a decision on an objection to the issues is not an agreement or action resulting

from the prehearing conference, but rather the ALJ's decision on a procedural matter for which the ALJ has discretion, and we do not believe the parties should have a right of veto through the prehearing conference order objection process. We also proposed at §423.2024(c) to adopt a corresponding revision for a decision on an objection to the issues in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received three comments on this proposal. One commenter asked whether a corrected notice of hearing would be sent to all parties who received the initial notice if a mistake, such as a typographical error in the beneficiary's name or the appeal number, was corrected in the response to the notice of hearing submitted by one of the recipients.

Response: Under OMHA's current practices, if OMHA staff is made aware of an error, such as a typographical error, in a notice of hearing, OMHA staff will contact the parties to notify them of the correction as soon as possible. This is generally accomplished through a corrected notice of hearing that is sent to all parties who received the initial notice, but may also be accomplished by contacting the parties and any CMS contractors that have elected to be participants or parties by telephone with appropriate documentation of the contact for the record, so that the hearing may proceed as scheduled. However, we note that if it appears that a party's ability to prepare for the hearing was negatively affected by the error, it may be necessary to reschedule the time and/or place of the hearing and issue an amended notice of hearing, consistent with proposed §405.1020(j).

Comment: Another commenter indicated that the time frame for sending notice of a hearing is too short considering the burden of moving the hearing once it is scheduled, and

suggested that OMHA reinstitute a policy of contacting the appellant's representative prior to sending the hearing notice.

Response: We did not propose to change the current rule that a notice of hearing is mailed or served at least 20 calendar days before the hearing (or 3 calendar days before the hearing for Part D expedited appeals). These time frames are necessary for scheduling and conducting the hearing as quickly as possible. While some ALJ teams had a practice of contacting the appellant, or the appellant's representative if a representative was involved, before scheduling a hearing, OMHA has not had a policy that required them to do so. Further, we believe that adding a requirement to contact the parties before scheduling a hearing would add administrative burden and slow the hearing process at a time of record workload volume. Our experience is that there are not a large number of requests to reschedule hearings when hearings are scheduled without contacting the appellant, or the appellant's representative if a representative was involved, prior to scheduling the hearing. Moreover, we believe the current standard for mailing or serving a notice of hearing at least 20 calendar days before the hearing, or 3 calendar days before the hearing for Part D expedited appeals, provides sufficient notice and time to prepare for the hearing, and if necessary, request to change the time or place of the hearing if there is good cause to do so, consistent with §§405.1020(e) and 423.2020(e).

Comment: One commenter supported the proposal to include a generalized statement of the issues, as well as any specific new issues that the ALJ may consider, in the notice of hearing. The commenter suggested that the notice of hearing should include the dates of service and/or the QIC number to help identify the specific claim that is being scheduled for hearing, as well as the name, address, telephone number, and fax number of the OMHA point of contact for any questions.

Response: We thank the commenter for its support of our proposal to include a generalized statement of the issues, as well as any specific new issues that the ALJ may consider, in the notice of hearing. However, we did not propose changing other content requirements for the notice of hearing, and thus we do not believe that it would be appropriate to include the suggested changes in this final rule. With respect to the dates of service of the claims being appealed, we note that under §405.1014, as finalized in this rule, the request for hearing must contain the dates of service for the claims being appealed, and a copy of the request must be sent to the other parties who were a sent a copy of the QIC's reconsideration. The parties who would receive a notice of hearing under §405.1020(c), as finalized in this rule, would generally also have received a copy of the QIC's reconsideration, and would thus be able to determine the dates of service by comparing the notice of hearing with the request for hearing. With respect to providing an OMHA point of contact, we note that the notices of hearing currently issued by OMHA include a mailing address, phone number, and fax number for the ALJ team assigned to the appeal. We also note that an appellant can find the QIC appeal number associated with an appeal by using AASIS, which provides public access to appeal status information and is accessed through the OMHA website (www.hhs.gov/omha).

Comment: One commenter suggested that the requirement to send a copy of any objection to the issues to the other parties should be waived for unrepresented beneficiaries because it adds to the cost and burden of maintaining an appeal.

Response: Consistent with our discussion of copy requirements in section II.B.3.g.v of this final rule above, we do not agree that unrepresented beneficiaries should be exempt from the regulatory requirement to send a copy of their objections to the issues to other parties; instead, we believe that unrepresented beneficiaries should be assisted with meeting this requirement. In

the event that an unrepresented beneficiary does not fulfill the requirement, OMHA will forward a copy of any objections submitted by the unrepresented beneficiary to the other parties who were sent a copy of the notice of hearing.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1022, 405.1024, 423.2022, and 423.2024 as proposed without modification.

I. Disqualification of the ALJ or attorney adjudicator (§§405.1026 and 423.2026)

As described below, we proposed several changes to §405.1026, which provides a process for a party to request that an ALJ disqualify himself or herself from an appeal, or for an ALJ to disqualify himself or herself from an appeal on the ALJ's own motion. 81 FR 43790, 43828. We proposed to revise §405.1026 to replace the current references to conducting a hearing with references to adjudicating an appeal, to make it is clear that disqualification is not limited to ALJs or cases where a hearing is conducted to help ensure that an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), also cannot adjudicate an appeal if he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision. Current §405.1026(b) requires that, if a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw. However, the current rule does not address appeals for which no hearing is scheduled and/or no hearing will be conducted. Therefore, we proposed to revise §405.1026(b) to require that if a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator any time before a

decision, dismissal order, or remand order is issued if no hearing is scheduled. We also proposed to revise §405.1026(c) to state that an ALJ or attorney adjudicator is “assigned” to adjudicate an appeal, rather than “appointed,” for consistency in terminology, and to replace “hearing decision” with “decision or dismissal” because not all decisions are issued following a hearing and an appellant may have objected in an appeal that was dismissed, for which review may also be requested from the Council. In addition, we proposed to add “if applicable” in discussing that the Council would consider whether a new hearing is held because not all appeals may have had or require a hearing. We proposed at §423.2026 to adopt corresponding revisions for disqualification of an ALJ or attorney adjudicator in part 423, subpart U proceedings.

Section 405.1026 does not address the impact of a party’s objection and adjudicator’s withdrawal on an adjudication time frame. We stated in the proposed rule that the withdrawal of an adjudicator and re-assignment of an appeal will generally cause a delay in adjudicating the appeal. We proposed in new §405.1026(d) that if the party objects to the ALJ or attorney adjudicator, and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any applicable adjudication time frame that applies is extended by 14 calendar days. We stated that this would allow the appeal to be re-assigned and for the new adjudicator to review the appeal. We proposed at §423.2026(d) to adopt a corresponding provision for the effect of a disqualification of an adjudicator on an adjudication time frame in part 423, subpart U proceedings, but proposed that if an expedited hearing is scheduled, the time frame is extended by 2 calendar days, to balance the need for the newly assigned adjudicator to review the appeal, and the enrollee’s need to receive a decision as quickly as possible.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter asked what recourse is available when, in the opinion of an appellant, an ALJ has not considered arguments, evidence, or testimony to the satisfaction of the appellant in its prior cases assigned to that ALJ. The commenter questioned whether the regulations should allow parties to enter a “peremptory challenge” to an assigned ALJ without explanation as to the reason for requesting that the ALJ withdraw from adjudicating an assigned appeal.

Response: Proposed §§405.1026 and 423.2026, which we are finalizing in this rule, extend the current provisions related to disqualifying an ALJ based on bias or a conflict of interest, to disqualifying an attorney adjudicator, to help ensure that the same standards and process for disqualifying an adjudicator at OMHA applies regardless of whether the adjudicator is an ALJ or attorney adjudicator. We believe that this is a necessary change to extend the safeguards in current §§405.1026 and 423.2026 to cases assigned to an attorney adjudicator. In response to the commenter’s question about the recourse available when an appellant believes an ALJ has not considered arguments, evidence, or testimony to the satisfaction of the appellant in its prior cases assigned to the ALJ, in such a situation, to the extent the appellant believes that the ALJ is prejudiced or partial to any party in the case at hand, the appellant could object to the assigned ALJ and request that the ALJ withdraw from an appeal using the procedures in §§405.1026 or 423.2026, as finalized in this rule. If the ALJ does not withdraw, the objection can be raised on appeal to the Council after the ALJ issues a disposition of the case. Similarly, any disagreement with the ALJ’s decision, including the ALJ’s consideration or analysis of the arguments, evidence, and testimony, could be raised in requesting a review of the decision by the Council.

With regard to the commenter's suggestion that the regulations should allow a preemptory challenge by which a party can request reassignment to a different adjudicator without providing a specific objection, we disagree. We do not believe that preemptory challenges would be appropriate or necessary at the OMHA level. A preemptory challenge is generally a feature of a trial by jury that allows attorneys for each side to reject a limited number of jurors without stating a reason for the challenge and without the judge's approval. The concept of a preemptory challenge is to allow both sides to contribute to the jury's composition to help ensure an unbiased result. Under 5 U.S.C. 3105, ALJs must be assigned to cases in rotation so far as practicable, and current §§405.1026 and 423.2026 help ensure an unbiased result by requiring the ALJ to withdraw if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

We believe allowing parties to request reassignment of an ALJ without explaining the basis for objecting to the ALJ is contrary to the principles of random rotational assignments and would be disruptive and inefficient in processing appeals. The recommendation would add a new administrative burden in reassigning appeals, resulting in an overall decrease in the efficient adjudication of appeals. Furthermore, we believe that the option of a preemptory challenge would further increase administrative burdens and inefficiencies in cases involving multiple parties, where the option of a preemptory challenge would need to be extended to all parties to the appeal. In addition, permitting an appellant to exercise a preemptory challenge in the manner suggested may lead to abuses such as forum shopping or retaliation against an ALJ or an attorney adjudicator for a prior decision with which the party did not agree, even if the ALJ's decision was supported by the evidence and affirmed on appeal to the Council. Also, preemptory challenges potentially used for reasons that have nothing to do with bias would go un rebutted

and may undermine the public's confidence in the appeals process. We believe that the potential for abuse, and the administrative burdens and inefficiencies associated with allowing a peremptory challenge outweigh any potential benefit to the adjudication process. In addition, we believe that the disqualification process in §§405.1026 and 423.2026 as finalized in this rule, and the opportunity to appeal to the Council any objection to an ALJ or the decision in a case if the ALJ does not withdraw, afford appellants and other parties with strong protections and remedies to address potential bias. The process outlined in §§405.1026 and 423.2026 contemplates that the party specify his or her reasons for objecting to the assigned adjudicator so that the adjudicator may consider the reasons and make an informed decision as to whether he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision, and therefore whether to proceed with the appeal or withdraw as the adjudicator. If the adjudicator does not withdraw, the party may request review of the adjudicator's action by the Council. When a reason is provided for the party's objection, even if it is a cursory reason, it is preserved in the record and the Council's review will therefore be better informed. Because the regulations already provide a process by which a party can object to an assigned adjudicator, and an opportunity to have the Council review the objections in cases where an adjudicator does not withdraw, we do not believe a peremptory challenge is necessary.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1026 and 423.2026 as proposed without modification.

m. Review of evidence submitted by the parties (§405.1028)

As discussed below, we proposed several revisions to §405.1028, which addresses the prehearing review of evidence submitted to the ALJ. 81 FR 43790, 43828–43830. We proposed

to revise the title of §405.1028 to reflect that the regulation would more broadly apply to the review of evidence submitted by the parties because a hearing may not be conducted and an attorney adjudicator would review evidence in deciding appeals as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above).

We proposed at §405.1028(a) to incorporate current §405.1028(a) to address new evidence. Current §405.1028(a) states that after a hearing is requested but before it is held, the ALJ will examine any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in §405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier, to determine whether there was good cause for submitting evidence for the first time at the ALJ level. However, this provision and the other provisions in current §405.1028 do not address the review of new evidence when no hearing is conducted for an appeal. Therefore, we proposed to revise §405.1028(a) to add §405.1028(a)(1), (2), (3), and (4), and proposed in §405.1028(a)(1) that after a hearing is requested but before it is held by an ALJ (to reinforce that hearings are only conducted by ALJs), or a decision is issued if no hearing is held, the ALJ or attorney adjudicator would review any new evidence. In addition, we proposed in §405.1028(a)(1) to remove the duplicative statement indicating the review is conducted on “any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in §405.1018,” because §405.1018 discusses when evidence may be submitted prior to a hearing and, as explained in section III.A.3.i of the proposed rule and II.B.3.i of this final rule above, proposed §405.1018 would revise the language that is duplicated in current §405.1028. We stated in the proposed rule that we believed that the better approach going forward is simply to reference §405.1018 by indicating that the review is conducted on “any new evidence submitted in

accordance with §405.1018.” This would remind parties that evidence must be submitted in accordance with §405.1018, while minimizing confusion on which section is authoritative with regard to when evidence may be submitted.

In a 2012 OIG report on the ALJ hearing process (OEI-02-10-00340), the OIG reported concerns regarding the acceptance of new evidence in light of the statutory limitation at section 1869(b)(3) of the Act on new evidence submitted by providers and suppliers. The OIG concluded that the current regulations regarding the acceptance of new evidence provide little guidance and only one example of good cause, and recommended revising the regulations to provide additional examples and factors for ALJs to consider when determining good cause.

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC reconsideration unless there is good cause which precluded the introduction of such evidence at or before that reconsideration. We stated in the proposed rule that this section presents a Medicare-specific limitation on submitting new evidence, and therefore limits the authority of an ALJ to accept new evidence under the broader APA provisions (see 5 U.S.C. 556(c)(3) (“Subject to published rules of the agency and within its power, employees presiding at hearings may— . . . receive relevant evidence . . . ”)). We also stated that section 1869(b)(3) of the Act presents a clear intent by Congress to limit the submission of new evidence after the QIC reconsideration, which must be observed.

In light of the OIG conclusion and recommendation and to more effectively implement section 1869(b)(3) of the Act, we proposed to incorporate current §405.1028(b) in proposed §405.1028(a)(2) on when an ALJ could find good cause for submitting evidence for the first time at the OMHA level, and to establish four additional circumstances in which good cause for submitting new evidence may be found. We also proposed to permit an attorney adjudicator to

find good cause because attorney adjudicators would be examining new evidence in deciding appeals on requests for an ALJ hearing as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), and we stated in the proposed rule that we believed the same standard for considering evidence should apply.

We proposed in §405.1028(a)(2)(i) to adopt the example in current §405.1028(b) and provide that good cause is found when the new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

We proposed in §405.1028(a)(2)(ii) to provide that good cause is found when the new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with §405.1032(b). This would provide parties with an opportunity to submit new evidence to address a new issue that was identified after the QIC's reconsideration. We stated, however, that the authority is limited to ALJs because, as discussed in proposed §405.1032, only an ALJ may raise a new issue on appeal.

We proposed in §405.1028(a)(2)(iii) to provide that good cause is found when the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. For example, if specific medical records are necessary to support a provider's or supplier's claim for items or services furnished to a beneficiary, the provider or supplier must make reasonable attempts to obtain the medical records, such as requesting records from a beneficiary or the beneficiary's physician when it became clear the records are necessary to support the claim, and following up on the request. We stated in the proposed rule that obtaining medical records, in

some cases from another health care professional, and submitting those records to support a claim for services furnished to a beneficiary is a basic requirement of the Medicare program (see sections 1815(a) and 1833(e) of the Act, and §424.5(a)(6)), and we expect instances where records cannot be obtained in the months leading up to a reconsideration should be rare. We stated that if the provider or supplier was unable to obtain the records prior to the QIC issuing its reconsideration, good cause for submitting the evidence after the QIC's reconsideration could be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration.

We proposed at §405.1028(a)(2)(iv) to provide that good cause is found when the party asserts that the evidence was submitted to the QIC or another contractor and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the new evidence was indeed submitted to the QIC or another contractor before the QIC issued the reconsideration. For example, if a provider or supplier submitted evidence to the QIC or another contractor and, through administrative error, the evidence was not associated with the record that is forwarded to OMHA, good cause may be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration.

Finally, we proposed at §405.1028(a)(2)(v) to provide that in circumstances not addressed in proposed paragraphs (i) through (iv), the ALJ or attorney adjudicator may find good cause for new evidence when the ALJ or attorney adjudicator determines the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration. We stated in the proposed rule that we expected proposed paragraphs (i) through

(iv) to cover most circumstances in which a provider or supplier attempts to introduce new evidence after the QIC reconsideration, but we also stated that we believed this additional provision is necessary to allow for a good cause finding in any other circumstance that meets the requirements of section 1869(b)(3) of the Act. We stated that paragraph (v) helps ensure that OMHA fulfills the statutory requirement by requiring that the ALJ or attorney adjudicator make a determination on whether the party could have obtained the evidence before the QIC issued its reconsideration.

To accommodate the new structure of proposed §405.1028, we proposed that current paragraphs (c) and (d) be re-designated as paragraphs (a)(3) and (a)(4), respectively. In addition, we proposed at §405.1028(a)(4) that notification about whether the evidence would be considered or excluded applies only when a hearing is conducted, and notification of a determination regarding new evidence would be made only to parties and participants who responded to the notice of hearing, since all parties may not be sent a copy of the notice of hearing or attend the hearing. We noted that if a hearing is not conducted, whether the evidence was considered or excluded would be discussed in the decision, pursuant to proposed §405.1046(a)(1), as discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule below. We also proposed at §405.1028(a)(4) that the ALJ would notify all parties and participants whether the new evidence would be considered or is excluded from consideration (rather than only whether the evidence will be excluded from the hearing) and that this determination would be made no later than the start of the hearing, if a hearing is conducted. We stated that if evidence is excluded, it is excluded from consideration at all points in the proceeding, not just the hearing, and evidence may be excluded from consideration even when no hearing is conducted. We stated that we believe that this would provide greater clarity to

parties and participants regarding the ALJ's determination with respect to new evidence, and the effect of the exclusion of such evidence on the proceedings.

Current §405.1028 does not address duplicative evidence. We stated in the proposed rule that duplicative evidence is a significant challenge for OMHA because appellants often submit copies of medical records and other submissions that were filed at prior levels of appeal and are in the record forwarded to OMHA. While we recognize that appellants want to ensure the evidence is in the record and considered, we are also mindful that the APA provides that as a matter of policy, an agency shall provide for the exclusion of unduly repetitious evidence (see 5 U.S.C 556(d)).

We proposed in §405.1028(b) that the ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA. In addition to establishing a general policy for the exclusion of unduly repetitious evidence, we stated that this would reduce confusion as to which of the multiple copies of records to review, and would reduce administrative burden.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter expressed support for allowing providers to submit evidence that may have been unavailable at the lower levels of appeal.

Response: We believe the commenter was referring to our proposal in §405.1028(a)(2)(iii) to allow for the submission of new evidence when a party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to

obtain the evidence before the QIC issued its reconsideration. We thank the commenter for its support.

Comment: We received a comment recommending that the proposed language in §405.1028(a) be modified to give the ALJ or attorney adjudicator discretion to admit new evidence, despite a party's inability to satisfy one of the examples of "good cause" listed in the regulation, when the adjudicator determines that "review of additional evidence is necessary in the interest of justice."

Response: We disagree with the recommendation. Section 1869(b)(3) of the Act establishes a specific prohibition on a provider or a supplier submitting evidence that was not presented at the reconsideration conducted by the QIC, unless there is good cause that precluded the evidence from being introduced at or before the QIC's reconsideration. This statutory provision limits the submission of new evidence by certain appellants late in the administrative appeals process, and provides an exception only if there is good cause which precluded the introduction of such evidence at or before the reconsideration. We believe that the standard suggested by the commenter could incorporate exceptions that are inconsistent with the good cause standard set forth in the statute. We believe that the enumerated examples in the regulations of when an ALJ or attorney adjudicator may find good cause for new evidence submitted by a provider or supplier for the first time at OMHA effectively implements section 1869(b)(3) of the Act and provides those parties with clearer guidance as to what is permissible under section 1869(b)(3). We believe that the enumerated good cause examples listed in §405.1028(a)(2) balance the interests of the parties in maintaining an avenue through which new evidence may be admitted for consideration while remaining faithful to the statutory requirement of section 1869(b)(3) of the Act.

Comment: One commenter expressed concern with proposed §405.1028(b), noting that the new language on duplicative evidence does not address the procedures that will be used to determine if a record is a duplicate or how a provider can request that a record omitted in error is placed back in the record. The commenter suggested that if records are removed, all parties to the appeal should have the opportunity to review the administrative record prior to a hearing to ensure that the record is complete.

Response: Pursuant to the procedures outlined in §§405.1042(b) and 423.2042(b) as finalized in this rule, parties may request a copy of the administrative record to review at any time while the appeal is pending at OMHA, including prior to the hearing. In addition, parties are provided with an opportunity to reference and discuss specific records or other evidence at the hearing, to confirm that the exhibited portion of the administrative record contains all the evidence that the ALJ will consider. Section 405.1028(b), as finalized in this rule, only provides that documents that are duplicative may be identified as such and, on that basis, are not marked as exhibits and are excluded from consideration. This section does not permit duplicative evidence to be removed from the administrative record, thus the documents are preserved and may be re-designated and placed back in the exhibited portion of the administrative record if it is determined that the document was identified as duplicative in error. The procedures for identifying and handling duplicates are outlined in the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency. The OCPM describes OMHA case processing procedures in greater detail and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA website (www.hhs.gov/omha), includes a detailed chapter on the administrative record and provides instructions on identifying and handling duplicative evidence.

Comment: Another commenter noted that the proposed changes allow attorney adjudicators to determine if a party has good cause for submitting evidence for the first time at the OMHA level or to exclude duplicative evidence from consideration. In the commenter's opinion, such judgments should be reserved for ALJs.

Response: We disagree with the commenter and believe that attorney adjudicators will have the necessary skills and training to address procedural determinations regarding whether there is good cause for submitting evidence for the first time at the OMHA level, which will be aided by the additional guidance in proposed §405.1028, and to identify or confirm that evidence is duplicative of evidence already in the record. As discussed in section II.A.2 of this final rule above, well-trained attorneys can perform a review of the administrative record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision on the matter. We believe that the procedural determinations regarding whether there is good cause for new evidence and whether evidence is duplicative are necessary for attorney adjudicators to establish the record upon which a decision will be made, and the determinations are not so complex as to require an ALJ. Moreover, allowing attorney adjudicators to make these procedural determinations on evidence in their cases will allow for ALJs to focus more of their time and attention on appeals that require a hearing, and the more complex procedural issues involved in those appeals.

Comment: One commenter requested that health plans be allowed the opportunity to respond to the submission of new evidence and indicate whether the plan believes good cause does not exist, why the case may require a remand for consideration of the new evidence, or why the newly provided evidence should not be afforded any weight in the adjudicator's decision.

Response: As discussed above (and section III.A.3.m of the proposed rule), the requirement that providers, suppliers, and beneficiaries represented by providers and suppliers, present any evidence for an appeal no later than the QIC reconsideration level, unless there is good cause for late submission, emanates from section 1869(b)(3) of the Act and is an existing regulatory requirement at §§405.1018 and 405.1028. Health plans are not parties to fee-for-service appeals conducted under section 1869 of the Act and, as explained in section II.A.3 of this final rule above (and section II.C of the proposed rule), we do not believe the part 405 regulatory requirements that implement section 1869(b)(3) of the Act are applicable to Part C MA appeals or cost plan appeals, because there is no similar requirement in section 1852(g) or 1876 of the Act. There is also no similar requirement in section 1860-D4 of the Act, and the Part D appeals regulations at part 423, subparts M and U have not implemented such a requirement. Therefore, we do not believe there would be any situations where a party would be required to make a showing of good cause for the introduction of new evidence in a Part C or Part D appeal in which a health plan was also a party. We note that §423.2018(a)(2) does require an ALJ to remand an appeal to the Part D IRE when an enrollee wishes evidence on his or her change in condition after a coverage determination to be considered, but this is compulsory under the regulations and not subject to ALJ discretion. Furthermore, although parties are permitted to respond to new evidence that is admitted into the administrative record, making a determination of whether good cause exists, whether a case requires a remand to the lower level, or whether evidence submitted should or should not bear weight in the decision are all assessments that are the responsibility of the adjudicator and are not subject to party or participant input. We believe that adding party or participant input to these types of adjudicator actions undermines the

adjudicator's role, and would result in unnecessary delays to an appeal, which is contrary to our goal of streamlining the appeals process.

Comment: One commenter urged OMHA to firmly reinforce with all ALJs, attorney adjudicators, and other staff that the limitation on submitting new evidence for the first time at the OMHA level does not apply to unrepresented beneficiaries and Medicaid State agencies.

Response: We agree with the commenter and note that the current regulation at §405.1028(a) states that the limitations apply only when new evidence is submitted by a provider, supplier, or a beneficiary represented by a provider or supplier. As discussed in section II.B.3.i of this final rule above, we are amending proposed §405.1018(d) to provide that the limitation on submitting new evidence for the first time at the OMHA level does not apply to evidence submitted by unrepresented beneficiaries, CMS or its contractors, a Medicaid State agency, an applicable plan, or beneficiaries represented by someone other than a provider or supplier. Current §405.1018(d) already explicitly states that the limitations on submitting evidence, including the limitations on the submission of new evidence, do not apply to an unrepresented beneficiary. In addition, OMHA provides training to its ALJs, attorneys, and other staff to help ensure understanding and compliance with all regulations applicable to processing appeals, and will provide training on all aspects of this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §405.1028 as proposed without modification.

n. ALJ hearing procedures (§§405.1030 and 423.2030)

The APA provides an ALJ with the authority to regulate the course of a hearing, subject to the rules of the agency (see 5 U.S.C. 556(c)(5)). As discussed below, we proposed several

revisions to §§405.1030 and 423.2030, which address ALJ hearing procedures. 81 FR 43790, 43830–43832. We stated in the proposed rule that in rare circumstances, OMHA ALJs have encountered a party or representative that makes it difficult or impossible for the ALJ to regulate the course of a hearing, or for other parties to present their side of the dispute. This may occur when a party or representative continues to present testimony or argument on a matter that is not relevant to the issues before the ALJ, or on a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. This may also occur when a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. Sections 405.1030 and 423.2030 set forth the rules that govern ALJ hearing procedures. We proposed to revise §§405.1030(b) and 423.2030(b) to add provisions to address these circumstances in a consistent manner that protects the interests of the parties and the integrity of the hearing process. To accommodate these proposals, we proposed to re-designate paragraph (b) in both §§405.1030 and 423.2030 as paragraph (b)(1), and, to be consistent with proposed §§405.1018 and 423.2018, to replace the current language stating that an ALJ may accept “documents that are material to the issues” with “evidence that is material to the issues,” because not all evidence that may be submitted is documentary evidence (for example, photographs).

We proposed in §405.1030(b)(2) to address circumstances in which a party or representative continues with testimony and argument that are not relevant to the issues before the ALJ or that address a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. In these circumstances, the ALJ may limit testimony and/or argument at the hearing, and may, at the ALJ’s discretion, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing, within a time frame designated by the

ALJ. Proposed §405.1030(b)(2) would allow the ALJ to effectively regulate the course of the hearing by providing the ALJ with the clear authority to limit testimony and/or argument during the hearing, while providing an avenue for the ALJ to allow the testimony and/or argument to be entered into the record. We proposed at §423.2030(b)(2) to adopt a corresponding revision for limiting testimony and argument at a hearing, and at the ALJ's discretion, provide an opportunity to submit additional written statements and affidavits in part 423, subpart U proceedings.

We proposed at §405.1030(b)(3) to address circumstances in which a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. In these circumstances, we proposed that the ALJ would have the clear authority to excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with the opportunity to offer testimony and/or argument. However, we stated in the proposed rule that in this circumstance, the ALJ would be required to provide the excused party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Further, we stated that the party also would be allowed to request a copy of the audio recording of the hearing in accordance with §405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing, within a time frame designated by the ALJ. These proposals would allow the ALJ to effectively regulate the course of the hearing and balance the excused party's right to present his or her case, present rebuttal evidence, and cross-examine the witnesses of other parties with allowing the party to submit written statements and affidavits. We proposed at §423.2030(b)(3) to adopt a corresponding revision for excusing an enrollee or representative who is uncooperative, disruptive, or abusive during the hearing in part 423, subpart U proceedings.

Current §405.1030(c) addresses evidence that the ALJ determines is missing at the hearing, and provides that if the evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine whether the appellant had good cause for not producing the evidence earlier. We proposed to revise §405.1030(c) to add that the ALJ must determine whether the appellant had good cause in accordance with §405.1028 for not producing the evidence. Section 1869(b)(3) of the Act applies to limit submission of all new evidence after the QIC reconsideration by a provider or supplier absent good cause, and the proposed addition would create consistent application of the standards for determining whether there is good cause to admit new evidence, regardless of when the evidence is submitted after the QIC reconsideration. We did not propose any corresponding changes to current §423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.

Current §405.1030(d) and (e) discuss what happens if an ALJ determines there was or was not good cause for not producing the new evidence earlier. Current §405.1030(d) provides that if the ALJ determines that good cause exists, the ALJ considers the evidence in deciding the case, and the adjudication period is tolled from the date of the hearing to the date that the evidence is submitted. Current §405.1030(e) provides that if the ALJ determines that good cause does not exist, the evidence is excluded, with no impact on an applicable adjudication period. We stated in the proposed rule that current §405.1030(d) and (e) have caused confusion in light of §405.1018, which indicates that the adjudication period will be affected if evidence is submitted later than 10 calendar days after receipt of the notice of hearing, unless the evidence is submitted by an unrepresented beneficiary. We stated that it has also potentially created an incentive for appellants to disregard §405.1018 because current §405.1030(b) appears to allow evidence to be

submitted at the hearing without affecting the adjudication time frame; and §405.1030(c) allows the ALJ to stop a hearing temporarily if there is material evidence missing, with the effect of tolling the adjudication time frame (under §405.1030(d)) from the date of the hearing to the date the evidence is submitted, if the evidence is in the possession of an appellant who is a provider or supplier or beneficiary represented by a provider or supplier, and the ALJ finds good cause to admit the evidence. In addition, we stated that OMHA ALJs have expressed concern that current §405.1030(e) does not affect the adjudication period when an equal amount of time is spent reviewing evidence and making a good cause determination, regardless of whether good cause is found.

Therefore, we proposed to revise §405.1030(d) to address the effect of an evidentiary submission on an adjudication period. We proposed in §405.1030(d) that any applicable adjudication period is extended in accordance with proposed §405.1018(b) if an appellant other than an unrepresented beneficiary submits evidence pursuant to proposed §405.1030(b), which generally allows for submission of evidence at the hearing, or proposed §405.1030(c), which specifically addresses evidence that the ALJ determines is missing at the hearing. Under proposed §405.1018(b), any adjudication period that applies to the appeal would be extended by the number of days starting 10 calendar days after receipt of the notice of hearing, and ending when the evidence is submitted, whether it is at the hearing pursuant to proposed §405.1030(b)(1), or at a later time pursuant to proposed §405.1030(c). We stated that proposed §405.1030(d) would provide appellants with an incentive to submit evidence they wish to have considered early in the adjudication process, allow the ALJ to consider the evidence and effectively prepare for the hearing, and minimize any delays in the adjudication process resulting from the late introduction of evidence during the hearing process. We further stated that

proposed §405.1030(d) would also remove the potential incentive to disregard §405.1018, and reconcile any inconsistency in the effect of a late evidentiary submission on an applicable adjudication period by incorporating the §405.1018 provisions by reference rather than establishing a different standard for evidence submitted during the course of or after a hearing. We proposed at §423.2030(d) to adopt a corresponding provision for the effect on an adjudication time frame when new evidence is submitted by a represented enrollee in a standard appeal, or an unrepresented or represented enrollee in an expedited appeal, in accordance with current §423.2018(b) or (c), as applicable.

Continuing a hearing is referenced in current §405.1030(c), but is not otherwise addressed in part 405, subpart I. We proposed in §405.1030(e)(1) that a hearing may be continued to a later date and that the notice of the continued hearing would be sent in accordance with proposed §405.1022, except that a waiver of the notice of hearing may be made in writing or on the record, and the notice of continued hearing would be sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate. We stated in the proposed rule that the notice requirement would help ensure that the general hearing notice requirements are met for a continued hearing, but allow a waiver of the notice of hearing to be made in writing or on the record. We stated that we believe the added option of waiving the notice of hearing on the record in the context of a continued hearing would facilitate scheduling the continued hearing when all parties and participants who are in attendance at the hearing agree to the continued hearing date, or alternatively agree on the record to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing. In addition, proposed §405.1030(e)(1) would only require that a notice of the continued hearing be sent to the participants and parties who attended the hearing,

but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants. We stated that we believe that a notice of the continued hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the continuance and an adjudication period applies to the appeal, we proposed in §405.1030(e)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the continued hearing date. We stated that we believe an appellant's request for a continuance of the hearing is similar to an appellant's request to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We proposed at §423.2030(e) to adopt corresponding provisions for continued hearings in part 423, subpart U proceedings.

On occasion, after a hearing is conducted, ALJs find that additional testimony or evidence is necessary to decide the issues on appeal, or a procedural matter needs to be addressed. Current §405.1030(f) allows an ALJ to reopen a hearing to receive new and material evidence pursuant to §405.986, which requires that the evidence (1) was not available or known at the time of the hearing, and (2) may result in a different conclusion. However, current §405.1030(f) does not provide a mechanism to address procedural matters, or to obtain additional information through evidence or testimony that may have been available at the time of hearing and may result in a different outcome but the importance of which was not recognized until after a post-hearing review of the case. We proposed in §405.1030(f)(1) to remove the "reopen" label and provide for a "supplemental" hearing rather than reopening the hearing to distinguish it from reopening a decision and the standards for reopening a decision. We also proposed that a supplemental hearing may be conducted at the ALJ's discretion at any time

before the ALJ mails a notice of decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. We stated in the proposed rule that the ALJ would determine whether a supplemental hearing is necessary, and if one is held, the scope of the supplemental hearing, including when evidence is presented and what issues are discussed. In addition, we proposed at §405.1030(f)(1) that a notice of the supplemental hearing be sent in accordance with §405.1022 to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants the ALJ determines are appropriate. Similar to the proposed notice of a continued hearing explained above, we stated that we believe that a notice of the supplemental hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the supplemental hearing and an adjudication period applies to the appeal, we proposed at §405.1030(f)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the supplemental hearing date. We stated that we believe an appellant's request for a supplemental hearing is similar to an appellant's request for a continuance or to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We proposed at §423.2030(f) to adopt corresponding provisions for supplemental hearings in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received two comments opposed to the language in proposed §§405.1030(b)(2) and 423.2030(b)(2) permitting an ALJ to limit the testimony and argument at

the hearing. The commenters believed that the proposals undercut an appellant's ability to get a full and fair hearing, and expressed concern that the language gives too much discretion to ALJs in allowing an ALJ to limit testimony and/or argument if the ALJ determines that he or she has sufficient information and in permitting the ALJ to decide whether to allow additional written submissions. The commenters also noted that an ALJ hearing is the first, and in some appeals only, time where an appellant can provide oral argument, and the commenters urged that under no circumstances should an appellant be prevented from presenting what the appellant deems to be a full argument to the ALJ.

Response: We believe our proposal strikes a necessary balance between protecting the interests of the parties and protecting the integrity of the hearing process. OMHA ALJs have sometimes encountered a party or representative that continues to present testimony or argument at a hearing that is not relevant to the issues before the ALJ, that is repetitive of evidence or testimony already in the record, or that relates to an issue that has been sufficiently developed or on which the ALJ has already ruled. When the testimony or argument is unrelated to an issue on appeal or an ALJ determines that additional evidence or testimony on the issue would be repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed or on which he or she has already ruled, the continued testimony or argument becomes repetitive or unnecessarily cumulative, and adds nothing of value to the proceedings. This continued testimony and argument is not only an inefficient use of time and resources for the ALJ and the parties, it may have the effect of monopolizing the time set for a hearing and causing other parties to limit their presentations because they have only allowed for the scheduled hearing time in their schedules.

We do not believe that limiting testimony that is unrelated, repetitive, or related to an issue that has been sufficiently developed or upon which the ALJ has already ruled prejudices a party's right to a full and fair hearing. ALJs have a responsibility pursuant to current §§405.1030(b) and 423.2030(b) to fully examine the issues on appeal, ensuring that all necessary testimony is considered, which would continue under the these rules as finalized. The proposals at §§405.1030(b) and 423.2030(b), which we are finalizing in this rule, would only limit the introduction of repetitive or unrelated evidence. Moreover, the proposal is based on the APA at 5 U.S.C. 556(c)(5), which provides that subject to the published rules of the agency, an ALJ may regulate the course of the hearing. We believe that ALJs, who have a responsibility to ensure both a fully examined and fairly administered hearing, will use these provisions only in the limited situations that the proposals are intended to address.

With regard to the concern that the proposed regulations give too much discretion to the ALJ, we believe such discretion is consistent with and authorized by the APA. As we stated above, we believe the ALJ needs to be able to effectively regulate the course of the hearing, including the exercise of discretion as outlined in the §§405.1030(b) and 423.2030(b), as finalized, in order to effectively protect the interest of parties and to preserve the integrity of the hearing process.

Comment: The same two commenters noted that limiting testimony could negatively impact appeals to the Council since the Council limits its review to the evidence in the record of the proceedings before the ALJ.

Response: We disagree that the proposals at §§405.1030(b)(2) and 423.2030(b)(2) will negatively impact appeals to the Council. Although the commenters refer to the language in §405.1122(a)(1) stating that when the Council is reviewing an ALJ's decision, the Council limits

its review to the evidence contained in the record of the proceedings before the ALJ, that regulation goes on to say in §405.1122(a)(2) that if the Council determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. A party that feels that certain evidence was not duly entered into the record because of an ALJ's decision to limit testimony at the hearing pursuant to the proposed regulations may appeal that issue to the Council. The hearing is preserved on audio recording and is available for review on appeal, and the Council may remand a case if the record shows that the party is entitled to a new hearing.

Comment: Another commenter specifically objected to the language in proposed §§405.1030(b)(2) and 423.2030(b)(2) permitting an ALJ to limit testimony or argument on the basis that “the ALJ believes he or she has sufficient information.” The commenter stated that limiting testimony and argument on that basis is dangerous precedent, potentially interrupts the logical flow of an argument, precludes an appellant from knowing what the ALJ understands and prevents the appellant from being able to build a rational case upon a common knowledge base. The commenter noted that some fields of medicine change rapidly and even though an ALJ may have recently heard and decided a similar case for a similar condition, due to the evolving information in the field, ALJs may not come into the hearing with sufficiently up-to-date information.

Response: We disagree with the commenter's suggestion that proposed §§405.1030(b)(2) and 423.2030(b)(2) could be used to limit argument or testimony related to new or updated information relevant to an issue on appeal. The language in the proposed regulations that the commenter specifically opposes is focused on testimony or argument that is unnecessarily

repetitive because the ALJ has determined that he or she has sufficient information to make an informed decision or has already ruled on the issue. As we stated above, an ALJ is responsible for fully examining the issues on appeal and therefore an ALJ cannot limit testimony or argument in the situation described by the commenter where a full examination requires additional updated or new information. However, we understand that the passage stating, “ALJ determines he or she has sufficient information” may not be widely understood and may be subject to varying interpretations, and we are therefore finalizing proposed §§405.1030(b)(2) and 423.2030(b)(2) with modification to clarify the intent of the provision as discussed above. Specifically, we are modifying §§405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. We believe this modification clarifies the intent of this provision and will mitigate the possibility that the provision would be used to limit argument or testimony related to new or updated information relevant to an issue on appeal.

With regard to the commenter’s concern that limiting testimony or argument would interrupt the logical flow of an argument or make it difficult for the party to present a coherent or rational case, we note that these concerns appear to relate mainly to a party being able to present its case in the manner that he or she believes is most logical, coherent, or rational and do not adequately recognize the ALJ’s role in the process. When an ALJ limits testimony or argument at the hearing, it is because the ALJ believes the testimony or argument was not relevant to an issue before the ALJ, was repetitive of evidence or testimony already in the record, or related to an issue that was sufficiently developed, and the ALJ has heard all necessary testimony,

understands the arguments being made, and is able to logically, rationally, and fully analyze the issue to make a decision. Moreover, we believe these concerns about being able to present a case in the order and manner an individual desires are outweighed by the ALJ's broader responsibilities to protect the interests of all parties and preserve the integrity of the hearing process. As we discuss above, allowing a party to continue presenting testimony and argument when the testimony or argument is not relevant to an issue before the ALJ, is repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed, is not only an inefficient use of time and resources, it may have the effect of monopolizing the time set for a hearing and causing other parties to limit their presentations because they have only allowed for the scheduled hearing time in their schedules.

Comment: Another commenter noted that ALJs may improperly use the discretion afforded in proposed §§405.1030(b)(2) and 423.2030(b)(2) to get through hearings faster or set unreasonably short periods of time for hearings that involve large numbers of cases.

Response: While efficient use of time and resources is an important interest, §§405.1030(b)(2) and 423.2030(b)(2), as finalized, do not provide authority to curtail hearings or limit appellants' presentations of evidence, argument, or testimony solely for the purpose of keeping the duration of a hearing within a specified time parameter. Given the ALJ's responsibility to examine the issues fully at the hearing, as discussed above, we do not believe that §§405.1030(b)(2) and 423.2030(b)(2) would be abused by ALJs as suggested by this comment, and to the extent that a party believes that inadequate time was provided and the ALJ did not provide additional time, that issue could be raised on appeal to the Council.

Comment: One commenter recommended modifying the proposed changes in §§405.1030(b)(3) and 423.2030(b)(3) to clarify that a party will only be excused from a hearing after an initial admonishment of the party's conduct by the ALJ.

Response: We agree that the recommended modification would provide better clarity to parties regarding the expectations or concerns of an ALJ during the course of a hearing and would provide a fair warning to parties that they must adjust their behavior or risk being excused from the hearing. We have therefore further modified proposed §§405.1030(b)(3) and 423.2030(b)(3) to state that an ALJ may excuse the party, enrollee, or representative from the hearing if that party, enrollee, or representative remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has given a warning.

Comment: One commenter expressed concern that the proposed regulations allowing an ALJ to excuse a party that is uncooperative, disruptive, or abusive during the hearing will be misconstrued to limit the ability of appellants to make their arguments and curtail due process. The commenter stressed that a high bar therefore should be imposed on the use of proposed §§405.1030(b)(3) and 423.2030(b)(3). The commenter argued that proposed §§405.1030(b)(3) and 423.2030(b)(3) would permit an ALJ to excuse a party or representative when a hearing becomes "spirited or contentious" and that parties and representatives may refrain from objecting to certain hearing procedures set by the ALJ because they do not want to risk alienating the ALJ and/or being excused from the hearing. The commenter also argued that even though proposed §§405.1030(b)(3) and 423.2030(b)(3) require that the ALJ provide the excused party or representative with an opportunity to submit written statements in lieu of testimony and/or argument at hearing, it would be impossible for an appellant to effectively present a case or cross examine witnesses in writing when the hearing continues without him or her.

Response: We anticipate that ALJs would rarely find the need to use the rules at proposed §§405.1030(b)(3) and 423.2030(b)(3) to excuse someone from the hearing but believe that the proposals are necessary to protect the integrity of the hearing process. An ALJ has authority to regulate the course of the hearing, consistent with §556(c) of the APA and §§405.1030 and 423.2030, which we believe includes excusing any party or representative that is being disruptive to the adjudication process. Especially with the additional modification discussed above requiring an initial warning by the ALJ, we believe §§405.1030(b)(3) and 423.2030(b)(3), as finalized, satisfactorily balance the excused party's right to present his or her case with the ALJ's authority to regulate the course of the hearing. As we note above, ALJs have a responsibility under current §§405.1030(b) and 423.2030(b) (and §§405.1030(b)(1) and 423.2030(b)(1) as finalized in this rule) to fully examine the issues on appeal. We believe that ALJs, who have a responsibility to ensure both a fully examined and fairly administered hearing, will use these provisions infrequently and only when necessary to support a full and fair hearing.

We note that any party that is excused from the hearing pursuant to proposed §§405.1030(b)(3) and 423.2030(b)(3) would be permitted to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Although the commenter noted that written statements would limit an excused party's or representative's ability to present a case or cross examine witnesses and other parties at the hearing, we believe that the required warning would effectively put the excused entity or individual on notice of the consequences of continued uncooperative, disruptive, or abusive behavior, and therefore the excused individuals or entities would have knowingly limited their own argument and testimony to written statements by continuing such behavior. While the format of the argument and testimony would be changed, we disagree with the commenter that written statements and affidavits are necessarily less

effective or persuasive than oral argument or testimony or that they curtail due process. The ALJ would give the same weight to argument or testimony that is presented in writing as to argument or testimony that is presented orally at the hearing. Moreover, any excused party would be able to request a copy of the audio recording of the hearing in accordance with §§405.1042 and 423.2042 so that the party could respond in writing to any statements or testimony made at the hearing, including the submission of rebuttal argument and evidence.

Finally, we disagree with the commenter's characterization that the type of behavior addressed in §§405.1030(b)(3) and 423.2030(b)(3) is synonymous with "spirited or contentious" or that parties or their representatives would refrain from objecting to certain hearing procedures set by the ALJ because they do not want to risk being excused from the hearing. The language used in the regulations— uncooperative, disruptive, or abusive— was specifically chosen to describe a certain degree of behavior that makes it difficult or impossible for an ALJ to regulate the course of a hearing or for other parties to present their side of the dispute. We believe that §§405.1030(b)(3) and 423.2030(b)(3) are necessary in order to allow the ALJ to effectively regulate the course of the hearing, including providing the other parties with their opportunity to offer testimony and/or argument. To the extent that a party believes it was inappropriately excused from a hearing, that issue could be raised on appeal to the Council.

Comment: We received one comment that supported the authority given in proposed §§405.1030(b)(3) and 423.2030(b)(3) allowing an ALJ to excuse a party or representative that is disruptive or abusive during the course of the hearing, but requested clarification of the term "uncooperative" as used in the proposed regulations. The commenter asked if it would be seen as "uncooperative" if a party disagrees with an ALJ's interpretation of the law.

Response: We thank the commenter for its support of §§405.1030(b)(3) and 423.2030(b)(3) and agree that ALJs need to have authority to excuse parties or representatives if they are being disruptive or abusive during the course of the hearing. We also believe that ALJs should have the authority to excuse parties or representatives who are uncooperative because uncooperative behavior can similarly disrupt the course of the hearing and/or negatively impact the integrity of the hearing process. While uncooperative behavior may take a range of forms, generally we believe that, in the context of §§405.1030(b)(3) and 423.2030(b)(3), “uncooperative” is behavior that has risen to a level that is impeding the ALJ’s ability to regulate the hearing or the other parties’ ability to present their side of the dispute. If a party disagrees with an ALJ, as suggested by the commenter’s question, even if the disagreement is spirited or contentious as another commenter suggested, such behavior would not rise to the level of “uncooperative” if it does not impede the ALJ’s ability to regulate the hearing or the other parties’ ability to present their case. We believe that the additional modification discussed above, adding that a party or representative may only be excused after the ALJ has warned the party or representative to stop the disruptive, abusive, or uncooperative behavior, will assist in providing clarity to parties regarding the expectations or concerns of an ALJ during the course of a hearing, and would provide a fair warning to parties and representatives that they must adjust their behavior or risk being excused from the hearing.

Comment: We received one request that CMS prepare basic informational documents that may be furnished to or accessed by any party whose testimony has been limited or who has been excused from a hearing, explaining their rights and options under the regulations.

Response: Any party who believes that his or her testimony has been unduly limited or who has been excused from a hearing pursuant to proposed §405.1030(b)(2) or (3), or

§423.2030(b)(2) or (3) may appeal the issue to the Council for review after the ALJ's decision has been issued. The hearing is preserved on audio recording and is available for review on appeal and the Council may remand a case if the record shows that the party is entitled to a new hearing. We intend to issue additional sub-regulatory guidance in the OCPM, but do not believe that a written document outlining a party's rights under §405.1030(b)(2) or (3) or an enrollee's rights under §423.2030(b)(2) or (3) is necessary because the party, enrollee, or the party's or enrollee's representative, would be informed prior to being excused from the hearing of the right under §405.1030(b)(3) or §423.2030(b)(3) to submit written statements and affidavits in lieu of testimony or argument at the hearing. Furthermore, when an ALJ limits testimony and/or argument at the hearing under §405.1030(b)(2) or §423.2030(b)(2) because the testimony and/or argument is not relevant to an issue before the ALJ, is repetitive of evidence or testimony already in the record, or relates to an issue that has been sufficiently developed or on which the ALJ has already ruled, no additional rights or options extend to the party or enrollee other than to appeal the ALJ's action to the Council. Rather, the ALJ may, but is not required to, provide the party, enrollee, or representative with an opportunity to submit additional written statements and affidavits on the matter.

Comment: One commenter asked for additional clarification regarding the statement that “[w]e are not proposing any corresponding changes to current §423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.”

Response: Part 423, subpart U includes detailed procedures for requesting and adjudicating a request for hearing or a request for review of a dismissal under Medicare Part D (the Voluntary Medicare Prescription Drug Benefit). The preamble to the final rule establishing the Medicare Part D claims appeals process issued in the Federal Register on December 9, 2009

(74 FR 65340) sets forth that the provisions of part 423, subpart U generally follow the part 405, subpart I procedures. However, there are some specific differences between the part 405, subpart I rules governing Medicare Part A and B appeals and the part 423, subpart U rules governing Medicare Part D appeals, including the absence of good cause limitations for the introduction of new evidence in Medicare Part D proceedings as discussed in the proposed and final Part D appeals rules (73 FR 14345, 74 FR 65345). In the final Medicare Part D appeals rule (74 FR 65345), we decided that the full and early presentation of evidence provisions of part 405 subpart I, including §405.1028, would not apply in Part D appeals. As discussed above, section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the reconsideration, unless there is good cause which precluded the introduction of evidence at or before the reconsideration. Part 405, subpart I extends this requirement to beneficiaries represented by providers or suppliers in an effort to ensure that providers or suppliers do not attempt to circumvent the full and early presentation of evidence rules by offering to represent beneficiaries. In the proposed and final Part D appeals rules (73 FR 14345, 74 FR 65345), we noted our desire to provide enrollees with as much flexibility as possible concerning the evidence that may be presented for an ALJ hearing and Council review, and stated that because an enrollee is the only party to the appeal in Medicare Part D cases, and because an enrollee would not be represented by a provider or supplier attempting to circumvent this rule, we were not including in the part 423, subpart U rules any provisions from part 405, subpart I on the full and early presentation of evidence. This flexibility extends to the submission of any written evidence about an enrollee's condition at the time of the coverage determination. However, the subpart U rules do provide that if an enrollee wishes to have evidence on changes in his or her condition since the coverage determination considered in the appeal, an ALJ or the

Council will remand the case to the Part D IRE. Accordingly, although the Medicare Part A and Part B regulations (part 405, subpart I) contain language limiting the submission of new evidence after the QIC reconsideration (see, for example, §§405.1018, 405.1028, and 405.1030), the corresponding Medicare Part D regulations (part 423, subpart U) do not contain that language.

The only proposed change to §405.1030(c)—the provision regarding procedures when an ALJ determines that there is material evidence missing at the hearing in Medicare Part A and Part B cases—is to add a reference to §405.1028 for consistency regarding the application of the standards for determining whether there is good cause to admit new evidence regardless of when the evidence is submitted after the QIC reconsideration. No changes were proposed for §423.2030(c)—the corresponding provision regarding procedures when an ALJ determines that there is material evidence missing at the hearing in Medicare Part D cases—because there is no corresponding language requiring good cause for the admission of new evidence in the Medicare Part D regulations as explained above.

Comment: We received one comment on proposed §405.1030(d) requesting that Medicaid State agencies be explicitly exempted, similar to unrepresented beneficiaries, from any extension of the adjudication period if new evidence is submitted at the hearing.

Response: Medicaid State agencies, in addition to unrepresented beneficiaries, CMS and its contractors, applicable plans, and beneficiaries represented by someone other than providers or suppliers, are not subject to the same limitations on the submission of new evidence after the QIC reconsideration as providers and suppliers are under section 1869(b)(3) of the Act. As discussed in section II.B.3.i above, we have modified language in §405.1018(d) to provide that those individuals and entities are exempt from the requirement to show good cause for the late submission of evidence. We do not agree, however, that because individuals and entities other

than unrepresented beneficiaries are not subject to the good cause requirements for the submission of late evidence that they should also be afforded the same treatment as unrepresented beneficiaries with respect to exemption from extension of the adjudication period when new evidence is submitted. We believe that individuals and entities other than unrepresented beneficiaries are generally more familiar with the appeals process than unrepresented beneficiaries, and are generally aware that evidence to be considered in deciding an appeal should be submitted as early in the process as possible (see also §§405.946 and 405.966). Further exempting individuals and entities—other than unrepresented beneficiaries—who are already exempt from the requirement to show good cause for the introduction of new evidence after the QIC reconsideration from an extension of the adjudication period could incentivize these individuals and entities to delay the submission of evidence until after a hearing has been scheduled, and possibly conducted. We believe this could have a detrimental effect on an ALJ's ability to issue a timely decision. Furthermore, we note that §§405.946 and 405.966 provide for extensions to the time frames for issuing a redetermination and reconsideration, respectively, when a party submits additional evidence after filing the request for redetermination or reconsideration. Our modification in §405.1018(d) makes it clear that although those entities are exempt from the requirement of submitting a statement and demonstrating good cause for new evidence, they are still subject to an extension on the applicable adjudication period pursuant to §405.1018(b), as they are under current §405.1018(b) and (d). To be consistent with the rules in §405.1018 regarding new evidence, we decline to make the commenter's suggested change to §405.1030(d).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1030 and 423.2030 as

proposed, with the following modifications. We are revising §§405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. In addition, we are revising §§405.1030(b)(3) and 423.2030(b)(3) to add language that a party or party's representative (or enrollee or enrollee's representative in the context of §423.2030(b)(3)) may be excused from a hearing if that individual remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior.

o. Issues before an ALJ or attorney adjudicator (§§405.1032, 405.1064 and 423.2032)

As described below, we proposed several changes to §§405.1032 and 423.2032, which address the issues that are before the ALJ. 81 FR 43790, 43832–43834. We proposed to revise the title of the section to indicate that the proposed provision also would apply to issues before an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), if an attorney adjudicator is assigned to an appeal.

Current §405.1032(a) states that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, we stated in the proposed rule that when a request for hearing involves a reconsideration of multiple claims and the appellant does not identify one or more of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, it is unclear whether the ALJ should review all of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, or just those claims specified by the appellant in the request for hearing. An

appellant is required to identify the dates of service for the claims that it wishes to appeal in its request for hearing under §405.1014, and some appellants have indicated that they do not specify a denied claim in a request for hearing when they agree that the record does not support coverage of the claim. To address the ambiguity, and in the interest of efficiency and consistency with §405.1014, we proposed in §405.1032(a) that the issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter (for example, for appeals that do not involve a claim for items or services furnished to a beneficiary, such as Medicare Secondary Payer appeals and terminations of coverage) specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. We proposed at §423.2032(a) to adopt a corresponding revision for issues in part 423, subpart U proceedings, except the term claims is not used because part 423, subpart U appeals do not involve claims.

Current §405.1032(a) also notes that if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ notifies the parties before the hearing and may consider it an issue at the hearing. As explained in the 2005 Interim Final Rule (70 FR 11462), this provision relates to the favorable portion of an appealed claim, and that the favorable issue is a new issue that must meet the requirements of current paragraph (b). However, in practice, this provision has been read to allow consideration of separate claims that were decided in a party's favor at lower appeal levels in multiple-claim appeals, and at times read independently from paragraph (b). To address this confusion, we proposed to move this language in §405.1032(a) to proposed §405.1032(b), with the revisions discussed below. We proposed at §423.2032(a) and (b) to adopt corresponding revisions for new issues in part 423, subpart U proceedings.

Current §405.1032(b) allows new issues to be considered at the hearing if: (1) the ALJ notifies the parties about the new issue before the start of the hearing; (2) the resolution of the new issue could have a material impact on the claim or claims that are the subject of the request for hearing; and (3) its resolution is permissible under the rules governing reopening of determinations and decisions. We proposed at §405.1032(b) to incorporate these provisions, with the revisions discussed below, as well as the language regarding consideration of favorable issues moved from current §405.1032(a), in a revised structure.

We proposed in §405.1032(b)(1) to address when a new issue may be considered. Specifically, we proposed that the ALJ may only consider the new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter, and (1) there is new or material evidence that was not available or known at the time of the determination and which may result in a different conclusion, or (2) the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination. We stated in the proposed rule that this would consolidate the current provisions to better convey when a new issue may be considered, clarify that a new issue relates to a claim or appealed matter specified in the request for hearing, and provide the applicable standards from the reopening rules referenced in current §405.1032(b)(1)(ii). We proposed in §405.1032(b)(1) to continue to provide that the new issue may be raised by the ALJ or any party and may include issues resulting from the participation of CMS, but also to correct the language so that it also references participation of CMS contractors. We proposed at §423.2032(b)(1) to adopt corresponding revisions for when new issues may be considered in part 423, subpart U proceedings.

We proposed at §405.1032(b)(2) to continue to provide that notice of the new issue must be provided before the start of the hearing, but would limit the notice to the parties who were or will be sent the notice of hearing, rather than the current standard to notice “all of the parties.” Because notice of the new issue may be made in the notice of hearing or after the notice of hearing, and parties generally have 10 calendar days after receipt of the notice of hearing to submit evidence, we proposed at §405.1032(b)(3) to also provide that if notice of the new issue is sent after the notice of hearing, the parties would have at least 10 calendar days after receiving the notice of the new issue to submit evidence regarding the issue. As provided in proposed §405.1028(a)(2)(ii), the ALJ would then determine whether the new evidence is material to the new issue identified by the ALJ. We also stated in the proposed rule that if an adjudication time frame applies to the appeal, the adjudication period would not be affected by the submission of evidence. Further, we proposed at §405.1032(b)(3) that if the hearing is conducted before the time to submit evidence regarding the issue expires, the record would remain open until the opportunity to submit evidence expires to provide the parties sufficient time to submit evidence regarding the issue. We proposed at §423.2032(b)(2) and (b)(3) to adopt corresponding provisions for providing notice of new issues to enrollees and an opportunity to submit evidence, and to add that an enrollee will have 2 calendar days after receiving notice of the new issue in an expedited appeal to submit evidence, which corresponds to the length of time permitted under proposed §423.2018(c) to submit evidence after receiving a notice of expedited hearing.

Current §405.1032(c) states that an ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless the claim has been adjudicated at the lower appeal levels and all parties are notified of the new issues before the start of the hearing. However, in practice, we are unaware that this provision is used, and to

the extent it may be used, we believe it would be disruptive to the adjudication process, result in filing requirements not being observed, and risk adjudication of the same claim by multiple adjudicators. Therefore, we proposed to maintain the topic of adding claims to a pending appeal, but replace the language of current §405.1032(c), as explained below.

A reconsideration may be appealed for an ALJ hearing regardless of the number of claims involved in the reconsideration. However, we recognize that a party may not specify all of the claims from a reconsideration that he or she wishes to appeal in the party's request for hearing. We proposed in §405.1032(c)(1) to address this circumstance by providing that claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed in the request for hearing, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims to be added in accordance with proposed §405.1014(e). We stated in the proposed rule that we believe that this would result in less disruption to the adjudication process, greater adherence to filing requirements, and reduce the risk of adjudication of the same claim by multiple adjudicators. To help ensure that the copy requirement of proposed §405.1014(d) is observed, we proposed at §405.1032(c)(2) to require that before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates that the information that constitutes a complete request for hearing in accordance with §405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with §405.1014(d). We proposed at §423.2032(c) to adopt a provision corresponding to proposed §405.1032(c)(1), but we did not propose to adopt a provision corresponding to

§405.1032(c)(2) because there is no §423.2014 requirement for an enrollee to send a copy of his or her request to others.

Current §405.1032 does not address issues related to an appeal that involves a disagreement with how a statistical sample and/or extrapolation was conducted. When an appeal involves a statistical sample and an extrapolation and the appellant wishes to challenge how the statistical sample and/or extrapolation was conducted, as discussed previously, we proposed at §405.1014(a)(3)(iii) to require the appellant to assert the reasons the appellant disagrees with how the statistical sampling and/or extrapolation was conducted in the request for hearing. We proposed at §405.1032(d)(1) to reinforce this requirement by excluding issues related to how the statistical sample and/or extrapolation were conducted if the appellant does not comply with §405.1014(a)(3)(iii). In addition to reinforcing the proposed requirement at §405.1014(a)(3)(iii), we stated in the proposed rule that we believed that excluding the issue is appropriate because an appellant should reasonably be aware of whether it disagrees with how the statistical sampling and/or extrapolation was conducted at the time it files a request for hearing, and raising the issue later in the adjudication process or at the hearing can cause significant delays in adjudicating an appeal because the ALJ may need to conduct additional fact finding, find it necessary to request participation of CMS or one of its contractors, and/or call expert witnesses to help address the issue.

Related to the issues that an ALJ must consider, the 2005 Interim Final Rule (70 FR 11466) explained that current §405.1064 was added to set forth a general rule regarding ALJ decisions that are based on statistical samples because a decision that is based on only a portion of a statistical sample does not accurately reflect the entire record. As discussed in the 2009 Final Rule (74 FR 65328), current §405.1064 explains that when an appeal from the QIC involves an

overpayment, and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of all claims in the sample. However, we stated in the proposed rule that while a review of the claims selected for the sample is necessary to review issues related to a contested sample and extrapolation, for example to determine whether the sample claims were appropriately selected for a representative sample of the universe, current §405.1064 has been read more broadly to also require adjudication of each sample claim, regardless of whether the sample claim was adjudicated favorably at lower appeal levels. We further stated in the proposed rule that we do not believe adjudicating sample claims that were decided favorably at lower levels of appeal, or sample claims that are not appealed by a party, is necessary to adjudicate broader issues with how sampling and extrapolation was conducted, and that the broader reading of current §405.1064 results in unnecessary adjudications of claims that were not appealed.

To clarify what is at issue and what must be considered in appeals involving statistical sampling and extrapolations, we proposed to remove current §405.1064, and address the matter in §405.1032(d)(2). We proposed in §405.1032(d)(2) that if a party asserts a disagreement with how the statistical sampling methodology and extrapolation were conducted in the request for hearing, in accordance with proposed §405.1014(a)(3)(iii), §405.1032(a) through (c) would apply to the adjudication of the sample claims. The result of applying proposed §405.1032(a) and (b) would be that only the sample units that were specified in the request for hearing are individually adjudicated, subject to a new issue being identified for an appealed claim. However, proposed §405.1032(c) would permit adding sample claims to a pending appeal if they were adjudicated in the appealed reconsideration and the time to request a hearing on the reconsideration has not expired, or the ALJ or attorney adjudicator extends the time to request an

ALJ hearing on those claims in accordance with §405.1014(e). To incorporate the principle embodied in current §405.1064, we proposed in §405.1032(d)(2) that in deciding issues related to how a statistical sample and/or extrapolation was conducted, the ALJ or attorney adjudicator would base his or her decision on a review of the entire sample to the extent appropriate to decide the issue. We stated in the proposed rule that we believed this more clearly conveys the intent of the rule and recognizes that an individual adjudication of each claim in the sample is not always necessary to decide an issue related to how a statistical sample and/or extrapolation was conducted, such as whether there is documentation so that the sampling frame can be re-created, as required by the Medicare Program Integrity Manual (Internet-Only Manual 100-08) (see chapter 8, section 8.4.4.4.1). We did not propose any corresponding changes in §423.2030 because statistical sampling and extrapolation are not currently used for matters that are subject to part 423, subpart U proceedings.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter noted that there were numerous changes proposed in part 405, subpart I concerning standards for ALJs to consider new issues, notice requirements for new issues, the submission and admissibility of evidence related to new issues, and rules governing whether claims may be added to a pending appeal. The commenter suggested that, if the proposals were finalized, OMHA publish “an expanded beneficiary handbook (online and elsewhere) that explains these provisions in ‘practical, understandable terms for the layperson.’”

Response: We thank the commenter for the suggestion, and will consider providing beneficiaries with enhanced or additional tools to help them understand the appeals process in

the future. Although we proposed many revisions to the existing rules in part 405, subpart I and other provisions that apply to benefit appeals, one of the stated goals of this rulemaking was to streamline and improve the efficiency of the appeals process. We believe many of the proposed changes add clarity to the rules and resolve areas of longstanding confusion for appellants, adjudicators, and other stakeholders in the appeals process. Wherever possible, we have used plain language and have defined terms that may be unfamiliar to beneficiaries or other appellants. However, because the rules sometimes involve complex procedures that require precise terminology (more often associated with provider and supplier appeals), there are instances where oversimplification of a stated rule could have the unintended consequence of introducing further areas of ambiguity and frustrating one of the primary purposes of this rulemaking.

In addition to existing CMS resources like the Medicare & You Handbook, 1-800 Medicare, chapter 29 of the Medicare Claims Processing Manual (Internet-Only Manual 100-4), and the Medicare claims appeals website at www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html, OMHA is currently in the process of developing and releasing the OCPM. The OCPM provides day-to-day operating instructions, policies, and procedures based on statutes, regulations, and OMHA directives. Development is ongoing, and although the OCPM is primarily intended to be a resource used by OMHA adjudicators and staff, chapters are made publicly available on the OMHA website (www.hhs.gov/omha) soon after they are published. The instructions and guidance in the OCPM describe many policies and procedures in greater detail and provide frequent examples to aid understanding.

OMHA also has a toll free beneficiary help line for Medicare beneficiaries and Part C or Part D plan enrollees who have questions about or need assistance with a request for an ALJ

hearing, as well as a separate OMHA national toll free assistance line for other appellants.

Information about both help lines can be found on the “Contact OMHA” portion of the OMHA website (www.hhs.gov/omha).

After review and consideration of the comment received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals to revise §§405.1032 and 423.2032 and to remove §405.1064 without modification.

p. Requesting information from the QIC or IRE, and remanding an appeal (§§405.1034, 405.1056, 405.1058, 423.2034, 423.2056, and 423.2058)

Current §§405.1034 and 423.2034 describe when an ALJ may request information from, or remand a case to a QIC or IRE. When the ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, including an IRE, or the Part D plan sponsor, current §§405.1034(a) and 423.2034(a) allow an ALJ to remand the case to the QIC or IRE that issued the reconsideration, or retain jurisdiction of the case and request that the entity forward the missing information to the appropriate hearing office. The 2005 Interim Final Rule (70 FR 11465) explained that in the rare instance in which the file lacks necessary technical information that can only be provided by CMS or its contractors, it was believed that the most effective way of completing the record is to return the case, via remand, to the contractor; however, the ALJ also had the option of asking the entity to forward the missing information to the ALJ hearing office. We stated in the proposed rule that, in practice, stakeholders have expressed frustration and concern with the remand provisions because in accordance with the definition of a remand in §405.902, a remand vacates the lower level appeal decision and therefore may require a QIC or IRE to issue a new reconsideration, for which the appellant must submit a new request for

hearing, which causes additional delay in reaching finality on the disputed claims. In addition, current §§405.1034 and 423.2034 do not address providing notice of a remand or the effects of a remand.

To address stakeholders' concerns with the current remand provisions, and areas not addressed in current §§405.1034 and 423.2034, we proposed to revise the sections to cover obtaining information that can be provided only by CMS or its contractors, or the Part D plan sponsor, and establishing new §§405.1056 and 405.1058 to address remands to a QIC, and new §§423.2056 and 423.2058 to address remands to an IRE. 81 FR 43790, 43834–43836.

We proposed in §405.1034(a) to maintain the current standards for requesting information that is missing from the written record when that information can be provided only by CMS or its contractors, but limit the action to a request for information directed to the QIC that conducted the reconsideration or its successor (if a QIC contract has been awarded to a new contractor). In addition, we proposed to review §405.1034(a) to include attorney adjudicators because attorney adjudicators would be authorized to adjudicate appeals, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). Also, while we proposed to retain the definition of “can be provided only by CMS or its contractors” in §405.1034(a)(2), we proposed at §405.1034(a)(1) to specify that official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. The redetermination and reconsideration are important documents that establish the issues on appeal, and while the parties often have copies of them, we stated in the proposed rule that we believed the record should include official copies from the contractors. In addition, we proposed at §405.1034(b) to specify that the ALJ or attorney adjudicator would retain jurisdiction of the case, and the case would remain pending at OMHA.

We proposed at §423.2034(a) and (b) to adopt corresponding provisions for when information may be requested from an IRE and that jurisdiction is retained at OMHA in part 423, subpart U proceedings.

We proposed in §405.1034(c) that the QIC would have 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the request for information, either directly or through CMS or another contractor. We stated that this would provide the ALJ or attorney adjudicator, the QIC, and the parties with a benchmark for obtaining the information and determining when adjudication of the case can resume. We proposed in §405.1034(d) that, if an adjudication period applies to the appeal in accordance with §405.1016, the adjudication period would be extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever is less. We stated that we recognize that other provisions that extend an applicable adjudication period generally involve an appellant's action or omission that delays adjudicating an appeal within an applicable time frame, but we stated in the proposed rule that we believed that an extension is also warranted to fully develop the record when the written record is missing information that is essential to resolving the issues on appeal, and that 20 calendar days (5 calendar days for the request to be received by the QIC and 15 calendar days for the QIC to respond) is a relatively modest delay in order to obtain missing information that is essential to resolving the appeal. We proposed at §423.2034(c) and (d) to adopt corresponding provisions for the IRE to furnish the information or otherwise respond to the request for information, either directly or through CMS or the Part D plan sponsor, and the effect on any applicable adjudication time frame in part 423, subpart U proceedings. In addition, we proposed at §423.2034(c) and (d) to provide for an accelerated response time frame for expedited appeals

because of the urgency involved. For expedited appeals, we proposed that the IRE would have 2 calendar days after receiving a request for information to furnish the information or otherwise respond to the request, and the extension to the adjudication time frame would be up to 3 calendar days, to allow for time to transmit the request to the IRE and for the IRE to respond.

We proposed to add new §405.1056 to describe when a request for hearing or request for review of a QIC dismissal may be remanded, and new §405.1058 to describe the effect of a remand. We proposed in §405.1056(a)(1) to permit a remand if an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with proposed §405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in §405.1034. We also proposed in §405.1056(a)(2) to permit a remand when the QIC does not furnish a case file for an appealed reconsideration. The remand under both provisions would direct the QIC or other contractor (such as a Medicare Administrative Contractor that made the redetermination) to reconstruct the record or initiate a new appeal adjudication. We stated in the proposed rule that we expected this type of remand to be very rare, but we also stated that we believed it was necessary to help ensure a complete administrative record of the administrative adjudication of a claim. To address the possibility that the QIC or another contractor is able to reconstruct the record for a remanded case, we proposed in §405.1056(a)(3) to provide that in the situation where a record is reconstructed by the QIC, the reconstructed record would be returned to OMHA, the case would no longer be remanded and the reconsideration would no longer be vacated, and if an adjudication period applies to the case, the period would be extended by the time between the date of the remand and the date the case is returned to OMHA (because OMHA was unable to adjudicate the appeal between when it was remanded and when it was returned to OMHA). We stated that this would help ensure that

appellants are not required to re-start the ALJ hearing or dismissal review process in the event that the QIC or another contractor is able to reconstruct the record. We proposed at §423.2056(a) to adopt corresponding provisions for remanding cases in which there is a missing appeal determination or the IRE is unable to furnish the case file in part 423, subpart U proceedings.

On occasion, an ALJ finds that a QIC issued a reconsideration that addresses coverage or payment issues related to the appealed claim when a redetermination was required and no redetermination was conducted, or the contractor dismissed the request for redetermination and the appellant appealed the contractor's dismissal. We stated in the proposed rule that, in either circumstance, the reconsideration was issued in error because the appellant did not have a right to the reconsideration in accordance with current §405.960, which only provides a right to a reconsideration when a redetermination is made by a contractor. We stated that we do not believe that an administrative error made by the QIC conveys rights that are not afforded under the rules. We proposed in §405.1056(b) to address these circumstances so that, if an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required) or the request for redetermination was dismissed (and not vacated), the reconsideration would be remanded to the QIC that issued the reconsideration, or its successor, to re-adjudicate the request for reconsideration. We again stated in the proposed rule that we expected this type of remand to be rare, but believed it was necessary to correct administrative errors in the adjudication process. We proposed at §423.2056(b) to adopt a corresponding provision for when an IRE issues a reconsideration that addresses drug coverage when no redetermination was conducted or a request for redetermination was dismissed and is appealed to OMHA under part 423, subpart U.

OMHA ALJs sometimes receive requests for remands from CMS or a party because the matter can be resolved by a CMS contractor if jurisdiction of the claim is returned to the QIC. Current §405.1034 does not address this type of request. We proposed at §405.1056(c)(1) to provide a mechanism for these remands. Specifically, we proposed that at any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors, may jointly request a remand of the appeal to the entity that conducted the reconsideration. We proposed that the request include the reasons why the appeal should be remanded and indicate whether remanding the case would likely resolve the matter in dispute. Proposed §405.1056(c)(2) would allow the ALJ or attorney adjudicator to determine whether to grant the request and issue the remand, based on his or her determination of whether remanding the case would likely resolve the matter in dispute. We stated that we believe this added flexibility would allow appellants and CMS and its contractors to expedite resolution of a disputed claim when there is agreement to do so. We proposed at §423.2056(c) to adopt corresponding provisions for requested remands in part 423, subpart U proceedings.

Current §405.1034(b) provides that if, consistent with current §405.1004(b), the ALJ determines that a QIC's dismissal of a request for reconsideration was in error, the case will be remanded to the QIC. We proposed at §405.1056(d) to incorporate this provision and to adopt a corresponding provision in §423.2056(d) to incorporate current §423.2034(b)(1) for remanding cases in which an IRE's dismissal of a request for reconsideration was in error, in part 423, subpart U proceedings. In addition, we proposed at §423.2056(e) to incorporate current §423.2034(b)(2), which provides that if an enrollee wants evidence of a change in his or her condition to be considered in the appeal, the appeal would be remanded to the IRE for consideration of the evidence on the change in condition.

Current §405.1034(c) provides that the ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), and provides that unless the appellant is entitled to such relief, the ALJ applies the LCD or NCD in place on the date the item or service was provided. We proposed to incorporate these provisions at §405.1056(e). We did not propose any corresponding provision for §423.2056 because there is not a similar current provision for part 423, subpart U proceedings.

As noted above, current §405.1034 does not address providing a notice of remand. We proposed at §405.1056(f) to provide that OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant to the proceedings or a party to the hearing. The notice would state that, as discussed below, there is a right to request that the Chief ALJ or a designee review the remand. We stated in the proposed rule that we believed this would help ensure that the parties and CMS and its contractors receive notice that the remand order has been issued. We proposed at §423.2056(f) to adopt a corresponding provision for a notice of remand in part 423, subpart U proceedings, except that only the enrollee receives notice because only the enrollee is a party, and CMS, the IRE, and the Part D plan sponsor only receive notice if they requested to participate and the request was granted.

Stakeholders have recounted instances in which they believe a remand was not authorized by the regulations, but were unable to take any action to correct the perceived error because a remand is not an appealable action and current §405.1034 does not provide a review mechanism. We stated that we do not believe that remands should be made appealable actions, but recognize

that stakeholders need a mechanism to address remands that they believe are not authorized by the regulation. We proposed in §405.1056(g) to provide a mechanism to request a review of a remand by allowing a party or CMS, or one of its contractors, to file a request to review a remand with the Chief ALJ or a designee within 30 calendar days of receiving a notice of remand. If the Chief ALJ or designee determines that the remand is not authorized by §405.1056, the remand order would be vacated. We also proposed that the determination on a request to review a remand order is binding and not subject to further review so adjudication of the appeal can proceed. We proposed at §423.2056(g) to adopt a corresponding provision for reviewing a remand in part 423, subpart U proceedings.

Current §405.1034 does not discuss the effect of a remand. We proposed at §405.1058, similar to current §§405.1048 and 405.1054 which describe the effects of a decision and dismissal, respectively, that a remand of a request for hearing or request for review is binding unless it is vacated by the Chief ALJ or a designee in accordance with proposed §405.1056(g). We stated in the proposed rule that we believed the provision would add clarity for the parties and other stakeholders on the effect of a remand order. We proposed at §423.2058 to adopt a corresponding provision for the effect of a remand in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received one comment requesting clarification on why proposed §§405.1034(a)(1) and 423.2034(a)(1) require that official copies of redeterminations and reconsiderations that were conducted on the appealed issues can only be provided by CMS and its contractors or by CMS, the IRE, and/or the Part D Plan Sponsor, respectively, when the appellant can also furnish a copy of the same documents. The commenter believes that it is

unnecessary and unfair to extend the adjudication period 15 days or more to obtain the “official copy.”

Response: Because OMHA is tasked with compiling the official administrative record, it is necessary that OMHA obtain official versions of the redetermination decision and the reconsideration decision directly from the contractors if they are missing on appeal. These documents establish the issues on appeal and are therefore important evidence in the administrative record. Although parties often have copies of these documents as well, copies may be altered or edited and there is no way to verify their authenticity unless they come directly from the contractor.

We do not believe that proposed §§405.1034(a)(1) and 423.2034(a)(1) place any unnecessary burden on the parties or that they will cause significant delays in the adjudication of appeals. First, we note that in many cases the lower levels decisions are available on a CMS case processing system that is accessible to OMHA. If the missing lower level decision is uploaded to an official system of record (generally the case processing system used by the contractor and accessible to OMHA), then OMHA could accept that document as the official copy. In these cases, no information request would be necessary under §§405.1034(a) or 423.2034(a). We are modifying the language in §§405.1034(a)(1) and 423.2034(a)(1) to clarify that prior to submitting an information request, OMHA must first check the system of record to confirm whether a copy of the missing lower level decision is available there. In the extremely small number of cases where official copies were not provided in the record and were not uploaded by the contractor to the case processing system, then the ALJ or attorney adjudicator would use the proposed regulations to request an official copy of the missing lower level decision. In these cases, the adjudication period may be extended pursuant to §§405.1034(d) or 423.2034(d).

However, given the ready availability of such evidence in the contractor's system, it should take minimal time for the contractor to produce the necessary documents, and we would anticipate that the extension also would be minimal.

Comment: One commenter expressed support for the sections in proposed §405.1056 and §405.1058 that describe when a request for hearing or a request for review of a QIC dismissal may be remanded and the effects of a remand. The commenter specifically appreciated the revisions that state that when a record has been reconstructed by the QIC on remand that it would be returned to OMHA, stating that this procedure helps ensure that appellants are not required to restart the whole review process. The commenter did have concerns, however, about proposed §405.1056(b), which requires a remand where the QIC issued a reconsideration decision but no redetermination decision had been made or the request for redetermination was dismissed, because the commenter felt that provision would result in the appellant unnecessarily having to start over at the first level of appeal. The commenter provided an example in which a redetermination decision was issued upholding a technical denial and then the appellant submitted evidence at the reconsideration level that cured the technical defect. In the example, the commenter argued that if the QIC proceeded to issue a reconsideration decision that addressed availability of coverage and payment issues and the reconsideration were appealed to OMHA, it would be a waste of time and resources for the ALJ or attorney adjudicator to remand the matter back to the QIC under §405.1056(b) to have the QIC remand the case back to the Medicare administrative contractor for a redetermination decision addressing coverage and payment. The commenter requested additional examples of how §405.1056(b) may impact appeals brought on behalf of Medicare beneficiaries and Medicaid State agencies.

Response: We thank the commenter for its support and agree that the proposals streamline the process for remands and will benefit appellants in instances when an appeal can be returned to the OMHA level of review without having to re-file an appeal, when the QIC or a contractor is able to reconstruct the record. We disagree, however, that proposed §405.1056(b) would result in appellants having to re-file appeals unnecessarily or result in a waste of time and resources. Proposed §405.1056(b) is intended to address two situations where a necessary redetermination was not issued but is required before the QIC can issue a reconsideration addressing coverage and payment issues. In the first situation, the contractor did not issue any redetermination. Pursuant to §405.972(b)(6), the QIC must dismiss the reconsideration request in this situation and does not have authority to issue a reconsideration decision addressing coverage or payment issues. In the second situation, the contractor dismissed the redetermination request. Pursuant to §405.974(b), a party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by the QIC. The QIC, however, does not have authority to issue a reconsideration decision addressing coverage and payment issues in this situation. As outlined in §405.974(b)(2) and (3), the QIC may either determine that the dismissal was in error and vacate the dismissal and remand the case to the contractor for a redetermination, or the QIC may affirm the dismissal as correct and the party is bound by that determination and has no further appeal review options. Because the QIC does not have authority to issue a reconsideration decision that addresses coverage and payment issues in either of the situations, if the QIC issues such a reconsideration decision it has done so in error. If the reconsideration decision was issued in error, the request for hearing must be remanded to the QIC pursuant to §405.1056(b). Although we believe that this type of remand will be rare, we believe it is necessary to correct administrative errors in the adjudication process. We do not believe that an

administrative error made by the QIC conveys rights that are not afforded under the rules and, therefore, believe that proposed §405.1056(b) is a necessary revision.

We do not believe that proposed §405.1056(b) would apply to the facts that were outlined in the commenter's example. In the example presented in the comment, the contractor did issue a redetermination, albeit a denial on technical grounds. The part 405, subpart I regulations do not make a distinction between redeterminations based on a technical denial and redeterminations based on other reasons, such as a denial because the item or service was not medically reasonable and necessary. Both redeterminations would give the party a right to request a QIC reconsideration on the coverage and payment issues. The party would then have a right to appeal the QIC's reconsideration for an ALJ hearing, provided the amount in controversy and other filing requirements were met, and the remand provisions of proposed §405.1056(b) would not apply.

Further, proposed §405.1056(b) applies to any request for hearing on a QIC reconsideration where the QIC issued a coverage and payment decision in error as discussed above. We do not believe there are any special considerations regarding the proposal that would apply differently based on the party appealing the claim, and therefore do not believe adding examples of how the proposal impacts an appeal filed by a beneficiary or a Medicaid State agency will be helpful.

Comment: The same commenter also had reservations about proposed §405.1056(c), which would allow the appellant and CMS or its contractor to jointly request a remand to the QIC or IRE at any time before the ALJ or attorney adjudicator issues a decision or dismissal. The commenter suggested that such "joint request" would likely be initiated and facilitated by CMS or its contractor and that those entities would have greater knowledge and bargaining power than

appellants, especially appellants who are unrepresented beneficiaries. The commenter suggested that ALJs should be required to hold pre-hearing conferences to confirm both parties' understanding of the possible ramifications if the remand is granted and requested additional information on how beneficiaries' interests would be protected under §405.1056(c).

Response: We disagree with the commenter that proposed §405.1056(c) would operate to place appellants, including appellants who are unrepresented beneficiaries, into a disadvantaged position. Proposed §405.1056(c) requires that any request for remand under this provision must be a joint request between the appellant and CMS or its contractors. We believe there is little incentive for an appellant to agree to a remand unless his or her claim will be paid in part or full or the resolution offered by CMS and its contractors on remand would be otherwise acceptable to the appellant, such as the review of new evidence in the appeal. We also see little advantage to CMS or its contractors in requesting remands unless they believe that they are able to effectively resolve a dispute in such a way that the resolution is mutually acceptable and the appellant will not appeal again. Although the commenter was concerned that appellants, and especially unrepresented beneficiaries, may have insufficient knowledge or bargaining power to protect themselves from entering joint remand requests that are not to their benefit, we believe that the requirements regarding a statement of the reasons for the remand, the likely resolution of the dispute, and the ALJ's or attorney adjudicator's review of these statements is a significant and sufficient safeguard. We believe that the adjudicator's review of the joint request and submitted statements will help ensure that the remand is truly jointly requested and that all individuals and entities involved are in agreement regarding the reasons for and likely resolutions of the remand. Although the commenter recommended a pre-hearing conference instead to determine that the parties understand the ramifications of a remand, we believe that requiring written reasons and a

statement indicating whether the remand will likely resolve the matter in dispute is sufficient. Further, under proposed §405.1056(c)(2), the ALJ or attorney adjudicator would have discretion in granting the remand request and may only grant the request if he or she determines that remanding the case will likely resolve the matter in dispute. If the appellant is not going to be favorably treated on remand, then the appellant is likely to appeal the issue again to the OMHA level and the dispute will not be resolved. Therefore, the requested remands will only be granted where the likely resolution is favorable and/or unlikely to lead to subsequent appeal. We believe that proposed §405.1056(c) provides a valuable tool to appellants that will allow expedited resolution of a disputed claim when there is agreement between the appellant and CMS and its contractors, and that the regulation contains sufficient safeguards to protect the appellants, including unrepresented beneficiaries.

Comment: We received one comment opposing the new review mechanisms for remand orders proposed in §§405.1056(g) and 423.2056(g). The commenter believes that these proposals result in an unprecedented authorization of power in the Chief ALJ or a designee to reverse the decisions of ALJs, and unnecessarily raise issues of ex parte communication and the appearance of impropriety. The commenter also suggested that the proposed review mechanism was problematic because the Chief ALJ's ability to delegate is not limited and the commenter believes the proposal conflicts with the APA concepts of an ALJ's qualified decisional independence and rotational assignment of appeals. The commenter stated that remands are rarely issued under the current rules, and recommended that a preferable alternative to the proposals would be to substantially limit the ALJs' remand authority.

Response: We proposed the review mechanisms in §§405.1056(g) and 423.2056(g) to give stakeholders, including appellants and CMS contractors, a means of recourse if an appeal is

remanded and they believe the remand is outside of the scope of the remand regulations. As we state above, although we do not believe that remands should be made appealable actions, we believe some mechanism to challenge remands is necessary to be responsive to stakeholders who, in the past, believed that some remands were not authorized by the regulations and who felt that they did not have any way to address or correct the perceived error. Because a remand likely adds additional adjudication time and delay to the appeals process, we believe that providing a review mechanism to stakeholders is fair and will help ensure that remands that are outside of the scope of the remand regulations do not derail appeals in error.

The review mechanisms proposed in §§405.1056(g) and 423.2056(g) also are intended to help ensure consistency in processing appeals. Previously, if an appeal was remanded to the QIC or IRE and that level of review did not agree that there was jurisdiction for the remand under current §§405.1034 or 423.2034, there was no clear guidance on how to proceed. Some QICs or IREs would reopen the previous decision while others would respond to the remand via a different mechanism. When ALJs issued remand orders outside of the scope of §§405.1034 or 423.2034, it created inconsistencies and confusion not only for CMS and its contractors regarding how to proceed, but also for appellants regarding the status and handling of their appeal. The proposed review mechanisms will help ensure that the procedural remand rules are applied in a consistent manner and that the processing of the remands at lower levels is also more uniform.

We limited the review authority to the Chief ALJ or a designee so that limited individuals within the agency will be tasked with this new review responsibility, which is a limited-scope review of a discrete procedural question. In this way, we believe that the requested reviews can be completed both consistently and efficiently. We added the ability for the Chief ALJ to

designate other individuals to assist with the review of remands, if necessary, to ensure that there will be adequate resources to complete the reviews as expeditiously as possible, so the appeal can proceed as remanded, or with the ALJ.

We disagree with the commenter that the proposed review mechanisms may be used to reverse ALJ decisions or to override the qualified decisional independence that ALJs have when making decisions. We believe that remands are distinct from the decisions described in sections 554 and 556 of the APA because the permitted remands are generally procedural mechanisms that do not resolve the issues on appeal, but rather return the appeal to the second level of the appeals process without a resolution of the appealed matter. The one exception to this distinction is when the remand is issued on a request for review of a QIC's or IRE's dismissal of a request for reconsideration. In §§405.1056(d) and 423.2056(d) as finalized in this rule, an ALJ or attorney adjudicator issues a remand to the appropriate QIC or IRE if the ALJ or attorney adjudicator determines that the dismissal of a request for reconsideration was in error. We recognize that remands issued on review of a QIC's or IRE's dismissal of a request for reconsideration are more akin to a determination than a purely procedural mechanism. Therefore, we are modifying the language in §§405.1056(g) and 423.2056(g) to specifically exempt remands that are issued under §§405.1056(d) and 423.2056(d) from potential review by the Chief ALJ or designee. The remaining remands, however, are issued on procedural grounds. We do not agree that creating a review mechanism for remands issued on procedural grounds impinges on an ALJ's qualified decisional independence with respect to his or her decisions. Further, we do not agree that the proposal interferes with rotational assignments of appeals because there is no right to an ALJ hearing when a request for review of an ALJ remand is made, thus the rotational assignment principle of 5 U.S.C 3105 does not apply.

We also do not agree with the commenter that this review mechanism will result in ex parte communications or the appearance of impropriety. Ex parte communications involve communications that are not on the record between an individual involved in the decisional process and an interested party outside of the agency about the merits of the proceedings. See 5 U.S.C. 557(d). The proposed review mechanisms in §§405.1056(g) and 423.2056(g) permit either a party or CMS, or one of its contractors, to file a request to review a remand within 30 calendar days of receiving the notice of remand, which would be made part of the record. The proposed regulation provides for the same procedure regardless of the entity or individual requesting the review.

Finally, with respect to the suggested alternative of substantially limiting the ALJs' remand authority, we disagree with the commenter that the stakeholders' concerns that prompted this proposal would be sufficiently addressed by that alternative. The current regulations already substantially limit the ALJs' authority to remand and yet there have been instances, despite those limitations, where stakeholders still felt that remands were issued that were not authorized by the regulations. In addition, §§405.1056 and 423.2056, as finalized in this rule, do not expand the ALJs' remand authority compared to the current remand regulations in §§405.1034 and 423.2034, but rather they set forth the limited circumstances in which a remand may be issued. Although §§405.1056 and 423.2056 list specific situations where a remand may be issued, these provisions are narrower than the current provisions at §§405.1034 and 423.2034 because they do not include the general language at §§405.1034 and 423.2034 providing for a remand when the ALJ believes the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors. Instead, §§405.1034(a) and 423.2034(a), as finalized in this rule, require that the ALJ or attorney

adjudicator first request that information from the QIC or IRE. Although the ALJ or attorney adjudicator may still remand a case under §§405.1056(a) and 423.2056(a) if the QIC or IRE fail to provide an official copy of a missing redetermination or reconsideration or fail to provide the case file after a request for information under §§405.1034(a) and 423.2034(a),, the specific circumstances in which remands can occur have been narrowed as compared to the broader remand authority set forth in current §§405.1034 and 423.2034. Because remands are only available in limited and narrowly defined circumstances in §§405.1056 and 423.2056, we anticipated that the review mechanisms created by this proposal will be used infrequently. We agree with the commenter that remands are rarely used today and, therefore, believe that the use of the review mechanisms proposed in §§405.1056(g) and 423.2056(g) would be even rarer.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing §§405.1058 and 423.2058 as proposed without modification, and we are finalizing the changes to §§405.1034, 405.1056, 423.2034, and 423.2056 as proposed, with the following modifications. We are amending §§405.1034(a)(1) and 423.2034(a)(1) to provide that prior to issuing a request for information to the QIC or IRE, OMHA will confirm whether an electronic copy of the missing redetermination or reconsideration is available in the official system of record, and if so, will accept the electronic copy as an official copy. In addition, we are amending §§405.1056(g) and 423.2056(g) to add language to specifically exempt remands that are issued under §§405.1056(d) and 423.2056(d) (on a review of a QIC's or IRE's dismissal of a request for reconsideration) from potential review by the Chief ALJ or designee. Finally, we are replacing "can only be provided by CMS, the IRE, and/or the Part D plan sponsor" in proposed §423.2034(a)(1), which was a drafting

error, with “can be provided only by CMS, the IRE, and/or the Part D plan sponsor,” for consistency with the definition in §423.2034(a)(2).

q. Description of the ALJ hearing process and discovery (§§405.1036, 405.1037, and 423.2036)

As described below, we proposed a number of changes to §§405.1036 and 423.2036, which describe the ALJ hearing process, including the right to appear and present evidence, waiving the right to appear at the hearing, presenting written statements and oral arguments, waiver of the adjudication period, what evidence is admissible at the hearing, subpoenas, and witnesses at a hearing. 81 FR 43790, 43836–43837. Current §405.1037 describes the discovery process in part 405, subpart I proceedings, which is permitted when CMS or a contractor elects to be a party to the ALJ hearing; there is no corresponding provision for part 423, subpart U proceedings because CMS, the IRE, and the Part D plan sponsor may not be made parties to the hearing.

Current §405.1036(b)(1) states that a party may “send the ALJ” a written statement indicating that he or she does not wish to appear at the hearing. We proposed at §405.1036(b)(1) to revise this provision to state that a party may “submit to OMHA” a written statement indicating that he or she does not wish to appear at the hearing. We stated in the proposed rule that while the written statement could still be sent to an ALJ who is assigned to a request for hearing, we proposed that the statement could be submitted to OMHA (for example, the statement could be submitted with the request for hearing), or to the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), after the request is assigned, to provide more flexibility and to accommodate situations where an ALJ or attorney adjudicator has not been assigned a request for hearing. We proposed at §423.2036(b)(1) to adopt a corresponding revision for submitting a waiver of the right to

appear in part 423, subpart U proceedings. In addition, we proposed at §423.2036(b)(1)(ii) to revise the current requirement for the “ALJ hearing office” to document oral requests to require “OMHA” to document oral requests, to help ensure that applicability of the requirement is clear regardless of whether the oral request is received by an adjudicator in an OMHA field office after the appeal is assigned to an ALJ or attorney adjudicator, or the oral request is received in the OMHA central office before the appeal is assigned to an ALJ or attorney adjudicator.

As discussed in section III.A.3.h of the proposed rule and II.B.3.h of this final rule above, we proposed to move the provision for waiving the adjudication period from current §405.1036(d) to proposed §405.1016(d) because proposed §405.1016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers. To accommodate moving current §405.1036(d) to proposed §405.1016(d), we proposed to re-designate current §405.1036(g), which describes witnesses at the hearing, as §405.1036(d), because it more logically follows the discussion of presenting witnesses and oral arguments in current §405.1036(c). For the same reasons, we proposed to move the provisions at §423.2036(d) to §423.2016(c), and proposed at §423.2036(d) to re-designate current §423.2036(g) as §423.2036(d) to describe witnesses at a hearing in part 423, subpart U proceedings.

Current §405.1036(f) discusses subpoenas. Current §405.1036(f)(5)(i) states that an ALJ ruling on a subpoena request is not subject to immediate review by the Council and may be reviewed solely during the course of the Council’s review specified in §405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), §405.1104 (for requests for escalation to the Council), or §405.1110 (for referrals for own motion review by the Council). As discussed in section III.A.3.h.ii of the proposed rule and II.B.3.h.ii of this final rule above, we proposed to remove section §405.1104 and relocate provisions dealing with escalation to the

Council to §405.1016. Because the process for requesting escalation to the Council is now described in proposed §405.1016(e) and (f), we proposed at §405.1036(f)(5)(i) to replace the reference to §405.1104 with a reference to §405.1016(e) and (f). Current §405.1036(f)(5)(ii) discusses CMS objections to a “discovery ruling” in the context of a paragraph on reviewability of subpoena rulings and current §405.1037(e)(2)(i) separately addresses CMS objections to a discovery ruling. We proposed to revise §405.1036(f)(5)(ii) to replace the current reference to a “discovery ruling” with “subpoena ruling” so it is consistent with the topic covered by §405.1036(f). No corresponding revisions are necessary in §423.2036(f) because there is no reference to a “discovery ruling.”

Current §405.1037(a)(1) provides that discovery is permissible only when CMS or its contractors elects to participate in an ALJ hearing as a party. We stated in the proposed rule that, while the intent is generally clear, the use of “participate” is potentially confusing given that CMS or one of its contractors can elect to be a participant in the proceedings, including the hearing, in accordance with current and proposed §405.1010, or elect to be a party to the hearing in accordance with current and proposed §405.1012. We proposed to revise §405.1037(a)(1) to state that discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with proposed §405.1012. As noted above, there are no provisions for discovery in part 423, subpart U proceedings because CMS, the IRE, or the Part D plan sponsor are not permitted to be a party to the hearing.

Current §405.1037(e)(1) states that an ALJ discovery ruling or disclosure ruling is not subject to immediate review by the Council and may be reviewed solely during the course of the Council’s review specified in §405.1100 (for Council review in general), §405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), §405.1104 (for requests for

escalation to the Council), or §405.1110 (for referrals for own motion review by the Council). For the reasons discussed above with regard to similar proposed changes in §405.1036, we proposed at §405.1037(e)(1) to replace the reference to §405.1104 with a reference to §405.1016(e) and (f).

Current §405.1037(f) describes the effect of discovery on an adjudication time frame, and provides that the time frame is tolled until the discovery dispute is resolved. However, we stated in the propose rule that it does not clearly state when the effect on an adjudication time frame begins, and “discovery dispute” is not used elsewhere in the section. In addition, we stated that current §405.1037(f) does not contemplate that an adjudication time frame may not apply (for example, when the adjudication time frame is waived in accordance with proposed §405.1016(d)). Therefore, we proposed to revise §405.1037(f) to state that if an adjudication period applies to the appeal in accordance with §405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery. We stated in the proposed rule that we believed this revision would provide a clearer standard for how an adjudication period is affected by discovery proceedings.

We received no comments on these proposals, other than comments discussed in section II.A.4 above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1036, 405.1037, and 423.2036 as proposed without modification.

r. Deciding a case without a hearing before an ALJ (§§405.1038 and 423.2038)

As described below, we proposed several changes to §§405.1038 and 423.2038, concerning when a case may be decided without a hearing before an ALJ. 81 FR 43790, 43837–43838. Current §405.1038(a) provides authority to issue a “wholly favorable” decision without a hearing before an ALJ and without giving the parties prior notice when the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue. We proposed in §405.1038 that if the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012. Proposed §405.1038(a) would replace “wholly favorable” with “fully favorable” in the subsection heading to align with language in §405.1000(g), which addresses a fully favorable decision being made on the record, and the nomenclature used in OMHA’s day to day operations. Proposed §405.1038(a) would also replace “hearing record” with “administrative record” for consistency with other references to the record, and replace “hearing decision” with “decision,” for consistency with other references to a decision. We proposed at §423.2038(a) to adopt corresponding revisions to align with language in §423.2000(g) and to make references to the record and decisions consistent in part 423, subpart U proceedings.

Proposed §405.1038(a) would also add two new limitations on issuing a decision without a hearing before an ALJ when the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. First, a decision could not be issued pursuant to proposed §405.1038(a) if another party to the appeal is liable for the claims at issue. Second, a

decision could not be issued pursuant to proposed §405.1038(a) if CMS or a contractor elected to be a party to the hearing in accordance with §405.1012. We stated in the proposed rule that we recognized that this may limit decisions that may be issued pursuant to §405.1038(a); however, we also stated that we believed only a small number of appeals would be affected, and the new limitations would mitigate the impact of such a decision on the other parties to the appeal and the likelihood of an appeal to, and remand from, the Council. No corresponding changes were proposed in §423.2038(a) because only the enrollee is a party in part 423, subpart U proceedings.

Current §405.1038(b)(1) permits the ALJ to decide a case on the record and not conduct a hearing if: (1) all the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or (2) an appellant lives outside of the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear. We proposed to retain this structure in proposed §405.1038(b) but did propose some changes. Current §405.1038(b)(1)(i) requires all parties to indicate in writing that they do not wish to appear before the ALJ at a hearing, and as indicated above, current §405.1038(b)(1)(ii) is contingent on no other parties wishing to appeal. However, the requirement to obtain a writing from all parties or determine the wishes of the non-appellant parties has limited the utility of the provisions. While all parties have a right to appear at the hearing, a notice of hearing is not sent to parties who did not participate in the reconsideration and were not found liable for the items or services at issue after the initial determination, in accordance with current §405.1020(c). We proposed at §405.1038(b)(1)(i) and (b)(1)(ii) to modify the requirements so writings only need to be obtained from, or wishes assessed from, parties who would be sent a notice of hearing, if a hearing were to be conducted. We stated that using the notice of hearing standard protects the interests of potentially liable

parties, while making the provisions a more effective option for the efficient adjudication of appeals. In addition, proposed §405.1038(b)(1) would reinforce that only an ALJ conducts a hearing by indicating an ALJ or attorney adjudicator may decide a case on the record without an ALJ conducting a hearing. Proposed §405.1038(b)(1)(ii) also would indicate that an appellant who lives outside of the United States would inform “OMHA” rather than “the ALJ” that he or she wants to appear at a hearing before an ALJ, so an appellant could make that indication before an appeal is assigned to an ALJ or attorney adjudicator. We proposed at §423.2038(b)(1) and (b)(1)(ii) to adopt corresponding revisions to reinforce that only an ALJ conducts a hearing and an enrollee who lives outside of the United States would inform OMHA that he or she wishes to appear at a hearing before an ALJ, but the other changes in proposed §405.1038(b) were not proposed in §423.2038(b) because only the enrollee is a party in part 423, subpart U proceedings. We also proposed in §405.1038(b)(1)(i) to replace “videoteleconferencing,” and in §423.2038(b)(1)(i) to replace “video teleconferencing,” with “video-teleconferencing,” for consistency with terminology used in §§405.1000, 405.1036, 423.2000, 423.2020, and 423.2036.

On occasion, CMS or one of its contractors indicates that it believes an item or service should be covered or payment made on an appealed claim, either before or at a hearing. However, there are no current provisions that address this circumstance, and we stated in the proposed rule that it is one that is ideal for a summary decision in favor of the parties based on the statement by CMS or its contractor, in lieu of a full decision that includes findings of fact, conclusions of law, and other decision requirements. We proposed to add §405.1038(c) to provide a new authority for a stipulated decision, when CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or paid. In this situation, an ALJ or attorney adjudicator may issue a stipulated decision

finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision. We proposed at §423.2038(c) to adopt a corresponding authority for stipulated decisions in part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received ten comments on the proposed limitations to issuing a decision without a hearing before an ALJ when the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. Six commenters opposed adding that a decision cannot be issued pursuant to proposed §405.1038(a) if CMS or a contractor elects to be a party to the hearing in accordance with §405.1012. The commenters stated that the position of CMS and its contractors will be well established in the administrative record by the time the appeal reaches OMHA, and the record will contain all of the information available to the contractor at the time of its determination. The commenters stated that CMS and its contractors should not be allowed to delay the ALJ's or attorney adjudicator's decision if the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. Two of the commenters stated that this limitation could result in CMS contractors electing party status to force a hearing even when the record supports a fully favorable decision.

Response: As discussed above, we believe only a small number of appeals will be affected by the limitation in proposed §405.1038(a) on issuing fully favorable decisions without a hearing before an ALJ when CMS or its contractor has elected to be a party to the hearing in accordance with §405.1012. In accordance with proposed §405.1012(a)(1), CMS or a contractor cannot elect to be a party to a hearing if the request for hearing was filed by an unrepresented

beneficiary. Further, CMS or a contractor can only elect to be a party to a hearing in response to the notice of hearing pursuant to §405.1012(b), or at the ALJ's request. Currently, very few decisions are issued under §405.1038(a) after a hearing is scheduled and the notice of hearing is sent to the parties and potential parties and participants. We expect that to continue to be true, but under current §405.1038(a) there have been occasions when an ALJ has issued a decision in an appellant's favor without conducting a hearing, after a hearing has been scheduled and CMS or its contractor has elected to be a party to the hearing.

If CMS or its contractor has properly elected to be a party, it has a right to appear at an ALJ hearing. As the claims payor, CMS and its contractors have an interest in the outcome of the case, similar to any other party to the appeal that is or may be liable for the claims at issue. Regardless of whether CMS's position may be apparent from the administrative record by the time an appeal reaches the OMHA level, CMS or a contractor that has properly elected party status has the right to present its arguments before the ALJ at the hearing. That right continues even if a fully favorable decision is issued under §405.1038(a) as finalized in this rule, which provides that the notice of decision informs the parties that they have a right to a hearing. Thus, issuing a decision in the appellant's favor after CMS or its contractor has elected to be a party and without conducting the scheduled hearing would be an appealable issue to the Council and possibly result in a remand to OMHA to conduct the hearing, resulting in wasted resources at the Council to process the appeal and remand, and further delaying finality of the appeal for the parties. We do not agree that the proposal will result in CMS or its contractors electing party status to "force a hearing" because a hearing would already have to be scheduled for CMS or its contractors to elect party status. As noted above, very few decisions are currently issued under §405.1038(a) after a hearing has been scheduled and CMS and its contractors have had the

opportunity to elect party status. Therefore, we do not believe that §405.1038(a), as finalized in this rule, will create a significant incentive for CMS or its contractors to elect party status just to force a hearing in those few cases where a decision might otherwise be issued on the record after a hearing has been scheduled. For the reasons discussed above, we believe that limiting decisions that can be issued under proposed §405.1038(a) when CMS or a contractor has elected to be a party will only affect a small number of cases, and will reduce the number of those cases that are appealed to, and remanded from, the Council.

Comment: Two commenters stated that limiting decisions that can be made without a hearing will weaken the effectiveness of attorney adjudicators by reducing the number of appeals they can decide.

Response: We do not agree that this proposal will weaken the effectiveness of attorney adjudicators. As noted above, these limitations will not affect a significant number of cases and will prevent attorney adjudicators from making decisions that would likely be subject to appeal to the Council by non-appellant parties seeking their right to a hearing, and possible remand back to OMHA for an ALJ to conduct the hearing.

Comment: One commenter suggested clarifying the procedure for transferring a case from an ALJ to an attorney adjudicator when the case is appropriate for a decision without conducting a hearing.

Response: As discussed in section II.A.2 above, OMHA's business practice is to assign appeals to ALJs in rotation so far as practicable, and appeals will be assigned to attorney adjudicators in the same manner. If an appeal is initially assigned to an ALJ but is deemed appropriate for a decision by an attorney adjudicator, the appeal would be reassigned to an attorney adjudicator in the same manner as a new appeal assignment to an attorney adjudicator.

More information on the appeal assignment process is available in the OCPM, which is accessible to the public at the OMHA website (www.hhs.gov/omha).

Comment: One commenter requested clarification regarding the time frame for requesting a hearing after a fully favorable decision is issued pursuant to §405.1038(a) or §423.2038(a), as the regulation states the parties have the right to a hearing but is silent regarding the time frame for requesting a hearing.

Response: The language in proposed §§405.1038(a) and 423.2038(a) stating that the parties have the right to a hearing is carried over from current §§405.1038(a) and 423.2038(a). As discussed in section II.A.2 above, parties to an appeal that is decided without a hearing may pursue their right to a hearing by requesting a review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision. The request for review by the Council must be filed in accordance with proposed §§405.1102 and 423.2102.

Comment: One commenter stated that an ALJ should be allowed to issue a decision that is fully favorable to the appellant without conducting a hearing even if another party is liable for the claims at issue, as long as the party that is liable for the claims at issue waives its right to appear at a hearing.

Response: If all of the parties who would be sent a notice of hearing, which under proposed §405.1020(c)(1) would include, among others, the appellant and any other party who is or may be liable for the claims at issue, indicate in writing that they do not wish to appear at a hearing, an ALJ or attorney adjudicator may decide a case on the record pursuant to §405.1038(b).

Comment: Two commenters stated that if an appellant waives the right to a hearing before an ALJ under §§405.1038 and 405.1020, and the case is decided by an attorney

adjudicator rather than an ALJ, the administrative record must demonstrate that the waiver was valid and informed. One commenter expressed concern that appellants may be motivated to waive a hearing in order to avoid the delay of waiting for an ALJ hearing, and stated that appellants should be assured that a decision will generally be made by an ALJ or attorney adjudicator in the same time frame.

Response: As finalized in this rule, §§405.1038(b) and 405.1020(d) provide that a decision may be issued by an attorney adjudicator or an ALJ if all the parties that would be sent a notice of hearing in accordance with §405.1020(c) waive a hearing before an ALJ in writing. Publication of this final rule will inform appellants of the possibility that an attorney adjudicator may decide a case if the parties waive the right to a hearing. Accordingly, we do not believe that any further documentation of a party's understanding is necessary to demonstrate a valid waiver. However, we will review the current optional HHS form for waiving an ALJ hearing (Form HHS-723, Waiver of Right to an Administrative Law Judge (ALJ) Hearing), and consider making changes to reinforce this provision of the rule for those who choose to use that form.

ALJs and attorney adjudicators will be subject to the same time frames for issuing a decision, dismissal, or remand, as discussed in section II.B.3.h above, including when decisions are issued under §§405.1038(b) and 423.2038(b) as finalized in this rule. However, we note that if all of the parties waive a hearing and a decision can be issued pursuant to §405.1038(b) or §423.2038(b) without conducting a hearing, the decision may be issued sooner than if a hearing were scheduled and conducted, regardless of whether an ALJ or attorney adjudicator issues the decision under §405.1038(b) or §423.2038(b). Scheduling a hearing requires the ALJ to determine an available hearing date and time and give the parties sufficient advance notice (at least 20 calendar days under §405.1022(a) and for non-expedited Part D hearings under

§423.2022(a)). Sections 405.1020(e)(4) and 423.2020(e)(4) allow for hearings to be rescheduled if a party or the enrollee objects to the scheduled date and/or time and the ALJ finds good cause to reschedule the hearing, which could result in even longer delays. Appellants who wish to avoid the additional time it takes to schedule and conduct a hearing before a decision can be issued may choose to waive the hearing.

Comment: Three commenters strongly supported our proposal to allow stipulated decisions in favor of the parties based on a statement by CMS or its contractor that an item or service should be covered or payment made on an appealed claim. One commenter questioned whether there may be circumstances in which it may be in a party's interest to obtain a full decision with findings of fact or conclusions of law regarding a specific policy, eligibility, or coverage issue, instead of a stipulated decision.

Response: We thank the commenters for their support. If CMS or its contractor agrees that an item or service should be covered or payment made on an appealed claim and an ALJ or attorney adjudicator issues a decision in accordance with proposed §405.1038(c), we do not believe that the decision will be detrimental to the parties' interests given that an ALJ's or attorney adjudicator's decision is limited to the appealed claims and binding only on the parties to the appeal, and is not precedential. However, we note that proposed §405.1038(c) does not require the ALJ or attorney adjudicator to issue a stipulated decision, but rather makes it an option. If a party believes that it has an interest in a full decision that includes findings of fact, conclusions of law, and the reasons for the decision, the party could express its desire for a full decision to the ALJ during the hearing if CMS or the contractor makes an oral statement at the hearing; to the assigned ALJ or attorney adjudicator if CMS or the contractor files a written

statement and provides a copy to the parties; or in a request for review to the Council if a stipulated decision has already been issued.

Comment: One commenter stated that it would be insufficient to issue a stipulated decision based on a statement from CMS that the item or service would be covered, without first disclosing the amount of payment that would be made on the claim and allowing the appellant to accept or reject the payment, because often the amounts paid by CMS contractors for certain items of durable medical equipment do not accurately reflect the cost of the items.

Response: We do not believe adding a requirement for all cases in which a stipulated decision may be issued that CMS disclose the amount of payment that would be made, and that the appellant be allowed to accept or reject the payment before a stipulated decision could be issued, would be necessary, and we believe it would waste resources and negate the intended efficiency of the proposal when CMS or a contractor believes an item or service should be covered or payment may be made. Section 405.1046(a)(3), as finalized in this rule, incorporates current §405.1046(c), which provides that an ALJ or attorney adjudicator may make a finding as to the amount of payment due for an item or service when the payment amount is at issue. However, under these regulations, such a finding is not binding on a CMS contractor for purposes of determining the amount of payment due and the amount of payment determined by the contractor in effectuating an ALJ's or attorney adjudicator's decision is a new initial determination under §405.924, which may be appealed. These rules would apply to a stipulated decision, and as such, if a payment amount is included in a stipulated decision, it does not guarantee that amount will be paid. Further, allowing an appellant to veto a stipulated decision by rejecting the payment that would be made on the claim would require the ALJ or attorney adjudicator to issue a full decision, including findings of fact, and conclusions of law, and

comply with other decision requirements in §405.1046, which would be subject to the same limitations of proposed §405.1046(a)(3) regarding payment amounts.

However, we agree that it would not be appropriate for an ALJ or attorney adjudicator to issue a stipulated decision when the amount of payment is specifically at issue before the ALJ or attorney adjudicator, if the statement from CMS or its contractor does not agree to the amount of payment the party believes should be made. If the amount of payment on a claim is at issue before the ALJ or attorney adjudicator, a general statement from CMS or its contractor that the item or service should be covered or payment may be made would not address the issue on appeal. We are therefore amending §405.1038(c) to provide that if the amount of payment is an issue before the ALJ or attorney adjudicator, a stipulated decision may be made if the statement from CMS or its contractor agrees to the amount of payment the party believes should be made. We are making a corresponding change to §423.2038(c) for stipulated decisions in part 423, subpart U proceedings.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1038 and 423.2038 as proposed with the following modification. We are amending §§405.1038(c) and 423.2038(c) to provide that if the amount of payment is an issue before an ALJ or attorney adjudicator, the statement upon which a stipulated decision is based must agree to the amount of payment the parties believe should be made.

s. Prehearing and posthearing conferences (§§405.1040 and 423.2040)

As described below, we proposed a number of changes to §§405.1040 and 423.2040 with respect to prehearing and posthearing conferences. 81 FR 43790, 43838–43839. Current §405.1040 discusses prehearing and posthearing conferences and permits the ALJ to hold these

conferences to facilitate the hearing or hearing decision. Current §405.1040(b) requires an ALJ to inform “the parties” of the time, place, and purpose of the prehearing or posthearing conference, unless a party indicates in writing that it does not wish to receive a written notice of the conference. In accordance with current §405.1020(c), the notice of hearing is not sent to a party who did not participate in the reconsideration and was not found liable for the services at issue after the initial determination. Therefore, we proposed to modify §405.1040(b) to state that the ALJ would inform parties who would be or were sent a notice of hearing in accordance with §405.1020(c). In addition, current §405.1040(b) does not provide for conference notice to be sent to CMS or a contractor that elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent, which has caused confusion when CMS or a contractor has made an election before or after a conference. Therefore, we proposed at §405.1040(b) that a conference notice be sent to CMS or a contractor that has elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent. We stated in the proposed rule that we believed these changes would help ensure the appropriate parties and participants are provided with notice of, and have an opportunity to attend, a conference. We proposed at §423.2040(b) and (c) to adopt corresponding revisions for prehearing conference notices in non-expedited and expedited hearings respectively to state that a conference notice is sent to CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant in the hearing, but we did not propose to make other changes in proposed §405.1040(b) to §423.2040 because only the enrollee is a party in part 423, subpart U proceedings. In addition, because an oral request not to receive a notice of the conference is permitted for expedited hearings, we proposed at §423.2040(d) to revise the requirement for an “ALJ hearing office” to document such an oral request to provide more generally that oral

requests must be documented, which is generally done by the ALJ's support staff, rather than other office staff. In addition, we proposed at §423.2040(d) that documentation of an oral request not to receive written notice of the conference must be added to the administrative record for consistency in how the record is referenced.

Current §405.1040(c) states that, at the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. However, OMHA ALJs have indicated that providing them with the discretion to delegate conducting a conference to an attorney would add efficiency to the process. OMHA attorneys are licensed attorneys who support ALJs in evaluating appeals and preparing appeals for hearing, as well as drafting decisions, and are well versed in Medicare coverage and payment policy, as well as administrative procedure. Therefore, we proposed at §405.1040(c)(1) that, at the conference, the ALJ or an OMHA attorney designated by the ALJ may conduct the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing. We stated in the proposed rule that this revision would allow an OMHA attorney designated by the ALJ assigned to an appeal to conduct a conference, but would only allow an ALJ conducting the conference to consider matters in addition to those stated in the conference notice. We stated that we believe allowing ALJs to delegate the task of conducting a conference (consistent with the conference notice stating the purpose of the conference, in accordance with §405.1040(b)) would provide ALJs with the flexibility to use OMHA attorneys and provide ALJs with more time to devote to hearings and decisions. We also stated that we believe using attorneys to conduct conferences is appropriate because conferences are informal proceedings to facilitate a hearing or decision, and do not involve taking testimony or receiving evidence, both of which occur at the hearing. We

also noted that the results of the conference embodied in a conference order are subject to review and approval by the ALJ, and ultimately subject to an objection by the parties, under the provisions of current §405.1040, which are carried over in proposed §405.1040. We proposed at §423.2040(e)(1) to adopt corresponding revisions for allowing an ALJ to delegate conducting a conference to an OMHA attorney in part 423, subpart U proceedings.

Current §405.1040(c) references the notice of hearing in discussing the matters that are considered at a conference. However, a notice of hearing may not have been issued at the time a prehearing conference is scheduled, and the matters being addressed in the appeal may have evolved since a notice of hearing was issued by the time a posthearing conference is scheduled, resulting in confusion on the permissible scope of the matters discussed at a conference. Therefore, §405.1040(c)(1) would state that the matters that are considered at a conference are those stated in the conference notice (that is, the purpose of the conference, as discussed in current §405.1040(b)).

Current §405.1040(c) states that a record of the conference is made. However, that requirement has been read and applied differently by adjudicators. We proposed at §405.1040(c)(2) to require that an audio recording of the conference be made to establish a consistent standard and because the audio recording is the most administratively efficient way to make a record of the conference. We proposed at §423.2040(e)(1) and (e)(2) to adopt corresponding revisions to reference a conference notice and clarify that an audio recording of the conference is made in part 423, subpart U proceedings.

Current §405.1040(d) requires the ALJ to issue an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on all parties. It does not state to whom a

conference order is issued, and again broadly references parties in indicating who may object to the order. In addition, current §405.1040(d) does not establish a time period within which an objection must be made before the order becomes part of the record and binding on the parties. Therefore, we proposed to revise §405.1040(d) to state that the ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. We proposed that if a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties. Proposed §405.1040(d) would provide that the order is issued to the parties and participants who attended the conference to help ensure the appropriate parties and participants receive the order, but as in current §405.1040(d), only a party could object to the order. Proposed §405.1040(d) would also establish that an objection must be made within 10 calendar days of receiving the order to establish a consistent minimum standard for making an objection to a conference order, but would also provide the ALJ with the discretion to grant additional time. In addition, proposed §405.1040(d) would replace “hearing record” with “administrative record” for consistency with other references to the record. Further, proposed §405.1040(d) would continue to only allow the ALJ to issue a conference order, because we believe the ALJ should review and approve the actions and agreements resulting from the conference, and only an ALJ should issue an order that would be binding on the parties, if no objection is made. We proposed at §423.2040(f) to adopt corresponding revisions to clarify to whom a conference order is sent and the time frame to object to the order, and to specify that agreements and actions resulting from the conference become part of the “administrative record” (rather than “hearing record”) in part 423, subpart U proceedings. However, we proposed to add that an enrollee must object to a conference order within 1 calendar day of receiving the order for

expedited hearings because of the abbreviated time frame under which an expedited hearing and decision must be completed.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter stated that audio recordings, while administratively efficient, may be incompatible with a party's playback equipment, and transcription costs are prohibitively expensive. The commenter recommended that the format and medium of the recorded file be restricted and a typed transcript be provided on request if the file is incompatible with a party's equipment.

Response: While we acknowledge that there may be playback compatibility concerns when dealing with any digital medium, we do not believe that it would be appropriate to constrain the audio recording of the oral proceedings to a particular format by regulation. OMHA makes audio recordings of conferences and hearings using electronic audio file formats that can be played using widely available and free software. If a party is unable to play the audio recording using his or her own equipment, OMHA will work with the party to help ensure that he or she has adequate access to the administrative record, and possibly provide the recording in a different format. However, we believe that this process is more appropriate for sub-regulatory guidance and the audio recordings should not be restricted to a specific format by regulation, as technology standards and software changes rapidly. We believe that the more general reference to audio recordings will accommodate future changes in recording formats and allow for more flexibility in responding to appellants' requests.

Comment: Another commenter questioned whether it was an acceptable practice for an ALJ to substitute a prehearing conference for a full hearing as long as the other parties had

already waived their appearances, no taking of testimony or receiving of additional evidence was required, only argument would be presented, and the conference was being recorded. The commenter expressed concern that this approach may catch unrepresented beneficiaries unprepared, and suggested publishing a handbook or other guidance for beneficiaries on what to expect at a conference.

Response: The purpose of a prehearing conference is to facilitate the hearing and it is not a substitute for a full hearing. If, after conducting a prehearing conference, the ALJ determines that a hearing is no longer necessary because a decision can be issued without conducting a hearing in accordance with §§405.1038 or 423.2038, the ALJ may issue the decision on the record without conducting a subsequent hearing, or may issue a dismissal or remand in accordance with applicable authorities. However, a prehearing conference is not a substitute for a full ALJ hearing and the rules do not provide for taking testimony or evidence at a conference, or for the ALJ to fully examine the issues and to question the parties and witnesses, as is done at a hearing in accordance with §§405.1030 and 423.2030. In addition, we note that the notice of a pre-hearing conference does not contain the same information as a notice of hearing, and does not have to be sent in the same time frame. With respect to what an appellant can expect at the conference, proposed §§405.1040(b) and 423.2040(b) provide that a conference notice will explain the matters to be discussed at the conference. There are also a number of resources available to provide beneficiaries with information and guidance regarding what to expect throughout the appeals process, as discussed in section II.B.3.o of this final rule above, including existing CMS resources like the Medicare & You Handbook, 1-800 Medicare, chapter 29 of the Medicare Claims Processing Manual (Internet-Only Manual 100-4), and the Medicare claims appeals website at www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html. OMHA

is also currently in the process of developing and releasing the OCPM. The OCPM provides day-to-day operating instructions, policies, and procedures based on statutes, regulations, and OMHA directives. Development is ongoing, and although the OCPM is primarily intended to be a resource used by OMHA adjudicators and staff, chapters are made publicly available on the OMHA website (www.hhs.gov/omha) soon after they are published. The instructions and guidance in the OCPM describe many policies and procedures in greater detail and provide frequent examples to aid understanding. We plan to address prehearing and posthearing conference procedures in a future OCPM chapter.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1040 and 423.2040 as proposed without modification.

t. The administrative record (§§405.1042 and 423.2042)

The administrative record is HHS's record of the administrative proceedings, and is initially established by OMHA ALJs and built from the records of CMS contractors that adjudicated the claim, or from records maintained by SSA in certain circumstances. After adjudication by OMHA, the Council may include more documents in the administrative record, if a request for Council review is filed or a referral to the Council is made. If a party then seeks judicial review, the administrative record is certified and presented to the Court as the official agency record of the administrative proceedings. The record is returned to the custody of CMS contractors or SSA after any administrative and judicial review is complete. We stated in the proposed rule that current practices in creating the administrative record in accordance with current §§405.1042 and 423.2042 vary widely. Given the importance of the administrative

record, we proposed to revise §§405.1042 and 423.2042 to provide for more consistency and to clarify its contents and other administrative matters. 81 FR 43790, 43839–43841.

Current §405.1042(a)(1) provides that the ALJ makes a complete record of the evidence, including the hearing proceedings, if any. However, we stated in the proposed rule that this provision has been limiting and causes confusion in developing procedures to ensure the completeness of the record and in bringing consistency to how the record is structured because individual adjudicators organize the record differently. We proposed to revise §405.1042(a)(1) to require OMHA to make a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted. Proposed §405.1042(a)(1) would vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter, including any prehearing and posthearing conferences and hearing proceedings. We stated that this would provide OMHA with more discretion to develop policies and uniform procedures for constructing the administrative record, while preserving the role of the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to identify the evidence that was used in making the determinations below and the evidence that was used in making his or her decision. We proposed at §423.2042(a)(1) to also adopt corresponding revisions to indicate OMHA makes a complete record of the evidence and administrative proceedings in the appealed matter in part 423, subpart U proceedings.

Current §405.1042(a)(2) discusses which documents in the record are marked as exhibits, and provides a non-exhaustive list of documents that are marked to indicate that they were considered in making the decisions under review or the ALJ's decision. It further states that in

the record, the ALJ also must discuss any evidence excluded under §405.1028 and include a justification for excluding the evidence. We proposed to revise §405.1042(a)(2) to state that the record would include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney admits. We proposed that attorney adjudicators could mark exhibits because as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), attorney adjudicators would be adjudicating requests for hearing and requests for review of a QIC dismissal, and should indicate the portions of the record that he or she considered in making the decision in the same manner as an ALJ. Proposed §405.1042(a)(2) would continue to require certain evidence to be marked as exhibits, but would clarify what would be marked, replacing "the documents used in making the decision under review," with "the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision." We stated in the proposed rule that we believed this would clarify that the exhibited portion of the record includes, at minimum, the appealed determinations, documents and other evidence used in making the appealed determinations, and documents and other evidence used in making the ALJ's or attorney adjudicator's decision. The illustrative list of documents that may be marked as exhibits pursuant to the rule in current §405.1042(a)(2) would be incorporated in proposed §405.1042(a)(2) without change. We also proposed to clarify at §405.1042(a)(2) that the record would include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative

evidence submitted by a party. We stated in the proposed rule that all evidence presented should be included in the record, even if excluded from consideration, in order to help ensure a complete record of the evidence. However, we stated that such excluded evidence would not be marked as an exhibit because the evidence was not considered in making the ALJ's or attorney adjudicator's decision. We proposed at §423.2042(a)(2) to adopt corresponding revisions to clarify what would be exhibited in part 423, subpart U proceedings, except the reference to new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established as an example of evidence excluded or not considered by the ALJ or attorney adjudicator, because there is no such limitation on new evidence in part 423, subpart U proceedings.

As stated previously, current §405.1042(a)(2) includes requirements to discuss any evidence excluded under current §405.1028 and include a justification for excluding the evidence. We proposed in §405.1042(a)(2) to remove these requirements. We stated in the proposed rule that we believed the requirement to justify excluding the evidence is not necessary and is in tension with the requirement for a provider or supplier, or beneficiary represented by a provider or supplier, to establish good cause for submitting new evidence before it may be considered. Section 1869(b)(3) of the Act establishes a general prohibition on new evidence that must be overcome, and proposed §405.1028 would implement the statute by requiring the party to explain why the evidence was not submitted prior to the QIC reconsideration, and the ALJ or attorney adjudicator to make a finding of good cause to admit the evidence. In place of the current §405.1042(a)(2) requirement, as we discuss later, we proposed at §405.1046(a)(2)(ii) to require that if new evidence is submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed §405.1028, the new evidence and good cause

determination would be discussed in the decision. We also stated in the proposed rule that we believed the decision is the appropriate place to discuss the new evidence and document the good cause determination, and the discussion should focus on the good cause determination required by proposed §405.1028, regardless of whether good cause was found. We did not propose any corresponding changes to §423.2042 because there is no provision equivalent to the current §405.1042(a)(2) requirement to discuss any excluded evidence.

Current §405.1042(a)(3) provides that a party may review the record “at the hearing,” or if a hearing is not held, at any time before the ALJ’s notice of decision is issued. However, this is rarely done in practice. More often, a party requests a copy of the record prior to the hearing, in accordance with current §405.1042(b). We proposed to revise §405.1042(a)(3) to state that a party may request and review the record prior to or at the hearing, or if a hearing is not held, at any time before the notice of decision is issued. This revision would allow a party to request and review a copy of the record “prior to or at the hearing” to more accurately reflect the practices of parties. In addition, proposed §405.1042(a)(3) would remove the reference to an “ALJ’s” decision in explaining that if a hearing is not held, a party may request and review the record at any time before the notice of decision is issued, because in that circumstance an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), may issue the decision. We proposed at §423.2042(a)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

Current §405.1042(a)(4) provides for the complete record, including any recording of the hearing, to be forwarded to the Council when a request for review is filed or the case is escalated to the Council. However, in noting that the record includes recordings, only a recording of the hearing is mentioned. We proposed at §405.1042(a)(4) to add that the record includes recordings

of prehearing and posthearing conferences in addition to the hearing recordings, to reinforce that recordings of conferences are part of the complete record. We proposed at §423.2042(a)(4) to adopt corresponding revisions for part 423, subpart U proceedings.

Current §405.1042(b)(1) describes how a party may request and receive copies of the record from the ALJ. However, after a case is adjudicated, OMHA releases custody of the record and forwards it to a CMS contractor or SSA, and the record may go on to the Council for another administrative proceeding. We stated in the proposed rule that this results in confusion for parties when they request a copy of the record and OMHA is unable to provide it. We proposed at §405.1042(b)(1) that a party may request and receive a copy of the record from OMHA while an appeal is pending at OMHA. We also proposed at §405.1042(b)(1) to replace the reference to an “exhibit list” with a reference to “any index of the administrative record” to provide greater flexibility in developing a consistent structure for the administrative record. We also proposed to change the parallel reference to “the exhibits list” in §405.1118 to “any index of the administrative record.” In addition, proposed §405.1042(b)(1) would replace the reference to a “tape” of the oral proceeding with an “audio recording” of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We also proposed to replace a parallel reference at §405.1118 to a copy of the “tape” of the oral proceedings with a copy of the “audio recording” of the oral proceedings. We proposed at §§423.2042(b)(1) and 423.2118 to adopt corresponding revisions for part 423, subpart U proceedings, but note that current §423.2118 refers to a “CD” of the oral proceedings.

Current §405.1042(b)(2) provides that if a party requests all or part of the record from an ALJ and an opportunity to comment on the record, the time beginning with the ALJ’s receipt of the request through the expiration of the time granted for the party’s response does not count

toward the 90 calendar day adjudication period. We proposed to revise §405.1042(b)(2) to state, if a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with §405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response. This proposed revision would clarify that a party may request a "copy of" all or part of the record, and would add that the request may be made to OMHA, or the ALJ or attorney adjudicator, because a party may request a copy of the record before it is assigned to an ALJ or attorney adjudicator. In addition, proposed §405.1042(b)(2) would revise the discussion of the effect of requesting an opportunity to comment on the record on an adjudication period to remove the specific reference to a 90 calendar day adjudication period, because in accordance with proposed §405.1016, an adjudication period may be 90 or 180 calendar days, or alternatively may be waived by the appellant and therefore not apply. We proposed at §423.2042(b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current §405.1042 does not address the circumstance in which a party requests a copy of the record but is not entitled to receive some of the documents in the record. For example, when an appeal involves multiple beneficiaries and one beneficiary requests a copy of the record, the records related to other beneficiaries may not be released to the requesting beneficiary unless he or she obtains consent from the other beneficiaries to release the records that pertain to them. Proposed §405.1042(b)(3) would address the possibility that a party requesting a copy of the record is not entitled to receive the entire record. Specifically, we proposed in §405.1042(b)(3) that if a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not

entitled to receive (for example, personally identifiable information or protected health information), those portions of the record would not be furnished unless the requesting party obtains consent from the individual. For example, if a beneficiary requests a copy of the record for an appeal involving multiple beneficiaries, the portions of the record pertaining to the other beneficiaries would not be furnished to the requesting beneficiary unless he or she obtains consent from the other beneficiaries. We stated in the proposed rule that we believed proposed §405.1042(b)(3) would help ensure that parties are aware that they may not be entitled to receive all portions of the record. We proposed at §423.2042(b)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received several comments requesting that parties be provided with a mechanism to request a copy of the administrative record after a notice of decision or dismissal is issued at the OMHA level but prior to requesting review of that determination by the Council. The commenters noted that parties may need to review the record after a decision or dismissal is issued to determine whether to pursue a subsequent appeal.

Response: After a case is adjudicated, OMHA releases custody of the administrative record and forwards it to a CMS contractor or SSA, at which time OMHA no longer has possession of the record to provide copies. If a request for review is filed with the Council, the regulations at §§405.1118 and 423.2118 address requesting and receiving a copy of the record from the Council. If a party wishes to request a copy of the record after a decision or dismissal is issued by an ALJ or attorney adjudicator and prior to filing a request for review with the Council, however, the requesting party may contact CMS or SSA to obtain a copy of the record.

Comment: We received one comment that expressed general support for the proposed changes, but requested that the agency clarify in the regulation that marking evidence as an exhibit does not create a legal presumption that the adjudicator actually considered it in rendering a decision. The commenter also requested that the agency reinforce that the good cause requirement for the submission of new evidence for the first time at the OMHA level does not apply to new evidence submitted by unrepresented beneficiaries and Medicaid state agencies.

Response: We thank the commenter for its support, but disagree that the regulation should incorporate the language suggested by the commenter, that marking evidence as an exhibit does not create a legal presumption that the adjudicator considered it. The rules that we are finalizing require that evidence in the administrative record that the ALJ or the attorney adjudicator considers in making a decision is marked as an exhibit, and specifies certain evidence that is considered and therefore is marked as an exhibit. Because the rules already convey certain evidence will be considered, and in accordance with §§405.1046 and 423.2046, the notice of decision contains a summary of the clinical or scientific evidence used in making the determination, we believe what the ALJ or attorney adjudicator considered or did not consider will be evident from the record and decision. Further, adding the suggested language could cause confusion given that the rules prescribe that certain evidence will be considered and marked as evidence. In addition, if a party believes that certain evidence was marked as an exhibit but not appropriately considered by the ALJ or attorney adjudicator, or was not given appropriate weight in the decision or dismissal, the matter may be appealed to the Council and the Council will undertake a de novo review of the record. Under de novo review, the Council is not bound by the findings of the lower levels of adjudication and does not give deference to the determinations of the prior adjudicators. Given this standard of review and the clarification

above, we do not believe that it is necessary or appropriate to specify in the regulations that marking an exhibit does not create a legal presumption that it was considered.

With respect to the commenter's second suggestion, as discussed in section II.B.3.i above, we are amending the language in §405.1018(d) to clarify that the limitation on submitting new evidence for the first time at the OMHA level (as set forth in §405.1018(c)) does not apply to evidence submitted by an unrepresented beneficiary, CMS or its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

Comment: One commenter requested clarification on the form that an individual's consent should take, and clarification on where the consent should be sent, under proposed §§405.1042(b)(3) and 423.2042(b)(3), regarding situations in which the party requesting a copy of the record is not entitled to receive some of the documents or information in the record because they pertain to another individual, and the requirement to obtain consent from the individual before OMHA will furnish a copy of the requested information.

Response: The proposed language does not specify a required form of individual consent; however, we recommend that parties use Form HHS-721 (Individual Appellant's Consent to Third-Party for Copies of the Individual Appellant's Record(s)), which is available on the HHS website at www.hhs.gov. Any individual consents obtained may be sent to OMHA, the assigned ALJ, or the assigned attorney adjudicator along with the party's request for a copy of the record consistent with §§405.1042(b) or 423.2042(b).

Comment: We received two comments suggesting that the proposed regulations did not sufficiently address the level of detail required in the index of the administrative record. One commenter noted that the lack of detail results in confusion about what evidence is actually

before the adjudicator. The commenter recommended that seven days prior to a hearing OMHA should provide all parties with a detailed exhibit list identifying the following elements: the exhibit number, the exhibit range of pages, the subject of each exhibit, the author of each exhibit, the total number of pages in each exhibit, and the date(s) appearing on each exhibit. Another commenter stated that because the regulations provide no requirements on the level of detail to be used in the index of the administrative record, parties that want to request only a part of a record are unable to do so due to the general nature of the indexes.

Response: One of the proposed revisions to §§405.1042 and 423.2042 is to vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter. This change would allow OMHA to develop and implement agency-wide policies and uniform procedures for constructing the administrative record, including preparing and distributing the index of the administrative record, which we believe will help address both commenters' concerns.

We do not agree with the commenters that the regulations are the appropriate place for specific agency instructions on creating the index of the administrative record. OMHA is in the process of developing the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency. The OCPM describes OMHA case processing procedures in greater detail than generally is included in regulation and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA website (www.hhs.gov/omha), includes a detailed chapter on the administrative record and guidance on creating and distributing an index of the administrative record, which the OCPM currently refers to as exhibit lists. Current policy, as outlined in the OCPM, requires that a typed exhibit list be created. This standardized form is organized by categories of evidence and

each exhibit number contains required minimum descriptions for some of the information recommended by the first commenter, including an exhibit number for each category, a description of the subject of each exhibit number, and the range of pages within each exhibit number. The OCPM does not require that the exhibit list contain a specific description of each document within a category or detailed information about individual exhibits within a category such as the dates of each exhibit or the author of each exhibit. It would be a significant burden on the staff assembling the record and creating the exhibit list to review each document and index information to the level of specificity suggested by the commenter. We believe that this administrative burden outweighs the limited potential benefits to the parties of having more specific information such as dates and authors of individual exhibits listed on an index. We also believe that by using standard categories for exhibits we are providing parties with useful information about the documents that will be considered by the adjudicator. For example, by placing all medical records in one exhibit category and providing a range of pages for that category, a party has information on the volume of records received to determine if it is likely that the record contains all of the necessary medical record evidence. While we understand that providing more specific descriptions, such as individual dates and authors for each exhibit, may further assist parties in confirming that certain evidence is in the record, we believe that there are other ways for parties to confirm that information, such as reviewing the total number of pages in each category, or by discussing the specific evidence at a hearing, or, if there are specific concerns regarding the evidence, by requesting a copy of all or any part of the record pursuant to §§405.1042(b) and 423.2042(b).

We are also not adopting the commenter's recommendation that OMHA send the exhibit list to all the parties seven days prior to the hearing. The OCPM already requires that an initial

copy of the exhibit list be provided with the notice of hearing to the parties and potential parties and participants who receive the notice, or at the first available opportunity before the hearing to the parties and potential parties and participants who responded to the notice of hearing. Under §§405.1022(a)(1) and 423.2022(a)(2), as finalized in this rule, the notice of hearing is mailed, transmitted, or served at least 20 calendar days before the hearing (except for expedited part D hearings, where notice is mailed, transmitted, or served at least 3 calendar days before the hearing), unless a party or participant agrees to fewer than 20 calendar days' or 3 calendar days' notice, as applicable. Therefore, the OCPM already requires that parties and potential parties and participants receive the exhibit list earlier than the commenter's recommendation of seven days prior to the hearing, or at the first available opportunity. (After the effective date of this final rule, we anticipate that revisions will be made to the OCPM to refer to an index of the administrative record, rather than an exhibit list.) In addition, proposed §§405.1042(b)(1) and 423.2042(b)(1) state that at any time while an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record, including a copy of the index of the administrative record. Finally, with regard to the second comment, we believe that if the exhibit lists are consistent across adjudicators, there will be improved clarity as to the types of documents within the specific exhibit categories. While it is not administratively possible given OMHA's docket and staffing constraints to create exhaustive lists of each document or item on an exhibit list, the implementation of uniform exhibiting procedures by OMHA, including the use of consistent exhibit categories, should make it easier for parties who only require certain documents or portions of a record to determine which exhibit number to request.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1042 and 423.2042 as proposed without modification.

u. Consolidated proceedings (§§405.1044 and 423.2044)

Current §§405.1044 and 423.2044 explain that a consolidated hearing may be held at the request of an appellant or on the ALJ's own motion, if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ, and CMS is notified of an ALJ's intention to conduct a consolidated hearing. If a consolidated hearing is conducted, current §§405.1044 and 423.2044 further provide that the ALJ may make a consolidated decision and record for the claims involved in the consolidated hearing, or may make a separate decision and record for each claim involved in the consolidated hearing. We stated in the proposed rule that this authority is useful in allowing an ALJ and the appellant to conduct a single proceeding on multiple appealed claims or other determinations that are before the ALJ, reducing time and expense for the appellant and the government to resolve the appealed matter. However, we stated that the current provisions have caused confusion, and have been limiting in circumstances in which no hearing is conducted, and proposed a number of revisions. 81 FR 43790, 43841–43842.

Current §405.1044 uses the terms “requests for hearing,” “cases,” and “claims” interchangeably, and we stated in the proposed rule that this has resulted in confusion because an appeal, or “case,” before an ALJ may involve multiple requests for hearing if an appellant's requests were combined into one appeal for administrative efficiency prior to being assigned to the ALJ. In addition, a request for hearing may involve one or more claims. We proposed in §405.1044 to use the term “appeal” to specify that appeals may be consolidated for hearing, and

a single decision and record may be made for consolidated appeals. We proposed to use “appeal” because an appeal is assigned a unique ALJ appeal number, for which a unique decision and record is made. We also proposed to move current §405.1044(b) to new subsection (a)(2), and to also replace the term “combined” with “consolidated” for consistent use in terminology. Further, we proposed at §423.2044 to adopt corresponding revisions to use consistent terminology in part 423, subpart U proceedings.

Current §405.1044(a) through (d) describes when a consolidated hearing may be conducted, the effect on an adjudication period that applies to the appeal, and providing notice of the consolidated hearing to CMS. Proposed §405.1044(a) would incorporate current §405.1044(a) through (c) to combine the provisions related to a consolidated hearing. In addition, proposed §405.1044(a)(4) would replace the current requirement to notify CMS that a consolidated hearing will be conducted in current §405.1044(d) with a requirement to include notice of the consolidated hearing in the notice of hearing issued in accordance with §§405.1020 and 405.1022. We stated that this would help ensure notice is provided to the parties and CMS, as well as its contractors, in a consistent manner, and reduce administrative burden on ALJs and their staff by combining that notice into the existing notice of hearing. We proposed at §423.2044(a) to adopt corresponding revisions for part 423, subpart U proceedings.

Current §405.1044(e) explains that when a consolidated hearing is conducted, the ALJ may consolidate the record and issue a consolidated decision, or the ALJ may maintain separate records and issue separate decisions on each claim. It also states that the ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable. However, there has been confusion on whether separate records may be maintained and a consolidated decision can

be issued, as well as what must be included with the records when separate records are maintained. Proposed §405.1044(b) would incorporate some of current §405.1044(e) and add provisions for making a consolidated record and decision. We proposed at §405.1044(b)(1) that if the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record, or a separate decision and record on each appeal. This proposed revision would maintain the current option to make a consolidated record and decision, or maintain separate records and issue separate decisions, but restructures the provision to highlight that these are two mutually exclusive options. This proposal is important because issuing a consolidated decision without also consolidating the record, or issuing separate decisions when a record has been consolidated, complicates effectuating a decision and further reviews of the appeal(s). We proposed in §405.1044(b)(2) that, if a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing, are included in each individual administrative record. We stated that proposed §405.1044(b)(2) would address the confusion that sometimes results in a copy of the audio recording of a consolidated hearing not being included in the administrative records of each constituent appeal when separate records are maintained, by clarifying that if a separate decision and record is made, audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual record. We stated that this proposal is important because the record for each individual appeal must be complete. We proposed at §423.2044(b)(1) and (b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current §405.1044 does not contemplate a consolidated record and decision unless a consolidated hearing was conducted, which is limiting when multiple appeals for an appellant can be consolidated in a decision issued on the record without a hearing. We proposed to add §405.1044(b)(3), which would provide that, if a hearing would not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion. We stated that this would provide authority for an ALJ or attorney adjudicator to make a consolidated decision and record on the same basis that a consolidated hearing may be conducted. We stated in the proposed rule that we believed this authority would add efficiency to the adjudication process when multiple appeals pending before the same adjudicator can be decided without conducting a hearing. We proposed at §423.2044(b)(3) to adopt a corresponding provision for part 423, subpart U proceedings.

Current §405.1044 also does not clearly address consolidating hearings for multiple appellants, including situations in which a beneficiary files a request for hearing on the same claim appealed by a provider or supplier, and the provider or supplier has other pending appeals that could be consolidated pursuant to current §405.1044. We stated that the general practice is that a consolidated hearing is conducted for the appeals of a single appellant. This is supported by the reference to "an" appellant in current §405.1044(b), and helps ensure the hearing and record is limited to protected information that the appellant is authorized to receive. Therefore, we proposed to add §405.1044(c) to provide that consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims

to meet the amount in controversy requirement in accordance with §405.1006, and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants. We stated that this would help ensure that beneficiary information is protected from disclosure to parties who are not authorized to receive it, including when a beneficiary requests a hearing for the same claim that has been appealed by a provider or supplier, and appeals of other beneficiaries' claims filed by the provider or supplier are also pending before the same ALJ or attorney adjudicator. We proposed at §423.2044(c) to adopt a corresponding provision for part 423, subpart U proceedings.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received one comment asking whether a decision by OMHA's central docket to combine appeals prior to assignment to an ALJ can be challenged by the appellant if the appeals involve different disputed items, different bases for denial, and different issues, and, if so, what the process for that challenge is. The commenter had multiple questions about tracking the status and progress of individual appeals throughout the appeals process, the ability to separately appeal one or more of the individual claims, and rules regarding the administrative record in combined cases.

Response: Proposed §405.1044 addresses the circumstances under which the proceedings for multiple ALJ appeals may be consolidated into one hearing, as well as the option for an ALJ or attorney adjudicator to make a consolidated decision and record, whether or not a hearing was conducted. Both of these actions would occur after assignment of the individual appeals to an ALJ or attorney adjudicator, either at the request of the appellant with the ALJ's or attorney adjudicator's approval or on the ALJ's or attorney adjudicator's own motion. However, we

believe the commenter's question relates to the combination—not consolidation—of appealed reconsiderations under one ALJ appeal number prior to assignment to an ALJ or attorney adjudicator. OMHA internal case processing guidance permits the combination of appealed reconsiderations under a single ALJ appeal number prior to assignment for administrative efficiency when certain criteria are met. The commenter may review Chapter II-2 of the OCPM, which is available to the public on the OMHA website (www.hhs.gov/omha), for more information on docketing and assignment of appeals, including combining appeals prior to assignment. Because the proposed changes to §405.1044 relate to consolidation rather than combination of appeals prior to assignment, the commenters specific questions regarding the combination of appeals are outside of the scope of the proposed rule.

Comment: We received two comments suggesting that the proposals go further and permit consolidation of all of an appellant's pending appeals at OMHA on the same issue, at the appellant's request, regardless of whether they are assigned to the same ALJ.

Response: We believe that proposed §§405.1044 and 423.2044, which we are finalizing in this rule, strike the appropriate balance between promoting administrative efficiency and maintaining rotational assignments, as well as allowing OMHA to balance workload among its ALJs and attorney adjudicators. Sections 405.1044 and 423.2044 contemplate that consolidation of proceedings is only available with respect to appeals pending before the same ALJ. We believe that allowing parties to request consolidation of proceedings that have been assigned to multiple adjudicators would be contrary to the concept of rotational assignment, disrupt the workflow of adjudicators, cause delays for other appellants, and add inefficiency to the process by requiring additional administrative resources to process such requests and reassign the appeals. However, as discussed previously, an appellant may request combination of multiple

appealed reconsiderations on its request for hearing and, if the criteria for combination are met, OMHA accommodates such a request to the extent feasible by combining the appealed reconsiderations under a single ALJ appeal number. If OMHA is unable to accommodate the request and multiple appeals are established and assigned to a single adjudicator, the adjudicator can then consider consolidation of the appeals.

Comment: We received multiple comments that discussed the desire for uniform procedures for creating records in consolidated proceedings, conducting consolidated hearings, and creating audio recordings of consolidated appeals, as well as requested additional guidance for adjudicators on issuing consolidated decisions that contain separate factual findings, legal authorities, and legal analysis for each appeal at issue. One commenter urged the agency to provide additional training and oversight on consolidated proceedings and requested that the agency make available a public resource regarding consolidated proceedings.

Response: The proposed revisions to §§405.1044 and 423.2044 were intended to reduce confusion and provide more consistent procedures for conducting consolidated hearings, and creating and maintaining records for consolidated appeals. OMHA is also in the process of developing the OCPM, a reference guide outlining the day-to-day operating instructions, policies, and procedures of the agency for adjudicating appeals under the rules. The OCPM describes OMHA case processing procedures in greater detail and provides frequent examples to aid understanding. This resource, which is available to the public on the OMHA website (www.hhs.gov/omha), includes detailed information on creating the administrative record both when an ALJ decides to make a consolidated decision and record, and when the ALJ decides to issue separate decisions and records. OMHA provides training to its ALJs, attorneys, and other

staff to help ensure understanding and compliance with all regulations applicable to processing appeals, and will provide training on all aspects of this final rule.

Comment: One commenter expressed concern that the proposed language in §405.1044(c) would complicate the consolidation of proceedings involving multiple appellants. The commenter noted that a provider's ability to consolidate proceedings will be hindered if it is unable to secure the necessary permissions from beneficiaries and asked for clarification on whether one of the HIPAA exceptions permitting providers to release protected health information in certain circumstances, even absent consent, may apply in this situation. Finally, the commenter recommended that the proposed regulation be revised to require only that a provider take "reasonable" steps to obtain such consent but that if consent cannot be obtained, that the parties will enter into a protective order to prohibit the unauthorized release of information and to require that the records be redacted as much as possible by removing, for example, the beneficiary's name, address, date of birth, and social security number. The commenter argued that by modifying §405.1044(c) to allow for consolidation in proceedings involving multiple appellants subject to protective orders and redacted documentation, if necessary, the appeals process would be even more efficient while still ensuring beneficiary information is as protected as possible in those circumstances.

Response: We believe the commenter is confusing an "appellant" with a "party" and we do not agree that §405.1044(c) places unnecessary limits on the ability to consolidate proceedings for appeals filed by multiple appellants. An appellant is the party that files a request for hearing or request for review of a dismissal. For example, a provider that is a party may file a request for hearing for a service that it furnished to the beneficiary, who is also a party; in that instance, the provider is then also the appellant. In addition, if the provider files multiple requests

for hearing for services that it furnished to different beneficiaries, the provider is the appellant in those appeals and proposed §405.1044(c) would not apply because a single appellant is involved. However, proposed §405.1044(c) would apply if multiple providers filed requests for hearing that were being consolidated because, in this case, there would be multiple appellants. In this situation, the providers may not have the necessary permissions from the beneficiaries to whom an individual provider did not furnish a service. We have a responsibility to protect individuals' personally identifiable information and protected health information, and that responsibility takes priority over any potential gains in administrative efficiency. As we note in the summary above, the purpose of the consolidation rules is to reduce time and expense for appellants and the government. While the commenter suggests that there would be even greater administrative efficiencies gained if appeals from multiple appellants were also subject to consolidation without the limitations of §405.1044(c), we believe that the limitations of §405.1044(c) are necessary in order to protect personally identifiable information and protected health information. Moreover, we believe that the commenter's alternative suggestions for safeguarding protected health information—entering protective orders and redacting certain information—would require additional administrative time and energy and, therefore, are contrary to the stated goal of administrative efficiency.

Although there may be rare and unusual circumstances where it may be permissible to release the protected health information of an individual to other parties (for example, a court order expressly authorizing such disclosure to litigants), we do not believe there are any generally applicable exceptions to the HIPAA privacy rules that would apply or be appropriate in this case to permit the consolidation of proceedings involving multiple appellants where the appellants are unable to obtain authorization from the beneficiaries whose claims are at issue to

disclose their protected information to the other parties and any participants. Consolidation of proceedings where multiple appellants are involved may result in disclosure of an individual's protected health information to other individuals, including other involved beneficiaries, who do not have a right to receive the information and have no use for the information.

Comment: We received one comment in support of proposed §405.1044(c) and the language that limits consolidated proceedings to appeals filed by the same appellant, unless multiple appellants have aggregated claims to meet the amount in controversy and the beneficiaries whose claims are at issue have authorized disclosure of protected information to other parties and any participants.

Response: We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1044 and 423.2044 as proposed without modification.

v. Notice of decision and effect of an ALJ's or attorney adjudicator's decision (§§405.1046, 405.1048, 423.2046, and 423.2048)

Current §§405.1046 and 423.2046 describe the requirements for a decision and providing notice of the decision, the content of the notice, the limitation on a decision that addresses the amount of payment for an item or a service, the timing of the decision, and recommended decisions. Current §§405.1048 and 423.2048 describe the effects of an ALJ's decision. However, the current sections only apply to a decision on a request for hearing, leaving ambiguities when issuing a decision on a request for review of a QIC or IRE dismissal. We proposed to consolidate the provisions of each section that apply to a decision on a request for hearing under proposed §§405.1046(a), 405.1048(a), 423.2046(a) and 423.2048(a), with further revisions discussed

below, and introduce new §§405.1046(b), 405.1048(b), 423.2046(b) and 423.2048(b) to address a decision on a request for review of a QIC or IRE dismissal, as well as to revise the titles and provisions of the sections to expand their coverage to include decisions by attorney adjudicators, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to remove current §405.1046(d), which addresses the timing of a decision on a request for hearing because it is redundant with §405.1016 and could lead to confusion if a different adjudication period applies, such as a 180-calendar day period for an escalated request for QIC reconsideration, or if no adjudication period applies, such as when the period is waived by the appellant. Similarly, we proposed to remove current §§423.2046(a)(1) and (d) because the adjudication time frames discussed in the provisions are redundant with provisions in proposed §423.2016. In addition, we proposed to re-designate current §§405.1046(e) and 423.2046(e), as proposed §§405.1046(c) and 423.2046(c) respectively, to reflect the revised structure of proposed §§405.1046 and 423.2046. 81 FR 43790, 43842–43843.

Current §405.1046 states that an ALJ will issue a decision unless a request for hearing is dismissed. We proposed to revise §405.1046(a) to state that an ALJ or attorney adjudicator would issue a decision unless the request for hearing is dismissed or remanded in order to accommodate those situations where the ALJ or attorney adjudicator remands a case to the QIC. We stated in the proposed rule that there has been confusion regarding the content requirements of the decision itself, as well as whether the findings or conclusions in a QIC reconsideration or the arguments of the parties may be referenced or adopted in the decision by reference. We stated that we believe that while the issues that are addressed in a decision are guided by the reconsideration, as well as the initial determination and redetermination, and a party may present arguments in a framework that reflects recommended findings and conclusions, the concept of a

de novo review requires an ALJ or attorney adjudicator to make independent findings and conclusions. To address this confusion, we proposed in §405.1046(a) to require that the decision include independent findings and conclusions to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others, though the ALJ or attorney adjudicator may ultimately make the same findings and conclusions. As discussed in and for the reasons stated in section III.A.3.t of the proposed rule and II.B.3.t of this final rule above, proposed §405.1046(a)(2)(ii) would also require that if new evidence was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed §405.1028, the new evidence and good cause determination would be discussed in the decision. We proposed at §423.2046(a) to adopt corresponding revisions for decisions on requests for hearing under part 423, subpart U, except the proposals related to discussing new evidence and good cause determinations related to new evidence because there are no current requirements to establish good cause for submitting new evidence in part 423, subpart U proceedings.

Current §405.1046(a) requires that a decision be mailed. As OMHA transitions to a fully electronic case processing and adjudication environment, new options for transmitting a decision to the parties and CMS contractors may become available, such as through secure portals for parties or through inter-system transfers for CMS contractors. We proposed in §405.1046(a) to revise the requirement that a decision be mailed to state that OMHA “mails or otherwise transmits a copy of the decision,” to allow for additional options to transmit the decision as technologies develop. We proposed to revise §423.2046(a) to adopt a corresponding revision for sending a decision under part 423, subpart U.

Current §405.1046(a) also requires that a copy of the decision be sent to the QIC that issued the reconsideration. However, if the decision is issued pursuant to escalation of a request for a reconsideration, no reconsideration was issued. To address this circumstance, we proposed in §405.1046(a) that the decision would be issued to the QIC that issued the reconsideration or from which the appeal was escalated. In addition, we proposed in §405.1046(a) to replace “reconsideration determination” with “reconsideration” for consistency in referencing the QIC’s action. Current §405.1046(a) also requires that a copy of the decision be sent to the contractor that made the initial determination. However, this requirement adds to the administrative burden on OMHA and we stated in the proposed rule we believed it was unnecessary in light of the requirement that a copy of the decision be sent to the QIC and the original decision is forwarded as part of the administrative record to another CMS contractor to effectuate the decision. Thus, we proposed in §405.1046(a) to remove the requirement to send a copy of the decision to the contractor that issued the initial determination. In addition, we proposed in §423.2046(a) to replace “reconsideration determination” with “reconsideration” for consistency in referencing the IRE’s action in part 423, subpart U proceedings, but we did not propose to incorporate other changes proposed for §405.1046(a) in proposed §423.2046(a) because: (1) escalation is not available in part 423, subpart U proceedings; and (2) the Part D plan sponsor, which makes the initial coverage determination, has an interest in receiving and reviewing ALJ and attorney adjudicator decisions related to an enrollee’s appeal of drug coverage.

As discussed above, we proposed to revise §405.1046(b) to explain the process for making a decision on a request for review of a QIC dismissal. In accordance with proposed §405.1004, we proposed in §405.1046(b)(1) that unless the ALJ or attorney adjudicator dismisses the request for review of a QIC’s dismissal or the QIC’s dismissal is vacated and

remanded, the ALJ or attorney adjudicator issues a written decision affirming the QIC's dismissal. We proposed in §405.1046(b)(1) that OMHA would mail or otherwise transmit a copy of the decision to all the parties that received a copy of the QIC's dismissal because, as we stated in the proposed rule, we believe that the QIC would appropriately identify the parties who have an interest in the dismissal, and that notice of the decision on a request for review of a QIC dismissal to any additional parties is unnecessary. We also stated that we believe that notice to the QIC is not necessary when its dismissal is affirmed because it has no further obligation to take action on the request for reconsideration that it dismissed. We proposed in §405.1046(b)(2)(i) that the decision affirming a QIC dismissal must describe the specific reasons for the determination, including a summary of the evidence considered and applicable authorities, but did not propose to require a summary of clinical or scientific evidence because such evidence is not used in making a decision on a request for a review of a QIC dismissal. In addition, we proposed that §405.1046(b)(2)(ii) and (iii) would explain that the notice of decision would describe the procedures for obtaining additional information concerning the decision, and would provide notification that the decision is binding and not subject to further review unless the decision is reopened and revised by the ALJ or attorney adjudicator. We proposed to revise §423.2046(b) to adopt corresponding provisions for a decision on requests for review of an IRE dismissal under part 423, subpart U, except that the notice of decision will only be sent to the enrollee because only the enrollee is a party.

We proposed to revise the title of current §405.1048 to read "The effect of an ALJ's or attorney adjudicator's decision" and to replace the current introductory statement in §405.1048(a) that "The decision of the ALJ is binding on all parties to the hearing" with "The decision of the ALJ or attorney adjudicator is binding on all parties" to make the subsection

applicable to decisions by attorney adjudicators and because the parties are parties to the decision regardless of whether a hearing was conducted. We also proposed in §405.1048(b) that the decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in §405.980. We proposed to revise §423.2048 to adopt corresponding provisions for the effects of ALJ and attorney adjudicator decisions under part 423, subpart U.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter suggested that the contents of the notice of decision should include an explanation of why any evidence was excluded from the record, especially in the absence of any contradictory evidence. The commenter also suggested that OMHA should continue to send the notice of decision to the CMS contractor that made the initial determination because the decision provides feedback that can assist the contractor in making quality claim decisions.

Response: As discussed above and as provided for in proposed §405.1046(a)(2)(ii), any new evidence submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed §405.1028 will be discussed in the ALJ's or attorney adjudicator's decision. The decision will include a discussion of the good cause determination, regardless of whether good cause was found. We disagree that the presence or absence of contradictory evidence in the record would have any bearing on the ALJ's or attorney adjudicator's decision as to whether the party had good cause to submit evidence for the first time at the OMHA level. The absence of contradictory evidence would not explain why a party

was unable to obtain and submit the evidence before the QIC issued its reconsideration, and would not fall under any of the other situations specified in §405.1028(a)(2) for when an ALJ may find good cause for the submission of evidence for the first time at the OMHA level.

With respect to sending a copy of the decision to the contractor that made the initial determination, as stated above and in the proposed rule, we believe that sending the ALJ's or attorney adjudicator's decision to a CMS contractor to effectuate the decision and a copy to the QIC will be sufficient to inform CMS and its contractors of the decision. We believe that in the majority of cases the benefit of sending an additional copy to the contractor that made the initial determination is outweighed by the administrative burden and costs, and CMS is in the best position to determine how decisions are shared among its contractors and whether or how those decisions should be used by its contractors.

Comment: Two commenters recommended explicitly prohibiting ALJs and attorney adjudicators from incorporating findings or conclusions offered by others in their decisions.

Response: We appreciate the commenters' support for our effort to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others. However, we do not believe it is necessary to rephrase this provision as a prohibition on incorporating the findings or conclusions of others. We believe that our proposal, to require that the decision include independent findings and conclusions, adequately expresses the requirement for de novo review, and are concerned that the language suggested by the commenter would unnecessarily preclude an ALJ or attorney adjudicator from including discussion of others' findings and conclusions in his or her decision for the purpose of discussing or analyzing them in the process of making his or her independent findings and conclusions. We believe the proposed language at §405.1046(a), which we are

finalizing in this rule, would preclude an ALJ or attorney adjudicator from merely adopting findings and conclusions offered by others, while providing the ALJ or attorney adjudicator with the flexibility to discuss or analyze the findings and conclusions offered by others, if appropriate in a specific appeal, in the process of making his or her independent findings and conclusions.

Comment: Two commenters urged HHS to ensure that beneficiaries always receive a written decision by regular mail, even when other methods of transmittal are available.

Response: The proposal to revise the current requirement in §§405.1046(a) and 423.2046(a)(3) that a decision be mailed, to require that OMHA “mails or otherwise transmits a copy of the decision,” will help ensure that OMHA has the flexibility to work with appellants to take advantage of developing technologies. However, these added flexibilities will be based on appellants, including beneficiaries, opting into receiving notices and correspondences by means other than regular mail. For example, if a beneficiary affirmatively chooses to receive a decision via a secure internet portal instead of by mail, it would waste resources and be inefficient to require OMHA to also send a paper copy of the decision to the beneficiary by mail. The flexibility to work with developing technologies will allow OMHA to increase efficiency as we transition to a fully electronic case processing and adjudication environment, and provide all appellants with new options for receiving notices and other correspondence.

Comment: One commenter suggested adding a provision to §§405.1046(b)(2) and 423.2046(b)(2) explaining that appellants have the right to appeal a decision affirming a QIC or IRE dismissal to the Council, including instructions on how to initiate an appeal under this section and how to request a copy of the administrative record.

Response: We do not believe that it is appropriate to add a provision to §§405.1046(b)(2) and 423.2046(b)(2) explaining how to appeal a decision affirming a QIC or IRE dismissal to the

Council because a decision affirming a QIC or IRE dismissal is not appealable to the Council. Incorporating provisions from current §§405.1004(c) and 423.2004(c) that make a decision on a QIC or IRE dismissal not subject to further review, proposed §§405.1046(b)(2)(iii) and 423.2046(b)(2)(iii) explain that a decision affirming a QIC or IRE dismissal is binding and not subject to further review, unless the decision is reopened and revised by the ALJ or attorney adjudicator. We explained in the preamble to the 2005 Interim Final Rule implementing current §405.1004(c) that limiting review of dismissals to one level of appeal balances the need for review with the need for finality. 70 FR 11420, 11444. Because dismissals are based on procedural circumstances involved with the appeal request rather than the merits of whether the claim is payable, we determined that further review was not necessary, and we did not propose any changes to the limitation on review of dismissals in this final rule.

With respect to the commenter's suggestion to include instructions on how to obtain a copy of the administrative record in a notice of decision, we note that §§405.1046(a)(2)(iii), (b)(2)(ii), 423.2046(a)(2)(ii), and (b)(2)(ii), as finalized, require that a notice of decision must include the procedures for obtaining additional information concerning the decision, which would include information on how to obtain a copy of the administrative record. As discussed in section II.B.3.t of this final rule above, after a case is adjudicated, OMHA releases custody of the administrative record and forwards it to a CMS contractor or SSA. We will explore the possibility of adding contact information for the CMS contractor or SSA to the notice of decision; however, we believe that this would best be managed through internal policy at OMHA and not as part of this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1046, 405.1048, 423.2046, and 423.2048 as proposed without modification.

w. Removal of a hearing request from an ALJ to the Council (§§405.1050 and 423.2050)

Current §§405.1050 and 423.2050 explain the process for the Council to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. We proposed to replace “an ALJ” with “OMHA” in the section title, and to replace “pending before an ALJ” with “pending before OMHA,” and “the ALJ send” with “OMHA send” in the section text. In accordance with section II.B of the proposed rule and II.A.2 of this final rule above, these proposed revisions would provide that a request for hearing may be removed to the Council regardless of whether the request is pending before an ALJ or an attorney adjudicator. We did not propose to replace the last instance of “ALJ” in the section text because it refers specifically to hearings conducted by an ALJ. 81 FR 43790, 43843.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1050 and 423.2050 as proposed without modification.

x. Dismissal of a request for hearing or request for review and effect of a dismissal of a request for hearing or request for review (§§405.1052, 405.1054, 423.2052 and 423.2054)

Current §§405.1052 and 423.2052 describe the circumstances in which a request for hearing may be dismissed and the requirements for a notice of dismissal, and current §§405.1054 and 423.2054 describe the effect of a dismissal of a request for hearing. However, both current sections apply to a dismissal of a request for hearing, leaving ambiguities when issuing a dismissal of a request for review of a QIC or IRE dismissal. We proposed to maintain the provisions of each section that apply to a dismissal of a request for hearing in proposed §§405.1052(a), 405.1054(a), 423.2052(a) and 423.2054(a), with further revisions discussed below. 81 FR 43790, 43843–43845. We proposed to introduce new §§405.1052(b), 405.1054(b), 423.2052(b) and 423.2054(b) to address a dismissal of a request for review of a QIC or IRE dismissal. However, we proposed to re-designate and revise §§405.1052(a)(1) and 423.2052(a)(1), as discussed below, and re-designate the remaining paragraphs in §§405.1052(a) and 423.2052(a) accordingly. We also proposed to remove the introductory language to current §§405.1052 and 423.2052 because it is unnecessary to state that a dismissal of a request for hearing is in accordance with the provisions of the section, as the provisions are themselves binding authority and state in full when a request for hearing may be dismissed. In addition, we proposed to revise the titles of the sections to expand their coverage to include dismissals of requests to review a QIC or IRE dismissal. Furthermore, we proposed to re-designate and revise current §§405.1052(b) and 423.2052(b), which describe notices of dismissal, as proposed §§405.1052(d) and 423.2052(d) respectively, to reflect the revised structure of proposed §§405.1052 and 423.2052. We also proposed to remove current §423.2052(a)(8) and (c) because current §423.2052(a)(8) restates current §423.1972(c)(1), which already provides that a request

for hearing will be dismissed if the request itself shows that the amount in controversy is not met, and current §423.2052(c) restates current §423.1972(c)(2), which already provides that if after a hearing is initiated, the ALJ finds that the amount in controversy is not met, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal. We noted that a dismissal would be warranted in these circumstances pursuant to current §423.2052(a)(3), which is carried over as proposed §423.2052(a)(2) because the enrollee does not have a right to a hearing if the amount in controversy is not met.

We proposed to re-designate and revise current §§405.1052(a)(1) and 423.2052(a)(1) as proposed §§405.1052(c) and 423.2052(c) to separately address dismissals based on a party's withdrawal. We proposed in §§405.1052(c) and 423.2052(c) to include withdrawals of requests to review a QIC dismissal because we also proposed to add provisions to address other dismissals of those requests at §§405.1052(b) and 423.2052(b). We also proposed that an ALJ or attorney adjudicator may dismiss a request for review of a QIC dismissal based on a party's withdrawal of his or her request because as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), both ALJs and attorney adjudicators would be able to adjudicate requests to review a QIC dismissal. In addition, we proposed that an ALJ or attorney adjudicator may dismiss a request for hearing based on a party's withdrawal of his or her request. As discussed in section II.B of the proposed rule and II.A.2 of this final rule above, we believe that well-trained attorneys can efficiently perform a review of these requests and issue dismissals. We stated in the proposed rule that we believe using attorney adjudicators to the maximum extent possible would help OMHA be more responsive to appellants and allow ALJs to focus on conducting hearings and issuing decisions. We also proposed to revise the language in current §§405.1052(a)(1) and 423.2052(a)(1) (as re-designated in proposed §§405.1052(c) and

423.2052(c)) to (1) replace “notice of the hearing decision” with “notice of the decision, dismissal or remand” to reflect that a decision may be issued without a hearing, and to reflect other possible outcomes of the proceeding (dismissal and remand), and (2) clarify that a request to withdraw a request for hearing may be made orally at a hearing before the ALJ because only an ALJ may conduct a hearing.

Current §405.1052(a)(2) describes three possible alternatives for dismissing a request for hearing when the party that requested the hearing, or the party’s representative, does not appear at the time and place set for the hearing. We stated in the proposed rule that the current alternatives have caused confusion for appellants in understanding whether they are required to submit a statement explaining a failure to appear. Further, current provisions do not require evidence in the record to document an appellant was aware of the time and place of the hearing, and we stated that this has resulted in remands from the Council. We proposed to simplify the provision to provide two alternatives, and to require that contact has been made with an appellant and documented, or an opportunity to provide an explanation for failing to appear has been provided before a request for hearing is dismissed for failing to appear at the hearing. We proposed at §405.1052(a)(1)(i) to set forth the first alternative which would provide that a request for hearing may be dismissed if the party that filed the request was notified before the time set for hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing or does contact the ALJ but does not provide good cause for not appearing. We proposed at §405.1052(a)(1)(ii) to set forth the second alternative which would provide that a request for hearing may be dismissed if the record does not contain documentation that the party acknowledged the notice of hearing, but the

ALJ sends a notice to the party at his or her last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does respond but does not provide good cause for not appearing. In either circumstance, we proposed to maintain in §405.1052(a)(1) the current standard that in determining whether good cause exists, the ALJ considers any physical, mental, educational, or linguistic limitations that the party may have identified. We stated in the proposed rule that we believed proposed §405.1052(a)(1) would help ensure that appellants have consistent notice of a possible dismissal for failure to appear and an opportunity to provide a statement explaining why they did not appear before a dismissal is issued. We proposed to revise §423.2052(a)(1) to adopt corresponding revisions for dismissing a request for hearing under part 423, subpart U.

Current OMHA policy provides that a request for hearing that does not meet the requirements of current §405.1014 may be dismissed by an ALJ after an opportunity is provided to the appellant to cure an identified defect (OCPM, division 2, chapter 3, section II-3-6 D and E). We stated that a dismissal is appropriate because as an administrative matter, the proceedings on the request do not begin until the information necessary to adjudicate the request is provided and the appellant sends a copy of the request to the other parties. Additionally, a request cannot remain pending indefinitely once an appellant has demonstrated that he or she is unwilling to provide the necessary information or to send a copy of the request to the other parties. Therefore, we proposed at §405.1052(a)(7) to explain that a request for hearing may be dismissed if the request is not complete in accordance with proposed §405.1014(a)(1) or the appellant did not send copies of its request to the other parties in accordance with proposed §405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send copies of the request to the other parties. We stated in the proposed rule that we believed adding this provision

would emphasize the importance of following the requirements for filing a request for hearing, and clarify the outcome if the requirements are not met and the appellant does not cure identified defects after being provided with an opportunity to do so. We proposed at §423.2052(a)(7) to adopt a corresponding provision for dismissing a request for hearing under part 423, subpart U.

As discussed above, we proposed to add §405.1052(b) to explain when a request for review of a QIC dismissal would be dismissed. Under proposed §405.1052(b), a request for review could be dismissed in the following circumstances: (1) the person or entity requesting the review has no right to the review of the QIC dismissal under proposed §405.1004; (2) the party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline; (3) a beneficiary or beneficiary's representative filed the request for review and the beneficiary passed away while the request for review is pending and all of the following criteria apply: (i) a surviving spouse or estate has no remaining financial interest in the case, (ii) no other individuals or entities have a financial interests in the case and wish to pursue an appeal, and (iii) no other individual or entity filed a valid and timely request for a review of the QIC dismissal; and (4) the appellant's request for review is not complete in accordance with proposed §405.1014(a)(1) or the appellant does not send a copy of the request to the other parties in accordance with proposed §405.1014(d), after being provided with an opportunity to complete the request and/or send a copy of the request to the other parties. We stated in the proposed rule that we believed these provisions would encompass the reasons for dismissing a request for a review of a QIC dismissal, and are necessarily differentiated from dismissing a request for hearing because, as explained in section III.A.3.c of the proposed rule and II.B.3.c of this final rule above, we also stated that we did not believe there is a right to a hearing for requests for a review of a QIC dismissal. We proposed at §423.2052(b) to adopt

corresponding provisions for dismissing requests for a review of an IRE dismissal under part 423, subpart U proceedings.

As discussed above, current §405.1052(b) describes the requirements for providing notice of the dismissal and we proposed to re-designate the paragraph as proposed §405.1052(d). For the same reasons discussed in section III.A.3.v of the proposed rule and II.B.3.v of this final rule above for allowing a notice of a decision to be provided by means other than mail, we proposed in §405.1052(d) that OMHA may mail or “otherwise transmit” notice of a dismissal. We proposed to revise §423.2052(d) to adopt a corresponding revision for notices of dismissal under part 423, subpart U.

Current §405.1052(b) requires notice of the dismissal to be sent to all parties at their last known address. However, we stated in the proposed rule that we believed that requirement is overly inclusive and causes confusion by requiring notice of a dismissal to be sent to parties who have not received a copy of the request for hearing or request for review that is being dismissed. Thus, we proposed to revise §405.1052(d) to state that the notice of dismissal is sent to the parties who received a copy of the request for hearing or request for review because only those parties are on notice that a request was pending. In addition, we proposed at §405.1052(d) that if a party’s request for hearing or request for review is dismissed, the appeal would proceed with respect to any other parties who also filed a valid request for hearing or review regarding the same claim or disputed matter. This would address the rare circumstance in which more than one party submits a request, but the request of one party is dismissed. In that circumstance, the appeal proceeds on the request that was not dismissed, and the party whose request was dismissed remains a party to the proceedings but does not have any rights associated with a party that filed a request, such as the right to escalate a request for hearing. We did not propose a

corresponding revision to §423.2052(c) because only the enrollee is a party to an appeal under part 423, subpart U.

Current §405.1052 does not include authority for an ALJ to vacate his or her own dismissal, and instead requires an appellant to request the Council review an ALJ's dismissal. As explained in the 2005 Interim Final Rule (70 FR 11465), the authority for an ALJ to vacate his or her own dismissal was not regarded as an effective remedy because the record was no longer in the ALJ hearing office, and the resolution was complicated when appellants simultaneously asked the ALJ to vacate the dismissal order and asked the Council to review the dismissal. However, we stated that in practice, the lack of the authority for an ALJ to vacate his or her own dismissal has constrained ALJs' ability to correct erroneous dismissals that can be easily remedied by the ALJ, and has caused unnecessary work for the Council. We proposed to add §405.1052(e) to provide the authority for an ALJ or an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), to vacate his or her own dismissal within 6 months of the date of the notice of dismissal, in the same manner as a QIC can vacate its own dismissal. We stated in the proposed rule that we believed that this authority would reduce unnecessary appeals to the Council and provide a more timely resolution of dismissals for appellants, whether the dismissal was issued by an ALJ or attorney adjudicator. We also noted that the coordination for obtaining the administrative record and addressing instances in which an appellant also requests a review of the dismissal by the Council can be addressed through operational coordination among CMS, OMHA, and the DAB. We proposed in §423.2052(e) to adopt a corresponding provision for vacating a dismissal under part 423, subpart U.

To align the effects of a dismissal with proposed §405.1052(e), we proposed to add §405.1054(a) to state that the dismissal of a request for hearing is binding unless it is vacated by the ALJ or attorney adjudicator under §405.1052(e), in addition to the current provision that allows the dismissal to be vacated by the Council under §405.1108(b). To explain the effect of a dismissal of a request for review of a QIC dismissal, consistent with §405.1004, we proposed in §405.1054(b) to provide that the dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under §405.1052(e). We proposed in §423.2054 to adopt corresponding revisions for the effect of dismissals of request for hearing and requests for review of an IRE dismissal under part 423, subpart U.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on this proposal. The commenter suggested that additional leeway should be allowed for unrepresented beneficiaries to complete a request for hearing and/or send copies of the request to the other parties before the request is dismissed, and dismissals for failing to meet these requirements should be used sparingly. The commenter also stated that the notice of dismissal should always be provided to beneficiaries by regular mail in addition to any other method of transmission that is used.

Response: As discussed above and in the proposed rule, we believe that the provision allowing for dismissal of an incomplete request for hearing or review of a QIC or IRE dismissal is necessary to emphasize the importance of the information required for filing a complete request, and to clarify the outcome if the required information is not provided after an opportunity to complete the request is provided. This provision will bring efficiencies to the

appeals process by helping to ensure that appellants furnish all information necessary to adjudicate the request to the adjudicator and the other parties as early in the process as possible and preventing appeals from remaining pending indefinitely if an appellant has demonstrated an unwillingness to complete the request. If there is information missing in a beneficiary's request for hearing or review of a QIC or IRE dismissal, the beneficiary will receive a letter explaining what information is missing, and providing the address and phone number of the OMHA field office to contact with any questions. In addition, OMHA maintains a dedicated beneficiary help line to assist beneficiaries with questions they may have about the appeals process at OMHA, including helping them to understand what information is necessary to complete the request.

However, as discussed in section II.B.3.g.v of this final rule above, we agree that unrepresented beneficiaries may have difficulty meeting the copy requirement of proposed §405.1014(d), and should be exempt from the consequence of failing to provide a copy of a request for hearing or review of a dismissal to the other parties. Consequently, we are revising §405.1052(a)(7) and (b)(4) to provide that a request filed by an unrepresented beneficiary will not be dismissed if the appellant fails to send a copy of the request to the other parties in accordance with proposed §405.1014(d).

With respect to the commenter's suggestion to always provide beneficiaries with the notice of dismissal by regular mail, we refer the commenter to our response to a similar comment in section II.B.3.v of this final rule above, where we explain why we do not believe a notice of decision sent to a beneficiary under §405.1046(a) and §423.2046(a) should always be sent by mail in addition to any other method of transmission that is used. We believe this explanation responds to the commenter's same suggestion with regard to a notice of dismissal.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1052, 405.1054, 423.2052 and 423.2054 as proposed, with the following modification. We are amending §405.1052(a)(7) and (b)(4) to state that a request filed by an unrepresented beneficiary will not be subject to dismissal if the appellant fails to send a copy of the request to the other parties in accordance with §405.1014(d).

4. Applicability of Medicare coverage policies (§§405.1060, 405.1062, 405.1063, 423.2062, and 423.2063)

Current §405.1060 addresses the applicability of national coverage determinations (NCDs) to claim appeals brought under part 405, subpart I and provides that an ALJ and the Council may not disregard, set aside, or otherwise review an NCD, but may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim. Current §405.1062 addresses the applicability of local coverage determinations (LCDs) and other policies, and specifies that ALJs and the Council are not bound by LCDs, local medical review policies (LMRPs), or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Similarly, current §423.2062 states that ALJs and the Council are not bound by CMS program guidance but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Current §§405.1062 and 423.2062 also provide that an ALJ or Council decision to

disregard a policy applies only to the specific claim being considered and does not have precedential effect. Further, §405.1062 states that an ALJ or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. Current §§405.1063 and 423.2063 address the applicability of laws, regulations, and CMS Rulings, and provide that all laws and regulations pertaining to the Medicare program (and for §405.1063 the Medicaid program as well), including but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs and the Council, and consistent with §401.108, CMS Rulings are binding on all HHS components that adjudicate matters under the jurisdiction of CMS.

We proposed to revise §§405.1060, 405.1062, 405.1063, 423.2062, and 405.2063 to replace “ALJ” or “ALJs” with “ALJ or attorney adjudicator” or “ALJs or attorney adjudicators” except in the second sentence of §405.1062(c). 81 FR 43790, 43846. We stated that an attorney adjudicator would issue certain decisions and dismissals and therefore would apply the authorities addressed by these sections. We stated in the proposed rule that requiring the attorney adjudicators to apply the authorities in the same manner as an ALJ would provide consistency in the adjudication process, regardless of who is assigned to adjudicate a request for an ALJ hearing or request for review of a QIC or IRE dismissal. We did not propose to revise the second sentence in current §405.1062(c) because attorney adjudicators would not review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 (part 426 appeals are currently heard by ALJs in the Civil Remedies Division of the DAB).

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that

decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1060, 405.1062, 405.1063, 423.2062, and 423.2063 as proposed without modification.

5. Council review and judicial review

a. Council review: general (§§405.1100, 423.1974 and 423.2100)

As described below, we proposed a number of changes to §§405.1100, 423.1974 and 423.2100 with respect to Council review, generally. 81 FR 43790, 43846–43847. Current §405.1100 discusses the Council review process. Current §405.1100(a) states that the appellant or any other party to the hearing may request that the Council review an ALJ’s decision or dismissal. We proposed to revise §405.1100(a) to replace “the hearing” with “an ALJ’s or attorney adjudicator’s decision or dismissal,” and “an ALJ’s decision or dismissal,” with “the ALJ’s or attorney adjudicator’s decision or dismissal” because the parties are parties to the proceedings and the resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), an attorney adjudicator would be able to issue certain decisions or dismissals for which Council review may be requested.

Current §423.1974 states that an enrollee who is dissatisfied with an ALJ hearing decision may request that the Council review the ALJ’s decision or dismissal as provided in §423.2102, and current §423.2100(a) states that consistent with §423.1974, the enrollee may request that the Council review an ALJ’s decision or dismissal. We proposed to revise §423.1974 to replace “ALJ hearing decision” with “an ALJ’s or attorney adjudicator’s decision or dismissal,” and to revise §§423.1974 and 423.2100(a) to replace “ALJ’s decision or dismissal”

with “an ALJ’s or attorney adjudicator’s decision or dismissal” because the parties are parties to the proceedings and resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), an attorney adjudicator may issue a decision or dismissal for which Council review may be requested.

Current §405.1100(b) provides that under the circumstances set forth in §§405.1104 and 405.1108, an appellant may request escalation of a case to the Council for a decision even if the ALJ has not issued a decision or dismissal in his or her case. We proposed to revise §405.1100(b) to provide that under circumstances set forth in §§405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case. We stated in the proposed rule that these revisions would reference §405.1016, which, as discussed in section III.A.3.h of the proposed rule and II.B.3.h of this final rule above, would replace the current §405.1104 provisions for escalating a case from the OMHA level to the Council. We stated that they would also provide that in addition to potentially issuing a decision or dismissal, an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), may issue a remand—this would present a complete list of the actions that an ALJ or attorney adjudicator could take on an appeal.

Current §§405.1100(c) and 423.2100(b) and (c) state in part that when the Council reviews an ALJ’s decision, it undertakes a de novo review, and the Council issues a final decision or dismissal order or remands a case to the ALJ. We proposed to revise §§405.1100(c) and 423.2100(b) and (c) to state that when the Council reviews an ALJ’s or attorney adjudicator’s decision, it undertakes a de novo review and may remand a case to an ALJ or

attorney adjudicator, so that the same standard for review is applied to ALJ and attorney adjudicator decisions. We also proposed to revise §§405.1100(c) and 423.2100(c) to state that the Council may remand an attorney adjudicator's decision to the attorney adjudicator so that like an ALJ, the attorney adjudicator can take the appropriate action ordered by the Council (however, if the Council were to order that a hearing must be conducted, the case would be transferred to an ALJ upon remand to the attorney adjudicator because only an ALJ may conduct a hearing).

Current §423.2100(c) and (d) provide that the Council issues a final decision, dismissal order, or remand no later than the period of time specified in the respective paragraph, beginning on the date that the request for review is received by the entity specified in the ALJ's written notice of decision. We proposed to revise §423.2100(c) and (d) to state that the period of time begins on the date that the request for review is received by the entity specified in the ALJ's or attorney adjudicator's written notice of decision because an attorney adjudicator may also issue a decision, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We also proposed to revise §423.2100(c) to correct a typographical error by inserting "day" into the current "90 calendar period," so it is clear to enrollees that the period of time being referenced is the 90 calendar day period.

Current §405.1100(d) states in part that when deciding an appeal that was escalated from the ALJ level to the Council, the Council will issue a final decision or dismissal order or remand order within 180 calendar days of receipt of the appellant's request for escalation. A remand from the Council after an appeal is escalated to it is exceedingly rare and done in circumstances in which the Council must remand to an ALJ so that the ALJ may obtain information under current §405.1034 that is missing from the written record and essential to resolving the issues on

appeal, and that information can only be provided by CMS or its contractors, because the Council does not have independent authority to obtain the information from CMS or its contractors. In addition, an appeal may have not yet have been assigned to an ALJ, or could be assigned to an attorney adjudicator as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), when the appeal was escalated by the appellant. We proposed to revise §405.1100(d) to state that if the Council remands an escalated appeal, the remand is to the OMHA Chief ALJ because the rare and unique circumstances in which an escalated appeal is remanded by the Council require immediate attention that the OMHA Chief ALJ is positioned to provide to minimize delay for the appellant, and to minimize confusion if the case was not assigned to an ALJ or attorney adjudicator when it was escalated.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received one comment that supported the proposal that the Council remand escalated appeals to the Chief ALJ to minimize confusion and delay for appellants. The commenter also requested that language be added to the regulation requiring the Council to acknowledge receipt of an appellant's request for review due to the Council's considerable backlog and delay in issuing decisions.

Response: We thank the commenter for its support and agree that the Council should acknowledge receipt of an appellant's request for review. Since 2009, it has been and will continue to be, the practice of the Council to issue acknowledgment letters to appellants when a request for review is received and docketed. In addition, the Council has started accepting electronically filed requests for review, using the Medicare Operations Divisions Electronic Filing (MOD E-File) system, located at <https://dab.E-File.hhs.gov/mod>. An appellant that

electronically files a request for review will receive an automated email response that acknowledges receipt of the request for review as well as provides the docket number assigned to the case. Finally, appellants may also use MOD E-File to check the status of appeals, regardless of whether the request for review was electronically filed. Appellants can check the status of an appeal by the docket number stated in the acknowledgment letter or e-mail or by the ALJ appeal number. Because of the Council's continued commitment to issuing acknowledgments, as well as electronic enhancements that allow parties to check the status of appeals pending before the Council, we find it unnecessary to modify the proposed regulation.

Comment: One commenter questioned the current rule granting the Council, which is comprised of Administrative Appeals Judges (AAJs), the authority to conduct de novo reviews of ALJ decisions. The commenter was concerned that AAJs lack the independence of ALJs and are beholden to the agency for their positions and, therefore, AAJs are not best suited to review ALJ decisions. Accordingly, the commenter suggested various revisions to the current rule to address this concern that are unrelated to the proposed rule.

Response: We appreciate the commenter's opinion and suggestion, but its comment is beyond the scope of the proposed rule, and thus we are not addressing it in this final rule.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1100, 423.1974 and 423.2100 as proposed without modification.

b. Request for Council review when ALJ issues decision or dismissal (§§405.1102 and 423.2102)

As described below, we proposed a number of changes to §§405.1102 and 423.2102, which discuss requests for Council review when an ALJ issues a decision or dismissal. 81 FR

43790, 43847. Current §§405.1102(a)(1) and 423.2102(a)(1) provide that a party or enrollee, respectively, to “the ALJ hearing” may request a Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ’s decision or dismissal, which is in accordance with the criteria specified in current §§405.1102 and 423.2102. However, we stated in the proposed rule that a party or enrollee is a party to the proceedings and resulting decision or dismissal, and may appeal the decision or dismissal regardless of whether a hearing was conducted in the appeal, and as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney adjudicator may issue a decision or dismissal for which Council review may be requested. To help ensure there is no confusion that a party or enrollee may seek Council review even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal, we proposed to revise §§405.1102(a)(1) and 423.2102(a)(1) to state a party or enrollee to a decision or dismissal issued by an ALJ or attorney adjudicator may request Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ’s or attorney adjudicator’s decision or dismissal.

Current §§405.1102(c) and 423.2102(c) provide that a party or enrollee, respectively, does not have a right to seek Council review of an ALJ’s remand to a QIC or IRE, or an ALJ’s affirmation of a QIC’s or IRE’s dismissal of a request for reconsideration. However, under current §§405.1004(c) and 423.2004(c), a party or enrollee, respectively, may currently seek Council review of a dismissal of a request for review of a QIC or IRE dismissal because, as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule above, an ALJ does not currently have the authority to vacate his or her own dismissal. As proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), an attorney

adjudicator could adjudicate requests for a review of a QIC or IRE dismissal. In addition, proposed §§405.1052(e) and 423.2052(e) would establish the authority for an ALJ or attorney adjudicator to vacate his or her own dismissal, and in accordance with the policy that a review of a dismissal is only reviewable at the next level of appeal, as discussed in section III.A.3.c of the proposed rule and II.B.3.c of this final rule above, proposed §§405.1102(c) and 423.2102(c) would be revised to indicate that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's dismissal of a request for review of a QIC dismissal. Therefore, we proposed at §§405.1102(c) and 423.2102(c) to add that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC or IRE, affirmation of a QIC's or IRE's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC or IRE dismissal.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment supporting the revised language that Council review may be sought even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal.

Response: We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1102 and 423.2102 as proposed without modification.

c. Where a request for review or escalation may be filed (§§405.1106 and 423.2106)

As discussed below, we proposed a number of changes to §§405.1106 and 423.2106 with respect to where a request for review or escalation may be filed. 81 FR 43790, 43847–43848.

Current §§405.1106(a) and 423.2106 provide that when a request for a Council review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action, and under §405.1106, the appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision or notice of dismissal. The sections also explain that if the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action, and upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame. In addition, current §405.1106(b) discusses that if an appellant files a request to escalate an appeal to the Council because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under §405.1016, the request for escalation must be filed with both the ALJ and the Council, and the appellant must also send a copy of the request for escalation to the other parties and failure to copy the other parties tolls the Council's adjudication deadline set forth in §405.1100 until all parties to the hearing receive notice of the request for Council review.

We proposed in §§405.1106 and 423.2106 to replace all instances of "ALJ" with "ALJ or attorney adjudicator," and "ALJ's action" with "ALJ's or attorney adjudicator's action," to provide that the sections apply to decisions and dismissals issued by an attorney adjudicator as well, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore appellants would have the same right to seek Council review of the attorney adjudicator's decision or dismissal, and the Council would have the authority to take the same

actions in reviewing an attorney adjudicator's decision or dismissal. We also proposed to replace "a copy of the hearing decision under §405.1046(a) or a copy of the notice of dismissal under §405.1052(b)" in §405.1106(a) with "notice of the decision or dismissal," because §§405.1046 and 405.1052 provide for notice of a decision or dismissal, respectively, to be sent, and a decision or dismissal may be issued by an ALJ or attorney adjudicator without conducting a hearing. In addition, in describing the consequences of failing to send a copy of the request for review to the other parties, we proposed to replace "until all parties to the hearing" in §405.1106(a) to "until all parties to the ALJ or attorney adjudicator decision or dismissal," to align the language with the preceding sentences.

We proposed to revise §405.1106(b) to align the paragraph with the revised escalation process proposed at §405.1016 (see section III.A.3.h.i of the proposed rule and II.B.3.h.i of this final rule above). Specifically, we proposed to revise §405.1106(b) to state that if an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under §405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. This proposed revision would align this section with the revised process in proposed §405.1016 by specifying that the request for escalation is filed with OMHA and removing the requirement for an appellant to also file the request with the Council. In addition, proposed §405.1106(b) would specify that the request for escalation must be sent to the other parties who were sent a copy of the QIC reconsideration, which would align with the parties to whom the appellant is required to send a copy of its request for hearing. Proposed §405.1106(b) would also refer to "an applicable adjudication period" under §405.1016, to align the

terminology and because an adjudication period may not apply to a specific case (for example, if the appellant waived an applicable adjudication time frame). Finally, proposed §405.1106(b) would provide that failing to copy the other parties would toll the Council's adjudication deadline until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation, rather than notice of the request for Council review as is currently required, because the revised escalation process proposed at §405.1016 would remove the requirement to file a request for Council review when escalation is requested from the OMHA to the Council level.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1106 and 423.2106 as proposed without modification.

d. Council actions when request for review or escalation is filed (§§405.1108 and 423.2108)

As described below, we proposed a number of changes to §§405.1108 and 423.2108, which describe the actions the Council may take upon receipt of a request for review or, for §405.1108, a request for escalation. 81 FR 43790, 43848. We proposed at §405.1108(d) introductory text to replace "ALJ level" with "OMHA level" to provide that the Council's actions with respect to a request for escalation are the same regardless of whether the case was pending before an ALJ or attorney adjudicator, or unassigned at the time of escalation. We also proposed at §405.1108(d)(3) to replace "remand to an ALJ for further proceedings, including a

hearing” with “remand to OMHA for further proceedings, including a hearing” because we stated in the proposed rule that we believed the Council could remand an escalated case to an ALJ or attorney adjudicator for further proceedings, but if the Council ordered that a hearing be conducted, the case would need to be remanded to an ALJ. We did not propose any corresponding changes to §423.2108 because escalation is not available for Part D coverage appeals.

We also proposed in §§405.1108(b) and 423.2108(b), to provide that the dismissal for which Council review may be requested is a dismissal of a request for a hearing, because as discussed in section III.A.3.x of the proposed rule and II.B.3.x of this final rule above, proposed §§405.1054(b) and 423.2054(b) would provide that a dismissal of a request for a review of a QIC or IRE dismissal of a request for reconsideration is binding and not subject to further review. Finally, we proposed to replace all remaining references in §§405.1108 and 423.2108 to “ALJ” with “ALJ or attorney adjudicator” and “ALJ’s” with “ALJ’s or attorney adjudicator’s” to further provide that the Council’s actions with respect to a request for review or escalation are the same for cases that were decided by or pending before an ALJ or an attorney adjudicator.

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer

explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1108 and 423.2108 as proposed without modification.

e. Council reviews on its own motion (§§405.1110 and 423.2110).

As described below, we proposed several changes to §§405.1110 and 423.2110, which discuss Council reviews on its own motion. 81 FR 43790, 43848–43849. Current §§405.1110(a) and 423.2110(a) state the general rule that the Council may decide on its own motion to review a decision or dismissal issued by an ALJ, and CMS or its contractor, including the IRE, may refer a case to the Council within 60 calendar days after the date of the ALJ’s decision or dismissal (for §405.1110(a)) or after the ALJ’s written decision or dismissal is issued (for §423.2110(a)). Current §§405.1110(b) and 423.2110(b) provide the standards for CMS or its contractors to refer ALJ decisions and dismissals to the Council for potential review under the Council’s authority to review ALJ decisions and dismissals on the Council’s own motion, and require that a copy of a referral to the Council be sent to the ALJ whose decision or dismissal was referred, among others. Current §§405.1110(c) and 423.2110(c) explain the standards of review used by the Council in reviewing the ALJ’s action. Current §§405.1110(d) and 423.2110(d) explain the actions the Council may take, including remanding the case to the ALJ for further proceedings, and state that if the Council does not act on a referral within 90 calendar days after receipt of the referral (unless the 90 calendar day period has been extended as provided in the respective subpart), the ALJ’s decision or dismissal is binding (§405.1110(d) further specifies that the decision or dismissal is binding on the parties to the decision).

We proposed at §§405.1110 and 423.2110 to replace each instance of “at the ALJ level” with “at the OMHA level” and “ALJ proceedings” with “OMHA proceedings.” We stated in the proposed rule that we believe the standards for referral to the Council by CMS or its contractor

would be the same regardless of whether the case was decided by an ALJ or an attorney adjudicator, and that “at the OMHA level” and “OMHA proceedings” would reduce confusion in situations where the case was decided by an attorney adjudicator. We proposed at §405.1110(b)(2) to replace the references to current §405.1052(b) with references to §405.1052(d) to reflect the structure of proposed §405.1052, and also proposed to revise §§405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in §405.1110(b)(2)) or CMS or the IRE (in §423.2110(b)(2)(ii)) sends a copy of its referral to the OMHA Chief ALJ. We stated that the current requirement to send a copy of the referral to the ALJ is helpful in allowing OMHA ALJs to review the positions that CMS is advocating before the Council, but at times has caused confusion as to whether the ALJ should respond to the referral (there is no current provision that allows the Council to consider a statement in response to the referral). In addition, we stated that the proposed revision would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We also proposed at §405.1110(b)(2) to replace “all other parties to the ALJ’s decision” with “all other parties to the ALJ’s or attorney adjudicator’s action” and at §405.1110(d) to replace “ALJ decision” with “ALJ or attorney adjudicator action” to encompass both decisions and dismissals issued by an ALJ or an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). We stated in the proposed rule that we believe that parties to an ALJ’s dismissal or an attorney adjudicator’s decision or dismissal have the same right to receive a copy of another party’s written exceptions to an agency referral as the parties to an ALJ’s decision, and that an ALJ’s or attorney adjudicator’s decision or dismissal is binding on the parties to the action. We proposed to replace each remaining instance in §§405.1110 and

423.2110 of “ALJ” with “ALJ or attorney adjudicator,” “ALJ’s decision or dismissal” with “ALJ’s or attorney adjudicator’s decision or dismissal,” “ALJ’s decision” with “ALJ’s or attorney adjudicator’s decision or dismissal,” and “ALJ’s action” with “ALJ’s or attorney adjudicator’s action.” We stated that these proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore CMS and its contractors would have the same right to refer attorney adjudicator decisions and dismissals to the Council, and the Council would have the authority to take the same actions and have the same obligations in deciding whether to review an attorney adjudicator’s decision or dismissal on its own motion.

Finally, we proposed at §423.2110(b)(1) to replace “material to the outcome of the claim” with “material to the outcome of the appeal” because unlike Part A and Part B, no “claim” is submitted for drug coverage under Part D.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received two comments on these proposals. The commenters both objected to the proposal to revise §§405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in §405.1110(b)(2)) or CMS or the IRE (in §423.2110(b)(2)(ii)) sends a copy of its referral for own motion review by the Council to the OMHA Chief ALJ, rather than the ALJ who issued the decision, as provided under current §§405.1110(b)(2) and 423.2110(b)(2)(ii). The commenters felt it would be more appropriate for notice of the Council’s action to be provided to the Chief ALJ, as the Council may not accept the referral for own motion review, or may not agree with

the reason(s) for the referral, and therefore the referral itself is not necessarily evidence of a training or policy clarification need.

Response: Current §§405.1110(b)(2) and 423.2110(b)(2)(ii) contain a requirement for CMS, or CMS or the IRE, to send a copy of its referral to the ALJ. As we explained above (and in section III.A.5.e of the proposed rule), we proposed to instead require that the copy of the referral be sent to the Chief ALJ because the current requirement has at times caused confusion about whether a response is required from the ALJ. The current requirement also makes it difficult to identify trends and training opportunities, because copies of the referrals are sent to individual ALJs rather than to one individual at OMHA or a centralized location. We stated in the proposed rule that sending copies of the referrals to the Chief ALJ would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We also believe sending a copy of the referral to the Chief ALJ would be administratively simpler for CMS or the IRE.

We understand the commenter's suggestion that the notice of the Council's action is a better measure to assess the need for possible training or policy clarifications. In practice, OMHA has a process in place to receive and review copies of all Council actions, such as decisions remanding, reversing, modifying, or affirming ALJ decisions and dismissals, and dismissals of requests for review and declinations of referrals for own motion review, and OMHA makes those available to all staff. However, due to the time lag between when a request for own motion review is filed and when the Council issues its action (which may be up to 90 days), we believe requiring CMS (under §405.1110), or CMS or the IRE (under §423.2110), to send a copy of its referral to OMHA, and specifically to the Chief ALJ, will help ensure OMHA

is aware of any trends that may necessitate action or further research for possible training or policy clarifications as early as possible, with the understood caveat that a referral in and of itself is not a basis for training or policy clarification because, as the commenter suggests, the Council's action on the referral is needed to fully assess any needed training or policy clarifications.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §405.908 as proposed with the following modification. We are correcting a drafting error in proposed §405.1110(b)(2) by removing two references to a "hearing decision" issued under §405.1046(a) and replacing them with "decision," because §405.1046(a) as finalized in this rule also addresses decisions issued by an ALJ or attorney adjudicator when a hearing is not held.

f. Content of request for review (§§405.1112 and 423.2112).

As described below, we proposed a number of changes to §§405.1112 and 423.2112, which discuss the content of a request for Council review. 81 FR 43790, 43849. Current §405.1112(a) requires a request for Council review to contain the date of the ALJ's decision or dismissal order, if any, among other information. Current §423.2112(a)(1) states that the request for Council review must be filed with the entity specified in the notice of the ALJ's action. Current §§405.1112(b) and 423.2112(b) state that the request for review must identify the parts of the ALJ action with which the party or enrollee, respectively, requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. Current §405.1112(b) provides an example that if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with

that authority. Current §§405.1112(c) and 423.2112(c) state that the Council will limit its review of an ALJ's action to those exceptions raised by the party or enrollee, respectively, in the request for review, unless the appellant is an unrepresented beneficiary or the enrollee is unrepresented.

We proposed at §§405.1112 and 423.2112 to replace "ALJ's decision or dismissal" with "ALJ's or attorney adjudicator's decision or dismissal," "ALJ action" with "ALJ's or attorney adjudicator's action," and "ALJ's action" with "ALJ's or attorney adjudicator's action." These revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore information on the attorney adjudicator's decision and dismissal must be included in the request for Council review, and the scope of the Council's review would be the same as for an ALJ's decision or dismissal.

Current §405.1112(a) states that a request for Council review must be filed with the Council or appropriate ALJ hearing office. However, we stated in the proposed rule that this provision may cause confusion when read with current §405.1106(a), which states that a request for review must be filed with the entity specified in the notice of the ALJ's action. In practice, OMHA notices of decision and dismissal provide comprehensive appeal instructions directing requests for Council review to be filed directly with the Council, and provide address and other contact information for the Council. Therefore, we proposed to revise §405.1112(a) to state that the request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action, which would align §405.1112(a) with current §405.1106(a), and reaffirm that a request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

Current §405.1112(a) also states that the written request for review must include the hearing office in which the appellant's request for hearing is pending if a party is requesting escalation from an ALJ to the Council. In light of the proposed revisions to the escalation process discussed in section III.A.3.h.i of the proposed rule and II.B.3.h.i of this final rule above, we proposed to remove this requirement from §405.1112(a) because proposed §405.1016 would provide that a request for escalation is filed with OMHA. In accordance with proposed §405.1016, if the request for escalation meets the requirements of §405.1016(f)(1) and a decision, dismissal, or remand cannot be issued within 5 calendar days after OMHA receives the request, the appeal would be forwarded to the Council.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter requested clarification as to whether the criteria specified in §405.1110 for agency referrals are also appropriate bases for requests for review.

Response: We clarify that appellants may file requests for Council review for any reason they disagree with the ALJ's decision or dismissal, including if they believe that the ALJ abused his or her discretion or that the decision or dismissal is not supported by the evidence. On the other hand, CMS or its contractors may refer cases to the Council only for the reasons specified in §405.1110(b) and §423.2110(b) (if CMS or a contractor believes that the ALJ's or attorney adjudicator's decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the public interest; or, where CMS or its contractor participated (or requested to participate, for Part D appeals) in the appeal at the OMHA level, then CMS is also permitted to refer cases to the Council on the additional bases

that it believes the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of the evidence or the ALJ or attorney adjudicator abused his or her discretion).

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1112 and 423.2112 as proposed without modification.

g. Dismissal of request for review (§§405.1114 and 423.2114)

We proposed at §405.1114(c)(3) to replace “ALJ hearing” with “ALJ's or attorney adjudicator's action.” This proposed revision would provide that the paragraph applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), and therefore a valid and timely request for Council review filed by another party to an attorney adjudicator's decision or dismissal would preclude dismissal of a request for Council review under §405.1114(c). We did not propose any corresponding changes to §423.2114 (which we inadvertently referenced as §423.1114 in the proposed rule) because there is no provision equivalent to current §405.1114(c)(3). 81 FR 43790, 43849.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §405.1114 as proposed without modification.

h. Effect of dismissal of request for Council review or request for hearing (§§405.1116 and 423.2116)

Current §§405.1116 and 423.2116 describe the effect of a dismissal by the Council of a request for Council review or a request for hearing. We proposed to replace “ALJ” with “ALJ or attorney adjudicator” to provide that the denial of a request for Council review of a dismissal issued by an attorney adjudicator is binding and not subject to judicial review in the same manner as the denial of a request for Council review of a dismissal issued by an ALJ. We stated in the proposed rule that we believe the Council’s denial of a request to review an attorney adjudicator’s dismissal would be subject to the same general rules described in sections III.A.3.c and III.A.3.x of the proposed rule and sections II.B.3.c and II.B.3.x of this final rule above pertaining to reviews of dismissals at the next adjudicative level, and that further review of the attorney adjudicator’s dismissal in Federal district court would be unavailable. 81 FR 43790, 43849–43850.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1116 and 423.2116 as proposed without modification.

i. Obtaining evidence from the Council (§§405.1118 and 423.2118)

As described below, we proposed several changes to §§405.1118 and 423.2118, which provide that a party or an enrollee, respectively, may request and receive a copy of all or part of

the record of the ALJ hearing. 81 FR 43790, 43850. We proposed to replace “ALJ hearing” with “ALJ’s or attorney adjudicator’s action.” We stated in the proposed rule that this proposed revision would provide that a party to an attorney adjudicator action, or to an ALJ decision that was issued without a hearing, may request and receive a copy of all or part of the record to the same extent as a party to an ALJ hearing. We also proposed to replace the reference to an “exhibits list” with a reference to “any index of the administrative record” to provide greater flexibility in developing a consistent structure for the administrative record. In addition, we proposed at §405.1118 to replace the reference to a “tape” of the oral proceeding with an “audio recording” of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We proposed a parallel revision to §423.2118 to replace the reference to a “CD” of the oral proceeding with an “audio recording” of the oral proceeding.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: One commenter asked that §405.1118 be revised to clarify exactly where parties should direct their requests for a copy of all or part of the record of the ALJ hearing. The commenter stated that it has had difficulty obtaining copies of the record from the ALJ who conducted the hearing once OMHA had released custody of the record. The commenter thought it would be helpful if the notice of decision issued by OMHA contained language that informed the appellant where to send such requests.

Response: Proposed §405.1118 is titled “Obtaining evidence from the Council,” and deals with requests for copies of all or part of the record of the ALJ hearing. After a party requests review by the Council, the entire administrative record, including audio recordings,

documentary evidence, and any index of the administrative record, is transferred to the Council. Thus, parties who are requesting a copy of all or part of the record of the ALJ hearing after a request for review has been filed with the Council may direct their requests directly to the Council. For requests that are made prior to a request for review being filed with the Council, see the discussion in section II.B.3.t of this final rule above. With respect to the commenter's suggestion regarding including language in the notice of an ALJ's decision, we may consider the suggestion in future revisions to the standard notice.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1118 and 423.2118 as proposed without modification.

j. What evidence may be submitted to the Council (§§405.1122 and 423.2122)

As described below, we proposed several changes to §§405.1122 and 423.2122, which describe the evidence that may be submitted to and considered by the Council, the process the Council follows in issuing subpoenas, the reviewability of Council subpoena rulings, and the process for seeking enforcement of subpoenas. 81 FR 43790, 43850. Current §405.1122(a)(1) provides that the Council will limit its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, unless the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level. We proposed at §405.1122(a) introductory text and (a)(1) to replace each instance of "ALJ's decision" with "ALJ's or attorney adjudicator's decision," "before the ALJ" with "before the ALJ or attorney adjudicator," and "the ALJ level" with "the OMHA level." We stated in the proposed rule that we believe the standard for review of evidence at the Council level would be the same regardless of whether the case was decided by an ALJ or attorney adjudicator, as proposed in section II.B of

the proposed rule (and discussed in section II.A.2 above), at the OMHA level. We also proposed corresponding revisions to §423.2122(a) introductory text and (a)(1). Also, to help ensure it is clear that the exception for evidence related to new issues raised at the OMHA level is not limited to proceedings in which a hearing before an ALJ was conducted, we proposed at §§405.1122(a)(1) and §423.2122(a)(1) to replace “hearing decision” with “ALJ’s or attorney adjudicator’s decision.” Current §405.1122(a)(2) provides that if the Council determines that additional evidence is needed to resolve the issues in the case, and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. For the reasons described above, we proposed at §405.1122(a)(2) to replace “ALJ” with “ALJ or attorney adjudicator” and “hearing record” with “administrative record,” along with corresponding revisions to §423.2122(a)(2). Current §405.1122(b)(1) describes the evidence that may be considered by the Council when a case is escalated from the ALJ level. For the reasons described above, we proposed to replace “ALJ level” with “OMHA level.” We did not propose any corresponding changes to §423.2122 because escalation is not available for Part D coverage appeals. Finally, we proposed to replace all remaining instances of “ALJ” in §405.1122(b)(1), (b)(2), (c)(2), (c)(3) introductory text, (c)(3)(i), and (c)(3)(ii) with “ALJ or attorney adjudicator,” as we believe the Council’s authority to consider evidence entered in the record by an attorney adjudicator and to remand a case to an attorney adjudicator for consideration of new evidence would be the same as the Council’s current authority to consider evidence entered in the record by an ALJ and remand a case to an ALJ. We did not propose any corresponding changes to §423.2122 because there are no remaining references to “ALJ.”

We received no comments on these proposals, other than: (1) comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs; and (2) comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1122 and 423.2122 as proposed without modification.

k. Case remanded by the Council (§§405.1126 and 423.2126)

As described below, we proposed a number of changes to the regulations at §§405.1126 and 423.2126 concerning cases that are remanded by the Council. 81 FR 43790, 43850–43851. Current §§405.1126(a) and (b) explain the Council’s remand authority. We proposed to replace each instance of “ALJ” with “ALJ or attorney adjudicator” to provide that the Council may remand a case in which additional evidence is needed or additional action is required by the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). Proposed §405.1126(b) would also provide that an ALJ or attorney adjudicator would take any action that is ordered by the Council, and may take any additional action that is not inconsistent with the Council’s remand order. We stated in the proposed rule that we believe it is necessary for the Council to have the same authority to remand an attorney adjudicator’s decision to the attorney adjudicator as the Council currently has to remand an ALJ’s decision to the ALJ, and that the attorney adjudicator’s actions with respect

to the remanded case should be subject to the same requirements as an ALJ's actions under the current provisions. We also proposed corresponding revisions to §423.2126(a)(1) and (a)(2). Current §§405.1126(c) and (d) describe the procedures that apply when the Council receives a recommended decision from the ALJ, including the right of the parties to file briefs or other written statements with the Council. Because we proposed in §405.1126(a) for the Council to have the same authority to order an attorney adjudicator to issue a recommended decision on remand as the Council currently has to order an ALJ to issue a recommended decision, we also proposed at §405.1126(c) and (d) to replace "ALJ" with "ALJ or attorney adjudicator" to provide that the provisions apply to attorney adjudicators to the same extent as the provisions apply to ALJs, along with corresponding revisions to §423.2126(a)(3) and (a)(4). Finally, current §405.1126(e)(2) provides that if the Council determines more evidence is required after receiving a recommended decision, the Council may again remand the case to an ALJ for further development and another decision or recommended decision. Because we believe the Council should have the same authority to remand a case to an attorney adjudicator following receipt of a recommended decision, we proposed at §405.1126(e)(2) to replace "ALJ" with "ALJ or attorney adjudicator," along with a corresponding revision to §423.2126(a)(5)(ii), and to insert "if applicable" after rehearing because a rehearing may not be applicable in every circumstance (for example, where an attorney adjudicator issued a recommended decision and the Council does not remand with instructions to transfer the appeal to an ALJ for a hearing).

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the

same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1126 and 423.2126 as proposed without modification.

I. Action of the Council (§§405.1128 and 423.2128)

Current §§405.1128 and 423.2128 explain the actions the Council may take after reviewing the administrative record and any additional evidence (subject to the limitations on Council consideration of additional evidence). We proposed at §§405.1128(a) and 423.2128(a) to replace “ALJ” with “ALJ or attorney adjudicator,” which would provide that the Council may make a decision or remand a case to an ALJ or to an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above). We stated in the proposed rule that we believe the Council should have the same authority to remand a case to an attorney adjudicator as the Council currently has to remand a case to an ALJ. Also, to help ensure there is no confusion that Council actions are not limited to proceedings in which a hearing before an ALJ was conducted, we proposed at §§405.1128(b) and 423.2128(b) to replace “the ALJ hearing decision” with “the ALJ’s or attorney adjudicator’s decision.” 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1128 and 423.2128 as proposed without modification.

m. Request for escalation to Federal court (§405.1132)

Current §405.1132 explains the process for an appellant to seek escalation of an appeal (other than an appeal of an ALJ dismissal) from the Council to Federal district court if the Council does not issue a decision or dismissal or remand the case to an ALJ within the adjudication time frame specified in §405.1100, or as extended as provided in subpart I. We proposed at §405.1132 to replace each instance of “ALJ” with “ALJ or attorney adjudicator.” We stated in the proposed rule that these revisions would provide that the appellant may request that escalation of a case, other than a dismissal issued by an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to Federal district court if the Council is unable to issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within an applicable adjudication time frame, and that appellants may file an action in Federal district court if the Council is not able to issue a decision, dismissal, or remand to the ALJ or attorney adjudicator within 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period. We did not propose any corresponding changes to part 423, subpart U, as there is no equivalent provision because there are no escalation rights for Part D coverage appeals. 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the

reasons discussed above and in the proposed rule, we are finalizing the changes to §405.1132 as proposed without modification.

n. Judicial review (§§405.1136, 423.1976, and 423.2136)

Current §§405.1136, 423.1976, and 423.2136 set forth the right to file a request for judicial review in Federal district court of a Council decision (or of an ALJ's decision if the Council declines review as provided in §423.1976(a)(1)). Current §405.1136 also provides that judicial review in Federal district court may be requested if the Council is unable to issue a decision, dismissal, or remand within the applicable time frame following an appellant's request for escalation. In addition, current §§405.1136 and 423.2136 specify the requirements and procedures for filing a request for judicial review, the Federal district court in which such actions must be filed, and describe the standard of review. We proposed at §§405.1136, 423.1976, and 423.2136 to replace each instance of "ALJ" with "ALJ or attorney adjudicator," and "ALJ's" with "ALJ's or attorney adjudicator's" to help ensure that there is no confusion that appellants may file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above) (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available for ALJ actions (or Council actions following an action by an ALJ). 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the

reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1136, 423.1976, and 423.2136 as proposed without modification.

o. Case remanded by a Federal court (§§405.1138 and 423.2138)

Current §§405.1138 and 423.2138 set forth the actions the Council may take when a Federal district court remands a case to the Secretary for further consideration. We proposed at §§405.1138 and 423.2138 to replace “ALJ” with “ALJ or attorney adjudicator” to provide that when a case is remanded by a Federal district court for further consideration by the Secretary, the Council may remand the case to an ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), to issue a decision, take other action, or return the case to the Council with a recommended decision. 81 FR 43790, 43851.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1138 and 423.2138 as proposed without modification.

p. Council review of ALJ decision in a case remanded by a Federal district court (§§405.1140 and 423.2140)

Current §§405.1140 and 423.2140 set forth the procedures that apply when a case is remanded to the Secretary for further consideration, and the Council subsequently remands the case to an ALJ, including the procedures for the Council to assume jurisdiction following the

decision of the ALJ on its own initiative or upon receipt of written exceptions from a party or the enrollee. We proposed to replace each instance of “ALJ” throughout §§405.1140 and 423.2140 with “ALJ or attorney adjudicator” and to replace the reference to “ALJ’s” at §§405.1140(d) and 423.2140(d) with “ALJ’s or attorney adjudicator’s.” We stated in the proposed rule that these revisions would provide that the Council may remand these cases to the ALJ or attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), following remand from a Federal district court, and that the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand unless the Council assumes jurisdiction. We stated that these revisions would further apply the rules set forth in this section to cases reviewed by an attorney adjudicator as well as an ALJ. As described above in relation to the Council’s general remand authority under §§405.1126 and 423.2126, we stated that we believe it is necessary for the Council to have the same authority to remand an attorney adjudicator’s decision to the attorney adjudicator as the Council currently has to remand an ALJ’s decision to the ALJ, and that would include cases that are remanded by a Federal district court to the Secretary for further consideration. 81 FR 43790, 43851–43852.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§405.1140 and 423.2140 as proposed without modification.

C. Specific provisions of part 405, subpart J expedited reconsiderations

In accordance with section 1869(b)(1)(F) of the Act, current §405.1204 provides for expedited QIC reconsiderations of certain QIO determinations related to provider-initiated terminations of Medicare-covered services and beneficiary discharges from a provider's facility. Current §405.1204(c)(4)(iii) explains that the QIC's initial notification may be done by telephone followed by a written notice that includes information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, and current §405.1204(c)(5) provides that if the QIC does not issue a decision within 72 hours of receipt of the request for a reconsideration, the case can be escalated to the "ALJ hearing level." For consistency with part 405, subpart I, and to explain the rules that apply to an ALJ hearing, we proposed at §405.1204(c)(4)(iii) and (c)(5) to amend these references to convey that a QIC reconsideration can be appealed to, or a request for a QIC reconsideration can be escalated to OMHA for an ALJ hearing in accordance with part 405, subpart I. We stated in the proposed rule that we believed these revisions would explain where a request for an ALJ hearing is directed from a subpart J proceeding, and the rules that would be applied to the request for an ALJ hearing following the QIC's reconsideration or escalation of the request for a QIC reconsideration. 81 FR 43790, 43852.

Current §405.1204(c)(5) states that the beneficiary has a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination is \$100 or more. However, this is inconsistent with the amount in controversy specified in section 1869(b)(1)(E) of the Act. We proposed to revise §405.1204(c)(5) to provide that there is a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under §405.1006. We stated in the proposed rule that we believed that this is more consistent with section 1869(b)(1)(E) of the Act,

which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than \$100, as adjusted annually after 2004, which is implemented in §405.1006, and would bring consistency to the amounts in controversy required for an escalation under subpart J and subpart I. 81 FR 43790, 43852.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on this proposal. The commenter supported the revision of §405.1204(c)(5) to align the amount in controversy with section 1869(b)(1)(E) of the Act and §405.1006.

Response: We thank the commenter for its support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §405.1204 as proposed without modification.

D. Specific provisions of part 422, subpart M

1. General provisions (§422.562)

Current §422.562(c)(1)(ii) states that if an enrollee receives immediate QIO review of a determination of non-coverage of inpatient hospital care, the QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of title 42, chapter IV. However, we stated in the proposed rule that we believe this provision is an outdated reference that has been superseded by current §422.622, which provides for requesting immediate QIO review of the decision to discharge an enrollee from an inpatient hospital setting and appeals of that review as described under part 422, subpart M. The regulatory provisions at §422.622 describe the processes for QIO review of the decision to discharge an MA enrollee from the inpatient hospital

setting. Section 422.622 also explains the availability of other appeals processes if the enrollee does not meet the deadline for an immediate QIO review of the discharge decision. These part 422, subpart M provisions govern the review processes for MA enrollees disputing discharge from an inpatient hospital setting. As noted above, we stated in the proposed rule that we believe the references to the procedures in parts 476 and 478 at §422.562(c)(1)(ii) are obsolete.

Therefore, we proposed to delete §422.562(c)(1) to remove the outdated reference in current §422.562(c)(1)(ii) and consolidate current (c)(1) and (c)(1)(i) into proposed (c)(1). 81 FR 43790, 43852.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §422.562 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we are also finalizing revisions to §422.562(d). In section II.A.3 of this final rule above, we discuss our proposal to revise §422.562(d), the comments we received related to this proposal, and the revisions we are finalizing to §422.562(d) in this rule.

2. Notice of reconsidered determination by the independent entity (§422.594)

Current §422.594(b)(2) requires the notice of the reconsideration determination by an IRE to inform the parties of their right to an ALJ hearing if the amount in controversy is \$100 or more, if the determination is adverse (does not completely reverse the MAO's adverse organization determination). We proposed at §422.594(b)(2) to amend this requirement so that the notice informs the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of §422.600, which in turn refers to the part 405 computation of the amount in controversy. We stated in the proposed rule that we believed this would increase accuracy in

conveying when a party has a right to an ALJ hearing, and would be more consistent with section 1852(g)(5) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than \$100, as adjusted annually in accordance with section 1869(b)(1)(E)(iii) of the Act, which is implemented in part 405 at §405.1006. 81 FR 43790, 43852. We discuss our proposed changes to §405.1006 in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §422.594 as proposed without modification.

3. Request for an ALJ hearing (§422.602)

Current §422.602(b) provides that a party must file a request for an ALJ hearing within 60 days of the date of the notice of the IRE's reconsidered determination. However, in similar appeals brought under Medicare Part A and Part B at §405.1002, and Part D at §423.2002, a request for an ALJ hearing must be filed within 60 calendar days of receipt of a notice of reconsideration. We proposed at §422.602(b)(1) to align the part 422 time frame for filing a request for an ALJ hearing with provisions for similar appeals under Medicare Part A and Part B, and Part D. We proposed that a request for an ALJ hearing would be required to be filed within 60 calendar days of receiving the notice of a reconsidered determination, except when the time frame is extended by an ALJ or, as proposed, attorney adjudicator, as provided in part 405. To provide consistency for when a notice of a reconsidered determination is presumed to have been received, we proposed at §422.602(b)(2) that the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary, which is the same presumption that is applied to similar

appeals under Medicare Part A and Part B at §405.1002, and Part D at §423.2002. 81 FR 43790, 43852–43853.

Provided below are summaries of the specific comments received and responses to these comments:

Comment: We received two comments on this proposal. One commenter supported revising §422.602(b) to state in paragraph (b)(1) that a request for hearing must be filed within 60 calendar days of receipt of the notice of a reconsidered determination, rather than 60 calendar days of the date of the notice. The other commenter also supported this proposed revision, as well as the proposal to create a presumption at §422.602(b)(2) that the date of receipt of the reconsideration is 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary. The commenter expressed that the current inconsistency between §422.602(b) and the part 405, subpart I rules has caused problems for beneficiaries, providers, and ALJs, and supported our efforts to standardize the time frames for requesting an ALJ hearing.

Response: We thank both commenters for their support.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §422.602 as proposed without modification.

4. Medicare Appeals Council (Council) review (§422.608)

Current §422.608 provides that any party to the hearing, including the MAO, who is dissatisfied with the ALJ hearing decision may request that the Council review the ALJ's decision or dismissal. We stated in the proposed rule that we believed that the reference to a "hearing" or "hearing decision," in the first instance, then "decision or dismissal" in the second

instance, may cause confusion regarding a party's right to request Council review. We proposed at §422.608 that any party (including the MAO) to the ALJ's or, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), attorney adjudicator's decision or dismissal, who is dissatisfied with the decision or dismissal, may request that the Council review that decision or dismissal. We stated in the proposed rule that we believed this would resolve any potential confusion regarding a party's right to request Council review of a decision when a hearing was not conducted and a dismissal of a request for hearing, and further provide that the section applies to decisions and dismissals issued by an attorney adjudicator. Therefore, we proposed to revise §422.608 to provide that a request for Council review may be filed by a party (including the MAO) if he or she is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §422.608 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we also are revising §422.608 to include a cross reference to §422.562(d)(2).

5. Judicial review (§422.612)

Current §422.612 provides the circumstances under which a party may request judicial review of an ALJ or Council decision, and directs appellants to the procedures in part 405 for

filing a request for judicial review. We proposed at §422.612(a) to replace each instance of “ALJ’s” with “ALJ’s or attorney adjudicator’s”. Thus, we proposed in §422.612(a) that appellants would be able to file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above) (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available under §412.622(a) for ALJ actions (or Council actions following an action by an ALJ). 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §422.612 as proposed without modification.

6. Reopening and revising determinations and decisions (§422.616)

Current §422.616(a) provides that the determination or decision of an MA organization, independent entity, ALJ, or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, subject to the rules in part 405. We proposed at §422.616(a) to replace “ALJ” with “ALJ or attorney adjudicator.” As described in section III.A.2.1 of the proposed rule and II.B.2.1 of this final rule above with respect to §§405.980, 405.982, 405.984, 423.1980, 423.1982, and 423.1984, we believe it is necessary for an attorney adjudicator to have the authority to reopen the attorney adjudicator’s decision on the same bases as an ALJ may reopen the ALJ’s decision under the current rules, and the action

should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under these provisions. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §422.616 as proposed without modification.

7. How an MA organization must effectuate standard reconsideration determinations and decisions, and expedited reconsidered determinations (§§422.618 and 422.619)

Current §422.618(c)(1) and (c)(2) provide instructions for effectuation of decisions issued by an ALJ, or at a higher level of appeal, that reverse an IRE's decision on a standard reconsidered determination or decision. We proposed to replace "ALJ" with "ALJ or attorney adjudicator" at §422.618(c)(1) and to make corresponding changes to §422.619(c)(1) for decisions that reverse an IRE's decision on an expedited reconsidered determination or decision. We stated in the proposed rule that we believe the process for effectuating the decision of an attorney adjudicator, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), should be the same as the process for effectuating the decision of an ALJ. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that

decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§422.618 and 422.619 as proposed without modification.

8. Requesting immediate QIO review of the decision to discharge from the inpatient hospital and fast-track appeals of service terminations to independent review entities (IREs) (§§422.622 and 422.626).

In accordance with section 1852(g)(3) and (g)(4) of the Act, current §§422.622 and 422.626 provide for reviews of QIO determinations and expedited IRE reconsiderations of certain QIO determinations related to terminations of covered provider services furnished by home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) to an MA enrollee, and MA enrollee discharges from an inpatient hospital. Current §422.622(g) provides that if an enrollee is still an inpatient in the hospital after a QIO determination reviewing a provider discharge from a hospital, the enrollee may request an IRE reconsideration of the QIO determination in accordance with §422.626(g); and if an enrollee is no longer an inpatient in the hospital, the enrollee may appeal the QIO determination to an ALJ. Current §422.626(g)(3) provides that if the IRE reaffirms its decision to terminate covered provider services furnished by an HHA, SNF, or CORF in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ. We proposed at §§422.622(g)(2) and 422.626(g)(3) to amend these references to provide that the appeal is made to OMHA for an ALJ hearing. We stated in the proposed rule that we believed these revisions would clarify where a request for an ALJ hearing is directed. 81 FR 43790, 43853.

We received no comments on these proposals, other than comments discussed in section II.A.4 of this final rule above related to our general proposal to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §§422.622 and 422.626 as proposed without modification.

E. Specific provisions of part 478, subpart B

1. Applicability and beneficiary's right to a hearing (§§478.14 and 478.40)

Current §478.14(c)(2) explains that for the purposes of part 478 reconsideration and appeals, limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act, and initial determinations under section 1879 of the Act and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G for determinations under Medicare Part A, and part 405, subpart H for determinations under Medicare Part B. In addition, current §478.40 states that an ALJ hearing may be obtained from the SSA Office of Hearings and Appeals, and the provisions of subpart G of 42 CFR part 405 apply unless they are inconsistent with the specific provisions of subpart B of 42 CFR part 478. We stated in the proposed rule that these references are outdated. Since §§478.14 and 478.40 were last updated in 1999, section 931 of the MMA transferred responsibility for the ALJ hearing function from SSA to HHS, and HHS established OMHA in 2005, to administer the ALJ hearing function, including ALJ hearings conducted under titles XI and XVIII of the Act (see 70 FR 36386). In addition, BIPA and the MMA established new appeal procedures that were implemented in 2005, at 42 CFR part 405, subpart I (70 FR 11420), and the portions of subparts G and H that previously applied to part 478, subpart B appeals were removed in 2012 (77 FR

29002). We proposed in §§478.14 and 478.40 to replace the current outdated references to part 405, subparts G and H, with references to part 405, subpart I. We also proposed in §478.40 to update the reference to the entity with responsibility for the ALJ hearing function by replacing the SSA Office of Hearings and Appeals with OMHA. 81 FR 43790, 43854.

We received no comments on these proposals. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing these changes to §§478.14 and 478.40 as proposed above without modification.

In addition to the revisions discussed above, as discussed in section II.A.3 of this final rule, we are also finalizing revisions to §478.40(c). In section II.A.3 of this final rule above, we discuss our proposal to revise §478.40(c), the comments we received related to this proposal, and the revisions we are finalizing to §478.40(c) in this rule.

2. Submitting a request for a hearing (§478.42)

Similar to current §478.40, as discussed above, current §478.42(a) has outdated references to SSA offices that are no longer involved in the Medicare claim appeals process. In addition, current §478.42(a) permits beneficiaries to file requests for an ALJ hearing with other entities, which could cause significant delays in obtaining a hearing before an OMHA ALJ. We proposed in §478.42(a) to direct beneficiaries to file a request for an ALJ hearing with the OMHA office identified in the QIO's notice of reconsidered determination. This revision would be clearer for beneficiaries, who are provided with appeal instructions by the QIOs, and reduce delays in obtaining a hearing by an OMHA ALJ. 81 FR 43790, 43854.

Current §478.42(b) requires that a request for hearing is filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination and the date of receipt is assumed to be 5 days after the date on the notice unless there is a reasonable showing to the contrary.

Current §478.42(b) also provides that a request is considered filed on the date it is postmarked. To align part 478, subpart B with procedures for requesting an ALJ hearing under part 405, subpart I; part 422, subpart M; and part 423, subpart U, we proposed in §478.42(b) to provide that the request for hearing must be filed within 60 “calendar” days of receiving notice of the QIO reconsidered determination and that the notice is presumed to be received 5 “calendar” days after the date of the notice. In addition, to further align the part 478, subpart B procedures for requesting an ALJ hearing with the other parts, we proposed in §478.42(c) to amend the standard to demonstrate that notice of QIO reconsidered determination was not received within 5 calendar days by requiring “evidence” rather than the current “reasonable showing,” and also to revise when a request is considered filed, from the date it is postmarked to the date it is received by OMHA. These changes would create parity with requests for hearing filed by beneficiaries and enrollees for similar services but under other parts of title 42, chapter IV. 81 FR 43790, 43854.

Provided below is a summary of the specific comment received and our response to this comment:

Comment: We received one comment on these proposals. The commenter asked whether there was an inconsistency in calculating time for transport of mail from the QIO to the appellant, as compared to mail from the appellant to OMHA. The commenter questioned why five calendar days were allowed for transport from the date on the QIO notice, while zero days were allowed on top of the statutory 60-day filing period for transport of the request for hearing from the appellant.

Response: Proposed §478.42(b) revises when a request is considered filed, from the date it is postmarked to the date it is received by OMHA, to create parity with requests for hearing and reviews of dismissals filed by beneficiaries and enrollees for similar services but under part

405, subpart I; part 422, subpart M; and part 423, subpart U, all of which consider a request to be filed on the date it is received by OMHA. For notices sent from the QIO to the appellant, the regulation presumes a mailing time of five calendar days to account for the time it takes to receive the notice through regular mail. However, as is currently required for appellants under part 405, subpart I; part 422, subpart M; and part 423, subpart U, we proposed that appellants filing requests for hearing and reviews of dismissals under part 478, subpart B would now be required to mail requests with sufficient time for the requests to be received by OMHA no later than the 60th day after receiving the QIO's reconsidered determination.

After review and consideration of the comments received, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §478.42 as proposed without modification.

3. Determining the amount in controversy (§478.44)

Current §478.44(a) explains how the amount in controversy for an ALJ hearing is determined in part 478, subpart B hearings. Current §478.44(a) has outdated references to §§405.740 and 405.817 from part 405, subparts G and H respectively, for calculating the amount in controversy for an individual appellant or multiple appellants. In 2012, subpart G was removed and subpart H was significantly revised and no longer applies to Medicare claim appeals (77 FR 29002). To update these reference to the current part 405 rules, we proposed in §478.44(a) to replace the outdated cross-references for calculating the amount in controversy with references to §405.1006(d) and (e), which describe the calculation for determining the amount in controversy and the standards for aggregating claims by an individual appellant or multiple appellants. 81 FR 43790, 43854. We discuss our proposed changes to §405.1006 in section III.A.3.d of the proposed rule and II.B.3.d of this final rule above.

Current §478.44(b) and (c) explain that if an ALJ determines the amount in controversy is less than \$200, the ALJ, without holding a hearing, notifies the parties to the hearing, and if a request for hearing is dismissed because the amount in controversy is not met, a notice will be sent to the parties to the hearing. However, when a request for hearing is dismissed because the amount in controversy is not met, no hearing is conducted and the parties to the proceedings are the same regardless of whether a hearing was conducted. To prevent potential confusion, we proposed in §478.44(b) and (c) to replace “parties to the hearing” with “parties” so it is understood that they are parties regardless of whether a hearing is conducted. Because an attorney adjudicator would have to determine whether appeals assigned to him or her, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 of this final rule above), meet the amount in controversy requirement, we also proposed at §478.44(a) and (b) that an attorney adjudicator may determine the amount in controversy, and may determine that the amount in controversy is less than \$200 and notify the parties to submit additional evidence to prove that the amount in controversy is at least \$200. However, because we did not propose authority for an attorney adjudicator to dismiss a request for an ALJ hearing because the amount in controversy is not met, we proposed in §478.44(c) that in cases where an attorney adjudicator has requested that the parties submit additional evidence related to the amount in controversy, an ALJ would dismiss the request for hearing if at the end of the 15-day period to submit additional evidence to prove that the amount in controversy is at least \$200, the ALJ determines that the amount in controversy is less than \$200. 81 FR 43790, 43854.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that

decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §478.44 as proposed without modification.

4. Medicare Appeals Council and judicial review (§478.46)

Current §478.46(a) states that the Council will review an ALJ's hearing decision or dismissal under the same circumstances as those set forth at 20 CFR 404.970, which is now an outdated reference to SSA Appeals Council procedures for Council review. We proposed at §478.46(a) to replace the outdated reference to 20 CFR 404.970 with references to current §405.1102 ("Request for Council review when ALJ or attorney adjudicator issued a decision or dismissal") and 405.1110 ("Council reviews on its own motion"). In addition, we proposed in §478.46(a) and (b) to replace "hearing decision" with "decision," and "ALJ" with "ALJ or attorney adjudicator" because hearings are not always conducted and a decision can generally be appealed regardless of whether a hearing was conducted, and attorney adjudicators may issue decisions or dismissals for which Council review may be requested, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above). 81 FR 43790, 43855.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §478.46 as proposed without modification.

5. Reopening and revision of a reconsidered determination or a decision (§478.48)

The title of current §478.48 references reopenings and revisions of reconsidered determinations and hearing decisions, and current §478.48 has an outdated reference to subpart G of 42 CFR part 405 for the procedures for reopening a decision by an ALJ or the DAB.

We proposed to revise the title of §478.48 to replace “hearing decision” with “decision,” and in proposed paragraphs (b) and (c) to replace “ALJ” with “ALJ or attorney adjudicator” so the provision is understood to apply to decisions by ALJs, regardless of whether a hearing was conducted, or, as proposed in section II.B of the proposed rule (and discussed in section II.A.2 above), attorney adjudicators, as well as review decisions, which are conducted by the Council at the DAB. We also proposed at §478.48(b) to replace the outdated reference to §405.750(b), which was part of the now removed part 405, subpart G (77 FR 29016 through 29018), with §405.980, which is the current part 405, subpart I reopening provision. 81 FR 43790, 43855.

We received no comments on these proposals, other than comments discussed in section II.A.2 of this final rule above related to our general proposals to provide authority for attorney adjudicators to issue certain decisions, dismissals and remands, and to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. Accordingly, for the reasons discussed above and in the proposed rule, we are finalizing the changes to §478.48 as proposed without modification.

F. Effective Date and Applicability of the Provisions of the Final Rule

In accordance with 5 U.S.C. 553(d) and section 1871 of the Act, publication of a final rule may be made not less than 30 days before its effective date. We are making this final rule effective 60 days after publication in the Federal Register to provide appellants, other parties and

potential parties and participants, and those who adjudicate appeals with additional time to make any necessary changes to comply with the provisions of the final rule.

Although we did not solicit comment on the effective date of the final rule, we did receive one comment on the subject. Provided below is a summary of that comment, along with our response to the comment and further details about the effective date and applicability of the final appeals provisions.

Comment: One commenter requested that the final rule not be made effective for Part D plan sponsors prior to the next contract year that is at least six months after the published effective date of the final rule. The commenter believed this additional time would be necessary to allow time for CMS to issue implementation guidance and for plans and pharmacy benefit managers to revise policies and documentation to describe the revised appeals procedures to enrollees.

Response: We do not believe further delaying the effective date of this rule for Part D plan sponsors is necessary. Part D plan sponsors will have 60 days from publication before the provisions of the final rule become effective. In addition, the changes we are finalizing relate primarily to the OMHA level of appeal. We proposed no changes to the part 423, subpart M rules governing Part D plan sponsor coverage determinations, redeterminations, or reconsiderations by an IRE, other than minor conforming edits associated with our attorney adjudicator proposal and the proposal to replace references to “MAC” with “Council.” We expect that enrollees will continue to receive information about the OMHA level of appeal in the notice of the IRE’s reconsideration, and therefore we believe it is unnecessary to allow additional time for Part D plan policies and documentation to be updated to inform beneficiaries of the changes in the final rule.

While the provisions of this final rule are effective with the effective date of this final rule, we recognize that there is currently a large volume of pending appeals at the OMHA and Council levels that were filed before the effective date of the final rule and are at various stages of the adjudication process, and it may be unclear how these final provisions will apply in those instances—and in a manner that avoids retroactive application. The provisions of this final rule will apply prospectively to all appeals, but specific provisions will not be applied to pending appeals filed before the effective date of the final rule in which certain actions or stages of the appeals process have already taken place prior to the effective date. For example, a revised requirement regarding the contents of a request for hearing is effective with the effective date of this final rule, but the requirement would not be applicable in a pending appeal if the hearing request was already filed prior to the effective date of this final rule (that is, the hearing request would not have to be re-filed to include the new contents of the request finalized in this rule). But for other appeals that are pending prior to the effective date of this final rule, provisions of this final rule may be applicable if a particular action or procedural step in those appeals has not yet taken place (for example, a revised final requirement regarding scheduling and sending notice of a hearing would apply if the hearing has not yet been scheduled and the notice of hearing has not yet been sent in a pending appeal).

Accordingly, the revised appeal procedures of this final rule are effective on the effective date of the final rule for all appeals filed on or after the effective date of the final rule, and appeals that were filed, but not decided, dismissed or remanded, prior to the effective date of the final rule. However, with regard to appeals that were filed, but not decided, dismissed or remanded, prior to the effective date of the final rule, we have provided a list of provisions in the table below as examples to help clarify how the revised rules will apply depending upon whether

certain actions or procedures in such appeals have taken place as of the effective date of the final rule. This guidance clarifying the application of certain provisions will help ensure pending appeals continue to move forward in the appeals process, and avoid retroactive application of the revised appeal provisions when certain actions or stages of the appeals process took place prior to the effective date of this final rule. We will provide additional guidance in the future, as necessary, to assist appellants and other parties, as well as OMHA and the Council, in regards to the application of the revised appeals procedures for appeals that were pending prior to the effective date of the final rule.

APPLICATION OF CERTAIN FINAL APPEALS PROVISIONS FOR APPEALS
THAT WERE FILED BUT NOT DECIDED, DISMISSED, OR REMANDED PRIOR TO THE
EFFECTIVE DATE OF FINAL RULE

| Section(s) | Applicability |
|----------------------|---|
| §405.910(d)(3) | Not applicable (any applicable time frame will not be impacted if an appointment of representative is defective). |
| §405.910(l) | Applicable to delegations of an appointment of representation that are made on or after the effective date of the final rule. |
| §405.990..... | Applicable to requests for expedited access to judicial review filed on or after the effective date of the final rule. |
| §405.1000(e) | Applicable to for waivers of the right to appear filed on or |

after the effective date of the final rule.

- §405.1006(e) Not applicable (the provisions of the rules related to aggregating claims to meet the amount in controversy in effect at the time the request for hearing or request for review of a QIC dismissal was filed (current §405.1006(e)) continue to apply).
- §405.1010, §405.1012..... Applicable to elections to participate in the proceedings on a request for an ALJ hearing and elections for party status made on or after the effective date of the final rule.
- §405.1014(a) Not applicable (the provisions of the rules related to the content of the request in effect at the time the request for hearing was filed (current §405.1014(a)) continue to apply).
- §405.1016(f)..... Applicable to requests for escalation filed on or after the effective date of the final rule.
- §405.1020–§405.1024..... Applicable to hearings that are scheduled or re-scheduled on or after the effective date of the final rule, regardless of when the hearing is scheduled to occur.
- §405.1028..... Applicable to reviews of evidence submitted by parties that occur on or after the effective date of the final rule.
- §405.1030..... Applicable to hearings that occur on or after the effective
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|--------------------------|--|
| | date of the final rule. |
| §405.1032(a)–(c)..... | Applicable unless a hearing was scheduled or re-scheduled before the effective date of the final rule, regardless of when the hearing is scheduled to occur. |
| §405.1032(d)..... | Not applicable (the provisions of the rules related to appeals involving statistical sampling and extrapolations in effect at the time the request for hearing was filed (current §405.1064) continue to apply). |
| §405.1038(b)(1)(i)..... | Applicable to waivers of the right to appear filed on or after the effective date of the final rule. |
| §405.1038(b)(1)(ii)..... | Not applicable (the provisions of the rules related to whether the ALJ may decide a case on the record and not conduct a hearing when the appellant lives outside of the United States in effect at the time the request for hearing was filed (current §405.1038(b)(1)(ii)) continue to apply). |
| §405.1040..... | Applicable to conferences scheduled on or after the effective date of the final rule, regardless of when the conferences are scheduled to occur. |
| §405.1042(a)..... | Applicable to requests for an ALJ hearing assigned to an ALJ or attorney adjudicator on or after the effective date of |

| | |
|--------------------|---|
| | the final rule. |
| §405.1056(g) | Applicable to remands issued on or after the effective date of the final rule. |
| §405.1104..... | Applicable to requests for escalation filed on or after the effective date of the final rule. |
| §423.1970(c) | Not applicable (the provisions of the rules related to aggregating claims to meet the amount in controversy in effect at the time the request for hearing or request for review of a QIC dismissal was filed (current §423.1970(c)) continue to apply). |
| §423.1990..... | Applicable to requests for expedited access to judicial review filed on or after the effective date of the final rule. |
| §423.2000(e) | Applicable to waivers of the right to appear filed on or after the effective date of the final rule. |
| §423.2010..... | Applicable to requests to participate in the proceedings on a request for an ALJ hearing made on or after the effective date of the final rule. |
| §423.2014(a) | Not applicable (the provisions of the rules related to the content of the request in effect at the time the request for hearing was filed (current §423.2014(a)) continue to apply). |

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- §423.2020–§423.2024..... Applicable to hearings that are scheduled or re-scheduled on or after the effective date of the final rule, regardless of when the hearing is scheduled to occur.
- §423.2030..... Applicable to hearings that occur on or after the effective date of the final rule.
- §423.2032..... Applicable unless a hearing was scheduled or re-scheduled before the effective date of the final rule, regardless of when the hearing is scheduled to occur.
- §423.2038(b)(1)(i)..... Applicable to waivers of the right to appear filed on or after the effective date of the final rule.
- §423.2038(b)(1)(ii)..... Not applicable (the provisions of the rules related to whether the ALJ may decide a case on the record and not conduct a hearing when the appellant lives outside of the United States in effect at the time the request for hearing was filed (current §423.2038(b)(1)(ii)) continue to apply).
- §423.2040..... Applicable to conferences scheduled on or after the effective date of the final rule, regardless of when the conferences are scheduled to occur.
- §423.2042(a) Applicable to requests for an ALJ hearing assigned to an ALJ or an attorney adjudicator on or after the effective date

of the final rule.

§423.2056(g) Applicable to remands issued on or after the effective date
of the final rule.

§478.40(a) Applicable to requests for an ALJ hearing filed on or after
the effective date of the final rule.

§478.42 Applicable to requests for an ALJ hearing filed on or after
the effective date of the final rule.

III. Comments Beyond the Scope of the Final Rule

In response to the proposed rule, some commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are generally not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information or recommendations in the comments. In a few instances, commenters captioned their comments indicating they were submitted in response to a particular proposal, but the comment was nevertheless outside the scope of the proposed rule. In these instances, we briefly summarized the comments in section II of this final rule above, in the appropriate subsection addressing the particular proposal.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows:

- In response to public comment, we added the following language to §401.109(a) to include the general criteria the DAB Chair may consider when selecting a Council decision as precedential: “In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.” We also added a parenthetical to indicate that the term “DAB Chair” is short for the Chair of the Department of Health and Human Services Departmental Appeals Board.
- For consistency with the rest of part 405, subpart I, and because the terms “ALJ” and “Council” are already defined in §405.902, we removed “Administrative Law Judge (ALJ)” and “Medicare Appeals Council (Council)” from §405.904(a)(1) and added “ALJ” and “Council” in their place, respectively.
- For consistency with §405.1038, we removed language that we inadvertently included in §405.1000(g) that is not consistent with the language in §405.1038(a) as finalized in this rule. We revised §405.1000(g) to state that “An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012.”
- In response to public comment, we did not finalize our proposal at §405.1006(d)(2)(i)(A) to use the Medicare allowable amount to calculate the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. In addition, we did not finalize §405.1006(d)(2)(i)(B) because,

given that we did not finalize §405.1006(d)(2)(i)(A), there was no longer a need to distinguish between items and services with and without a published Medicare fee schedule or contractor-priced amount. We also did not finalize proposed §405.1006(d)(2) and (d)(2)(i) introductory text or proposed §405.1006(d)(1) introductory text.

Accordingly, we maintained the text of current §405.1006(d)(1), except that we: (1) added “In general” as a paragraph heading, as proposed; (2) replaced “for the items and services in question” with “for the items and services in the disputed claim” in §405.1006(d)(1) introductory text, as proposed; and (3) replaced “Any deductible and coinsurance amounts applicable in the particular case” in current §405.1006(d)(1)(ii) with “Any deductible and/or coinsurance amounts that may be collected for the items or services,” as proposed. In addition, we also did not finalize our proposal to revise and re-designate current §405.1006(d)(2) as §405.1006(d)(3), except for the proposal to add “Limitation on liability” as a paragraph heading. However, for consistency with paragraph (d)(1)(ii), as finalized, we replaced “any deductible and coinsurance amounts applicable in the particular case” in current §405.1006(d)(2) with “any deductible and/or coinsurance amounts that may be collected for the items or services.” We also did not finalize proposed §405.1006(d)(2)(ii) and (iii).

- We finalized proposed §405.1006 paragraphs (d)(4), (5), (6), and (7) with the modifications discussed below, but re-designated them as paragraphs (d)(3), (4), (5), and (6), respectively, because we did not finalize proposed §405.1006(d)(2) or re-designate current §405.1006(d)(2) as §405.1006(d)(3). We replaced “in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy” in paragraph (d)(3) (proposed paragraph (d)(4)) with “in accordance with paragraph (d)(1)

of this section, except that the amount charged to the individual.” In addition, we replaced “Notwithstanding paragraphs (d)(1) and (2) of this section” in paragraphs (d)(4), (5), and (6) (proposed paragraphs (d)(5), (6), and (7)) with “Notwithstanding paragraph (d)(1) of this section.”

- We corrected a drafting error in the text of proposed §405.1010(c)(3)(i) by replacing “by within 14 calendar days” with “within 14 calendar days.”
- In response to public comment, we added a requirement in §§405.1010(c)(3)(ii), 405.1012(c)(2)(ii) and 423.2010(d)(3)(ii) that copies of position papers and/or written testimony (and for purposes of §405.1012(c)(2)(ii), any evidence) submitted to OMHA must be sent to the other parties within the same time frames that apply to the submissions to OMHA.
- We added language to §405.1010(d)(3) to provide that CMS or a contractor that is precluded from participating in the oral hearing may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012. In light of this change, we also made a corresponding revision to §405.1010(c)(2) to state that when CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in §405.1010(d)(3).
- We clarified in §405.1012(a)(2) that an ALJ may not request that CMS and/or one or more of its contractors be a party to the hearing if the request for hearing was filed by an unrepresented beneficiary.
- In response to public comment, we did not finalize our proposals at §§405.1014(a)(1)(vii) and 423.2014(a)(1)(vii), which would have required that the request for hearing contain a

statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by OIG or other law enforcement agencies.

- In response to public comment, we did not finalize our proposal at §405.1014(a)(1)(viii), which would have required that, for requests filed by providers, suppliers, Medicaid State agencies, applicable plans, or a beneficiary who is represented by a provider, supplier or Medicaid State agency, the request for hearing must include the amount in controversy applicable to the disputed claim determined in accordance with §405.1006, unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services.
- We removed the term “entity office,” which was a drafting error, from proposed §405.1014(c)(2) and added “office” in its place.
- We clarified §§405.1014(c)(2) and 423.2014(d)(2)(i) to state that if the request for hearing is timely filed with an office other than the office specified in the QIC’s reconsideration, the request is not treated as untimely.
- We revised 405.1014(d)(3) to state that unrepresented beneficiaries are exempt from the potential consequences of failing to send a copy of the request, materials, and/or evidence or summary thereof to the other parties.
- We corrected a drafting error by adding a missing comma to §423.2018(b)(1) and (c)(1) for consistency with §405.1018(a) and to clarify that there are three time frames when a represented enrollee may submit written or other evidence he or she wishes to have considered: (1) with the request for hearing; (2) by the date specified in the request for hearing in accordance with §423.2014(a)(2); or (3) if a hearing is scheduled, within 10

calendar days (or 3 calendar days for expedited Part D appeals) of receiving the notice of hearing.

- We revised §405.1018(d) to provide in paragraph (d)(1) that the requirements in paragraphs (a) and (b) do not apply to oral testimony given at a hearing or to evidence submitted by unrepresented beneficiaries, and in (d)(2) that the requirement in paragraph (c) to support new evidence with a statement of good cause does not apply to oral testimony given at a hearing or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.
- We revised §405.1020(c)(1) to state that the notice of hearing is also sent to CMS or any contractor that has elected to participate in the proceedings in accordance with §405.1010(b).
- Because we proposed to adopt in §423.2020(b)(2) the same revisions as in §405.1020(b)(2), we revised §423.2020(b)(2)(ii)(A) to state “video-teleconferencing and telephone technology are not available,” rather than “video-teleconferencing or telephone technology is not available,” for consistency with §405.1020(b)(2)(ii)(A) as finalized.
- In response to public comment, we revised §§405.1030(b)(2) and 423.2030(b)(2) to provide that the ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled.
- In response to public comment, we revised §§405.1030(b)(3) and 423.2030(b)(3) to clarify that a party or party’s representative (or enrollee or enrollee’s representative in the

context of §423.2030(b)(3)) may be excused from a hearing if that individual remains uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior.

- We revised §§405.1034(a)(1) and 423.2034(a)(1) to provide that OMHA will confirm whether an electronic copy of the redetermination or reconsideration is available in the official system of record prior to issuing a request for that information to the QIC or IRE and if so, will accept the electronic copy as the official copy. We also replaced “can only be provided by CMS, the IRE, and/or the Part D plan sponsor” in proposed §423.2034(a)(1), which was a drafting error, with “can be provided only by CMS, the IRE, and/or the Part D plan sponsor,” for consistency with the definition in §423.2034(a)(2).
- We revised §405.1038(c) to provide that if the amount of payment is an issue before the ALJ or attorney adjudicator, a stipulated decision may be made if the statement from CMS or its contractor agrees to the amount of payment the party believes should be made. We made a corresponding change to §423.2038(c) for stipulated decisions in part 423, subpart U proceedings
- We revised §405.1052(a)(7) and (b)(4) to provide that a request for hearing or a request for review of a QIC dismissal filed by an unrepresented beneficiary will not be dismissed if the appellant fails to send a copy of the request to the other parties in accordance with proposed §405.1014(d).
- We revised §§405.1056(g) and 423.2056(g) to add language to specifically exempt remands that are issued on a review of a QIC’s or IRE’s dismissal of a request for reconsideration from potential review by the Chief ALJ or designee.

- We corrected a drafting error in proposed §405.1110(b)(2) by removing two references to a “hearing decision” under §405.1046(a) and replacing them with “decision,” because §405.1046(a) as finalized in this rule also addresses decisions issued by an ALJ or attorney adjudicator when a hearing is not held.
- We revised §§422.562(d) and 478.40(c) to specify in greater detail those part 405 provisions that implement specific sections of section 1869 of the Act that are not also included in sections 1852 and 1155 of the Act, and that we do not believe apply to part 422, subpart M or part 478, subpart B adjudications. Specifically, we are revising these regulations to provide that the following regulations in part 405, and any references thereto, do not apply to proceedings under part 422, subpart M or part 478, subpart B: (1) §405.950 (time frames for making a redetermination); (2) §405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level); (3) §405.1016 (time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council); (4) The option to request that an appeal be escalated from the OMHA level to the Council as provided in §405.1100(b) and the time frame for the Council to decide an appeal of an ALJ’s or attorney adjudicator’s decision or an appeal that is escalated from the OMHA level to the Council as provided in §405.1100(c) and (d); (5) §405.1132 (request for escalation to Federal court); and (6) §§405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other references to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

- We revised the second sentence of §422.608 to reference §422.562(d), such that this sentence states, “The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent they are appropriate, except as provided in §422.562(d)(2).”
- For consistency with the title of part 423, subpart U as finalized, the revisions finalized related to attorney adjudicator reviews, and the revisions finalized to replace references to “MAC” with “Council,” we made technical conforming revisions to §423.558(b) replace the reference to “MAC” with “Council” and the reference to “ALJ hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions.” We also made a technical edit to replace “Judicial review” with “judicial review.”

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The PRA exempts most of the information collection activities referenced in this final rule. In particular, the implementing regulations of the PRA at 5 CFR 1320.4 exclude collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party. Civil actions include administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment, or MAO organization determination or Part D plan sponsor coverage determination. However, one requirement contained in this final rule is subject to the PRA because the burden is imposed prior to an administrative action or denial of payment. This requirement is discussed below.

In summary, §405.910 requires that when a provider or supplier is the party appointing a representative, the appointment of representation would include the Medicare National Provider Identifier (NPI) of the provider or supplier that furnished the item of service. Although this is a new regulatory requirement, the current Medicare Claims Processing Manual already states that the NPI should be included when a provider or supplier appoints a representative. The standardized form for appointing a representative, Form CMS-1696, currently provides a space for the information in question. Importantly, this form is currently approved under OMB control number 0938-0950 and expires June 30, 2018.

The burden associated with this requirement is the time and effort of an individual or entity who is a provider or supplier to prepare an appointment of representation containing the NPI. As stated earlier, this requirement and the related burden are subject to the PRA; however, because we believe that this information is already routinely being collected, we estimate there

would be no additional burden for completing an appointment of representative in accordance with §405.910.

If you wish to view the standardized form and the supporting documentation, you can download a copy from the CMS Web site at <https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html>.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above.

If you wish to comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, HHS-2016-79

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

VI. Regulatory Impact Statement

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches

that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have determined that the effect of this final rule does not reach this economic threshold and thus is not considered a major rule. As detailed above, this final rule would only make minimal changes to the existing Medicare appeals procedures for claims for benefits under or entitlement to the original Medicare programs, and coverage of items, services, and drugs under the MA and voluntary Medicare prescription drug programs. Thus, this final rule would have negligible financial impact on beneficiaries and enrollees, providers or suppliers, Medicare contractors, MAOs, and Part D plan sponsors, but would derive benefits to the program and appellants.

HHS recognizes that the current appeals backlog is a matter of great significance, and it has made it a priority to adopt measures that are designed to reduce the backlog and improve the overall Medicare appeals process. To that end, HHS has initiated a series of measures, including this final regulation, that are aimed at both reducing the backlog and creating a more efficient Medicare appeals system.

We believe the changes in this regulation will help address the Medicare appeals backlog and create efficiencies at the ALJ level of appeal by allowing OMHA to reassign a portion of workload to non-ALJ adjudicators and reduce procedural ambiguities that result in unproductive efforts at OMHA and unnecessary appeals to the Medicare Appeals Council. In addition, the other changes, including precedential decisions and generally limiting CMS and CMS contractor participation or party status at the OMHA level unless the ALJ determines participation by additional entities is necessary for a full examination of the matters at issue (as provided in

proposed §§405.1010(d) and 405.1012(d)), will collectively make the ALJ hearing process more efficient through streamlined and standardized procedures and more consistent decisions, and reduce appeals to the Medicare Appeals Council.

In particular, we are able to estimate the impact from one of the changes—the expansion of the pool of adjudicators. Based on FY 2016, and an assumption that future years are similar to FY 2016, we estimate that the expansion of the pool of adjudicators at OMHA could redirect approximately 24,500 appeals per year to attorney adjudicators who would be able to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload. If in future years the number of requests for hearing, waivers of oral hearing, requests for review of a contractor dismissal, or appellant withdrawals of requests for hearing vary from FY 2016 data, then the number of appeals potentially addressed by attorney adjudicators would likely also vary.

In the proposed rule, we also estimated that the proposed modifications to calculating the amount in controversy required for an ALJ hearing could potentially remove appeals related to over 2,600 Part B low-value claims per year from the ALJ hearing process, after accounting for the likelihood of appellants aggregating claims to meet the AIC. 81 FR 43790, 43856. However, as discussed in section II.B.3.d of this final rule above, we are not finalizing our proposal under §405.1006(d)(2)(i)(A) to use the Medicare allowable amount as the basis for the amount in controversy for items and services that are priced based on a published Medicare fee schedule or published contractor-priced amount. Although we are finalizing separate calculations of the amount in controversy to address the situations in proposed §405.1006(d)(3) through (7), we do not expect these provisions will have a meaningful effect on the number of appeals eligible for an ALJ hearing.

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) requires agencies to prepare a final regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as: (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

For purposes of the RFA, most providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. In addition, a number of MAOs and Part D plan sponsors (insurers) are small entities due to their nonprofit status; however, few if any meet the SBA size standard for a small insurance firm by having revenues of \$38.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. We have determined and we certify that this final rule would not have a significant economic impact on a substantial number of small entities because as noted above, this final rule makes only minimal changes to the existing appeals procedures. Therefore, we did not prepare an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For final rules, this analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and

has fewer than 100 beds. We have determined that this final rule would not have a significant effect on the operations of a substantial number of small rural hospitals. As noted above, this final rule makes only minimal changes to the existing appeals procedures and thus, would not have a significant impact on small entities or the operations of a substantial number of small rural hospitals. Therefore, we did not prepare an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$146 million. This final rule would not impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector in the amount of \$146 million in any one year, because as noted above, this final rule makes only minimal changes to the existing appeals procedures.

VII. Federal Analysis

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes a proposed rule and subsequent final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule does not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate Federalism.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 401 continues to read as follows:

AUTHORITY: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w-5).

2. Section 401.109 is added to read as follows:

§401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential. In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the FEDERAL REGISTER.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

3. The authority citation for part 405 continues to read as follows:

AUTHORITY: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

4. Section 405.902 is amended by adding the definitions of “Attorney Adjudicator”, “Council”, and “OMHA” in alphabetical order and removing the definition of “MAC”.

The additions read as follows:

§405.902 Definitions.

* * * * *

Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

* * * * *

Council stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

* * * * *

OMHA stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

* * * * *

5. Section 405.904 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) * * *

(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Council to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's

redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

* * * * *

§405.906 [Amended]

6. Section 405.906(b) introductory text is amended by—

a. Removing from the paragraph heading the phrase “hearing and MAC” and adding “proceedings on a request for hearing, and Council review” in its place.

b. Removing the phrase “hearing, and MAC review” and adding “proceedings on a request for hearing, and Council review” in its place.

§405.908 [Amended]

7. Section 405.908 is amended by removing the term “ALJ” and adding “OMHA” in its place and by removing the term “MAC” and adding “Council” in its place.

8. Section 405.910 is amended by—

a. Revising paragraph (c)(5).

b. Adding paragraph (d)(3).

c. Revising paragraphs (f)(1) and (i)(2) and (3).

d. Revising paragraph (l).

e. Adding paragraph (m)(4).

The additions and revisions read as follows:

§405.910 Appointed representatives.

* * * * *

(c) * * *

(5) Identify the beneficiary's Medicare health insurance claim number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

* * * * *

(d) * * *

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

* * * * *

(f) * * *

(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

* * * * *

(i) * * *

(2) *Appeals*. When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

* * * * *

(1) *Delegation of appointment by appointed representative*. (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (1)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (1)(1)(ii) of this section, unless the appointed representative and designee

are attorneys in the same law firm or organization, in which case the notice described in paragraph (l)(1)(i) of this section may be submitted even though the acceptance described in paragraph (l)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) * * *

(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

9. Section 405.926 is amended by revising paragraphs (l) and (m) to read as follows:

§405.926 Actions that are not initial determinations.

* * * * *

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

* * * * *

§405.956 [Amended]

10. Section 405.956(b)(8) is amended by removing the phrase "an ALJ hearing" and adding "the OMHA level" in its place.

11. Section 405.968 is amended by revising paragraph (b)(1) to read as follows:

§405.968 Conduct of a reconsideration.

* * * * *

(b) * * *

(1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under §401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

* * * * *

12. Section 405.970 is amended by revising the section heading and paragraphs (a) introductory text, (b), (c) introductory text, (e)(1), (e)(2)(i) and (ii) to read as follows:

§405.970 Timeframe for making a reconsideration following a contractor redetermination.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

* * * * *

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with §405.962(b), the QIC's 60 calendar day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of §405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with §405.964(c), the QIC must issue a

reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with §405.966(b).

(c) *Responsibilities of the QIC*. Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

* * * * *

(e) * * *

(1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with §405.972 or §405.976.

(2) * * *

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with §405.972 or §405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

13. Section 405.972 is amended—

a. By revising the section heading.

b. In paragraph (b)(3) by removing the phrase “reconsideration of a contractor’s dismissal” and adding “review of a contractor’s dismissal” in its place.

c. In paragraph (e) by adding the phrase “or attorney adjudicator” after the phrase “modified or reversed by an ALJ” and removing the phrase “reconsideration of a contractor’s dismissal” and adding “review of a contractor’s dismissal” in its place.

The revision reads as follows:

§405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor’s dismissal of a request for redetermination.

* * * * *

14. Section 405.974 is amended by revising the section heading, the heading to paragraph (b), and paragraph (b)(3) to read as follows:

§405.974 Reconsideration and review of a contractor’s dismissal of a request for redetermination.

* * * * *

(b) *Review of a contractor’s dismissal of a redetermination request.*

* * * * *

(3) A QIC’s review of a contractor’s dismissal of a redetermination request is binding and not subject to further review.

15. Section 405.976 is amended—

a. In paragraph (b)(5)(ii) by removing the phrase “at an ALJ level, or made part of the administrative record” and adding “at the OMHA level” in its place.

b. By revising paragraph (b)(7).

The revision reads as follows:

§405.976 Notice of a reconsideration.

* * * * *

(b) * * *

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

* * * * *

§405.978 [Amended]

16. Section 405.978(a) is amended by removing the phrase “An ALJ decision” and adding “An ALJ or attorney adjudicator decision” in its place.

17. Section 405.980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(4) and (5), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

§405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

* * * * *

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with §405.986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision, at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with §405.986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by a party.

* * * * *

(2) A party to an ALJ or attorney adjudicator decision may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with §405.986.

(3) A party to a Council review may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with §405.986.

§405.982 [Amended]

18. Section 405.982(a) and (b) are amended by removing the phrase “ALJ, or the MAC” and adding the phrase “ALJ or attorney adjudicator, or the Council” in its place.

19. Section 405.984 is amended—

a. In paragraph (c) by removing the phrase “in accordance with §405.1000 through §405.1064” and adding “in accordance with §405.1000 through §405.1063” in its place.

b. By revising paragraphs (d) and (e).

The revisions read as follows:

§405.984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with §405.1100 through §405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

* * * * *

20. Section 405.990 is amended—

a. In paragraph (a)(2) by removing the phrase “Medicare Appeals Council (MAC)” and adding the term “Council” in its place.

b. In paragraphs (b)(1) introductory text, (b)(1)(i)(B), (b)(4), and (d)(2)(ii) by removing the term “MAC” each time it appears and adding “Council” in its place.

c. In paragraph (b)(1)(i)(A) by removing the phrase “the ALJ has” and adding “the ALJ or attorney adjudicator has” in its place.

d. In paragraph (b)(1)(ii) by removing the phrase “to the ALJ level” and adding “to OMHA for an ALJ hearing” in its place.

e. In paragraphs (c)(3), (4), and (5) by removing the term “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

h. By revising paragraph (d)(1).

i. In paragraph (d)(2)(i) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

j. In paragraph (d)(2)(ii) by removing the term “MAC’s” and adding “Council’s” in its place.

k. By revising paragraphs (i)(1) and (2).

The revisions read as follows:

§405.990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The requestor may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA, or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

(i) * * *

(1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

* * * * *

21. Section 405.1000 is revised to read as follows:

§405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator:

General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in §405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in §405.1018 and §405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under §405.1010, or join the hearing before an ALJ as a party under §405.1012.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with §405.1020(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with §405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012.

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

§405.1002 [Amended]

22. Section 405.1002 is amended—

a. In paragraph (a) introductory text by removing the phrase “may request” and adding “has a right to” in its place

b. In paragraph (a)(4) by removing the word “entity” and adding “office” in its place.

c. In paragraph (b)(1) by removing the phrase “to the ALJ level” and adding “for a hearing before an ALJ” in its place.

23. Section 405.1004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

§405.1004 Right to a review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

* * * * *

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration in accordance with §405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with §405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with §405.1052(b).

24. Section 405.1006 is amended by—

a. Revising the section heading and paragraphs (d)(1) introductory text, (d)(1)(ii), and (d)(2).

b. Adding paragraphs (d)(3) through (6).

c. Revising paragraphs (e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory text, and (e)(2)(ii) and (iii).

The revisions and additions read as follows:

§405.1006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(d) * * *

(1) *In general.* The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—

* * * * *

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Limitation on liability.* Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or §411.400 of this chapter, or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the

amount in controversy is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under §411.400 of this chapter or if that liability was not limited under §411.402 of this chapter, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

(3) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(4) *Overpayments.* Notwithstanding paragraph (d)(1) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter.

(5) *Coinsurance and deductible challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(6) *Fee schedule or contractor price challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) * * *

(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

* * * * *

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve

common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

* * * * *

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

* * * * *

25. Section 405.1008 is revised to read as follows:

§405.1008 Parties to the proceedings on a request for an ALJ hearing.

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in §405.1012.

26. Section 405.1010 is revised to read as follows:

§405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made—*(1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator, and the parties who were sent a copy of the notice of reconsideration.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (3) of this section, participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in paragraph (d)(3) of this section. However, the parties may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS or contractor position papers and written testimony are subject to the following:

(i) A position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled unless the ALJ grants additional time to submit the position paper or written testimony.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent within the same time frame specified in paragraph (c)(3)(i) of this section to—

(A) The parties who were sent a copy of the notice of reconsideration, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal;
or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames

described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has been made a party to a hearing in accordance with §405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with §405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with §405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under §405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.

27. Section 405.1012 is revised to read as follows:

§405.1012 When CMS or its contractors may be a party to a hearing.

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after the QIC receives the notice of hearing.

(2) Unless the request for hearing is filed by an unrepresented beneficiary, an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties identified in the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent within the same time frame specified in paragraph (c)(2)(i) of this section to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under §405.1010, subject to §405.1010(d)(1) and (3), unless the

ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

28. Section 405.1014 is revised to read as follows:

§405.1014 Request for an ALJ hearing or a review of a QIC dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the appellant will be provided with an opportunity to complete the request, and if an adjudication time frame applies, it does not begin until the request is complete. If the appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely, and any applicable time frame specified in §405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the office specified in the QIC's reconsideration or dismissal, OMHA must notify the

appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or "cc" line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant, other than an unrepresented beneficiary, again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant's request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an extension for good cause (See §405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of a QIC dismissal with the office specified in the notice of reconsideration or dismissal.

(3) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or

request for review of a QIC dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in §405.942(b)(2) and (3).

(4) If a request for hearing is not timely filed, any applicable adjudication period in §405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

29. Section 405.1016 is revised to read as follows:

§405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in §405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with §405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in

this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation*—(1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with §405.1102(a), and the appeal will be escalated to the Council for a review in accordance with §405.1108; and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

30. Section 405.1018 is revised to read as follows:

§405.1018 Submitting evidence.

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with §405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in §405.1016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see §405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.* (1) The requirements in paragraphs (a) and (b) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

(2) The requirements in paragraph (c) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

31. Section 405.1020 is amended by—

- a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).
- b. Adding paragraphs (g)(3)(vii) and (viii).
- c. Revising paragraphs (h), (i) paragraph heading, and (i)(1), (2), (4), and (5).
- d. Adding paragraph (j).

The revisions and additions read as follows:

§405.1020 Time and place for a hearing before an ALJ.

* * * * *

(b) *Determining how appearances are made—(1) Appearances by unrepresented beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

- (A) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record, the QIC that issued the reconsideration, and CMS or a contractor that elected to participate in the proceedings in accordance with §405.1010(b) or that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the party or representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with §405.1038(b). As provided in §405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) * * *

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

* * * * *

(g) * * *

(3) * * *

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in §405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

* * * * *

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with §405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in §405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication time frame in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with §405.1022(a).

32. Section 405.1022 is revised to read as follows:

§405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties and other potential participants, as provided in §405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with §405.1032.

(2) The notice will inform the parties that they may designate a person to represent them during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at §405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with §405.1020(e).

33. Section 405.1024 is amended by revising paragraphs (b) and (c) to read as follows:

§405.1024 Objections to the issues.

* * * * *

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

34. Section 405.1026 is revised to read as follows:

§405.1026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator considers the party's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the party may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with §405.1100 through §405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before

the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with §405.1016 is extended by 14 calendar days.

35. Section 405.1028 is revised to read as follows:

§405.1028 Review of evidence submitted by parties.

(a) *New evidence*—(1) *Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with §405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with §405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

36. Section 405.1030 is revised to read as follows:

§405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with §405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with §405.1028 for not producing the evidence earlier.

(d) *Effect of new evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in §405.1016 is extended in accordance with §405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with §405.1022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with §405.1016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with §405.1022, except that the notice is sent to the parties and participants

who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with §405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

37. Section 405.1032 is revised to read as follows:

§405.1032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term “party” does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues—(1) When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the parties that were or will be sent the notice of hearing about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with §405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with §405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with §405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations—(1) Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with §405.1014(a)(3)(iii),

issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with §405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

38. Section 405.1034 is revised to read as follows:

§405.1034 Requesting information from the QIC.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. Prior to issuing a request for information to the QIC, OMHA will confirm whether an electronic copy of the redetermination or reconsideration is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS or its contractors” means the information is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is

not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with §405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

§405.1036 [Amended]

39. Section 405.1036 is amended—

- a. In paragraph (b)(1) by removing the phrase “send the ALJ” and adding “submit to OMHA” in its place.
- b. By removing paragraph (d).
- c. By redesignating paragraph (g) as new paragraph (d).
- d. In paragraphs (f)(5)(i), (ii), (iii), (iv), (v), and (vi) by removing the term “MAC” each time it appears and adding “Council” in its place.
- e. In paragraphs (f)(5)(i) and (ii) by removing the term “MAC’s” and adding “Council’s” in its place.

f. In paragraph (f)(5)(i) by removing the phrase “specified in §405.1102, §405.1104, or §405.1110” and adding “specified in §405.1016(e) and (f), §405.1102, or §405.1110” in its place.

g. In paragraph (f)(5)(ii) by removing the phrase “discovery ruling” each time it appears and adding “subpoena ruling” in its place.

40. Section 405.1037 is amended—

a. By revising paragraph (a)(1).

b. In paragraph (e)(1) by removing the phrase “specified in §405.1100, §405.1102, §405.1104, or §405.1110” and adding “specified in §405.1016(e) and (f), §405.1100, §405.1102, or §405.1110” in its place.

c. In paragraphs (e)(1), (e)(2) introductory text, (e)(2)(i), (ii), (iii), (iv), and (v) by removing the term “MAC” each time it appears and adding “Council” in its place.

d. In paragraphs (e)(1) and (e)(2)(i) by removing the term “MAC’s” and adding “Council’s” in its place.

e. By revising paragraph (f).

The revisions read as follows:

§405.1037 Discovery.

(a) * * *

(1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with §405.1012.

* * * * *

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with §405.1016, and a party requests discovery from another party to the hearing, the adjudication

period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

41. Section 405.1038 is revised to read as follows:

§405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with §405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with §405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with §405.1020(c) and who wish to appear.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment

may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

42. Section 405.1040 is revised to read as follows:

§405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing in accordance with §405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

43. Section 405.1042 is revised to read as follows:

§405.1042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the Council, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with §405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the requesting party obtains consent from the individual.

44. Section 405.1044 is revised to read as follows:

§405.1044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account

any adjudication deadlines for each appeal and may require an appellant to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§405.1020 and 405.1022.

(b) *Consolidated or separate decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with §405.1006 and the

beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

45. Section 405.1046 is revised to read as follows:

§405.1046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to §405.1028, a discussion of the new evidence and the good cause determination that was made.

- (iii) The procedures for obtaining additional information concerning the decision; and
- (iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under §405.924.

(b) *Decisions on requests for review of a QIC dismissal—(1) General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

- (i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;
- (ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to all the parties at their last known address.

46. Section 405.1048 is revised to read as follows:

§405.1048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties unless—

(1) A party requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in §405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at §405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in §405.980;

(3) The expedited access to judicial review process at §405.990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in §405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in §405.980.

§405.1050 [Amended]

47. Section 405.1050 is amended—

a. In the section heading by removing the phrase “an ALJ” and adding “OMHA” in its place.

b. In the text of the section by removing the phrase “pending before an ALJ” and adding “pending before OMHA” in its place, and by removing the term “the ALJ” and adding “OMHA” in its place.

c. By removing the term “MAC” each time it appears and adding “Council” in its place wherever it appears.

48. Section 405.1052 is revised to read as follows:

§405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar

days after the hearing, or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(2) The person or entity requesting a hearing has no right to it under §405.1002.

(3) The party did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in §405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under §405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to §405.1014.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with §405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with §405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under §405.1004.

(2) The party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in §405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation of liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under §405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to §405.1014.

(4) The appellant's request is not complete in accordance with §405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with §405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed

with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to all parties who were sent a copy of the request for hearing or review at their last known address. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

49. Section 405.1054 is revised to read as follows:

§405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under §405.1108(b), or vacated by the ALJ or attorney adjudicator under §405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under §405.1052(e).

50. Section 405.1056 is added before the undesignated center heading “Applicability of Medicare Coverage Policies” to read as follows:

§405.1056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with §405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in §405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with §405.1016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand—(1) Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may jointly request a remand of the appeal to the entity that conducted the

reconsideration. The request must include the reasons why the appeal should be remanded and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding a QIC's dismissal of a request for reconsideration.* Consistent with §405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC's dismissal of a request for reconsideration was in error.

(e) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to §426.460(b)(1), §426.488(b), or §426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to §426.460(b)(1), §426.488(b), or §426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by a party or CMS or one of its contractors filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The

determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph are not available for and do not apply to remands that are issued under paragraph (d) of this section.

51. Section 405.1058 is added before the undesignated center heading “Applicability of Medicare Coverage Policies” to read as follows:

§405.1058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with §405.1056(g).

§405.1060 [Amended]

52. Section 405.1060 is amended—

a. In paragraph (a)(4) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place and removing the term “MAC” and adding “Council” in its place.

b. In paragraph (b) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place wherever it appears.

c. In paragraph (c) by removing the term “MAC” and adding “Council” in its place wherever it appears.

§405.1062 [Amended]

53. Section 405.1062 is amended—

a. In the section heading and paragraphs (a) and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (a) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place.

c. In the section heading and paragraph (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

d. In paragraph (c) by removing the phrase “An ALJ or MAC” and adding “An ALJ or attorney adjudicator or the Council” in its place.

54. Section 405.1063 is revised to read as follows:

§405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS.

Consistent with §401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with §401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

§405.1064 [Removed]

55. Section 405.1064 is removed.

56. Section 405.1100 is revised to read as follows:

§405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

57. Section 405.1102 is revised to read as follows:

§405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at §405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§405.1100 through 405.1140), unless specifically excepted, the term “party”, includes CMS where CMS has entered into a case as a party according to §405.1012. The term, “appellant,” does not include CMS, where CMS has entered into a case as a party according to §405.1012.

§405.1104 [Removed]

58. Section 405.1104 is removed.

59. Section 405.1106 is revised to read as follows:

§405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the

notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in §405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under §405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in §405.1100 until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

§405.1108 [Amended]

60. Section 405.1108 is amended—

a. In the section heading and paragraphs (a), (b), (c), (d) introductory text, (d)(2), and (4) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraphs (a), (b), (c), (d)(1), and (5) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

c. In paragraphs (a) and (b) by removing the term “ALJ’s” each time it appears and adding “ALJ’s or attorney adjudicator’s” in its place.

d. In paragraph (b) by removing the first use of “dismissal” in the paragraph and adding “dismissal of a request for a hearing” in its place.

e. In paragraph (d) introductory text by removing the term “ALJ level” and adding “OMHA level” in its place.

f. In paragraph (d)(3) by removing the phrase “to an ALJ” and adding “to OMHA” in its place.

61. Section 405.1110 is revised to read as follows:

§405.1110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's or attorney adjudicator’s decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is issued. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under §405.1046(a) or the notice of dismissal under §405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under §405.1046(a) or the notice of dismissal under §405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

62. Section 405.1112 is revised to read as follows:

§405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's

or attorney adjudicator’s decision or dismissal order, if any; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator’s action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator’s decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's or attorney adjudicator’s action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator’s actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

§405.1114 [Amended]

63. Section 405.1114 is amended—

a. In the introductory text and paragraphs (b) and (c)(1) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (c)(3) by removing the phrase “ALJ hearing” and adding “ALJ’s or attorney adjudicator’s action” in its place.

§405.1116 [Amended]

64. Section 405.1116 is amended by—

- a. Removing the term “MAC” each time it appears in the heading and text and adding “Council” in its place.
- b. Removing the term “MAC’s” and adding “Council’s” in its place.
- c. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§405.1118 [Amended]

65. Section 405.1118 is amended by—

- a. Removing the term “MAC” each time it appears in the heading and text and adding “Council” in its place.
- b. Removing the phrase “ALJ hearing” and adding “ALJ’s or attorney adjudicator’s action” in its place.
- c. Removing the phrase “the exhibits list” and adding “any index of the administrative record” in its place.
- d. Removing the term “tape” and adding “audio recording” in its place.
- e. Removing the term “MAC’s” and adding “Council’s” in its place.

§405.1120 [Amended]

66. Section 405.1120 is amended in the heading and text by removing the term “MAC” each time it appears and adding “Council” in its place.

§405.1122 [Amended]

67. Section 405.1122 is amended

- a. In the section heading and paragraphs (a) paragraph heading, (a)(1) and (2), (b) paragraph heading, (b)(1) and (2), (c)(1), (2), and (3) introductory text, (c)(3)(ii), (d)(1) and (3), (e)(1), (2), (3), and (4), and (f)(1), (2), and (3) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraphs (e)(5) and (6), and (f)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

c. In paragraph (a)(1) by removing the term “hearing decision” and adding “ALJ’s or attorney adjudicator’s decision” in its place.

d. Amending paragraphs (a)(1) and (b)(1) by removing the term “ALJ level” and adding “OMHA level” in its place.

e. In paragraphs (a)(1) and (2), (b)(1) and (2), (c)(2), (c)(3) introductory text, and (c)(3)(i) and (ii) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

f. In paragraph (a) heading and paragraph (a)(1) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

g. In paragraph (a)(2) by removing the term “hearing record” and adding “administrative record” in its place.

§405.1124 [Amended]

68. Section 405.1124 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

§405.1126 [Amended]

69. Section 405.1126 is amended—

a. In the section heading and paragraphs (a), (b), (c), (d) paragraph heading, (d)(1) and (2), (e) paragraph heading, and (e)(1) and (2) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (b) by removing the term “MAC’s” and adding “Council’s” in its place.

c. In paragraphs (a), (b), (c), (d) paragraph heading, and (e)(2) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

d. In paragraph (e)(2) by adding “if applicable” after the word “rehearing”.

§405.1128 [Amended]

70. Section 405.1128 is amended—

a. In the section heading and paragraphs (a), (b), and (c) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (a) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

c. In paragraph (b) by removing the term “ALJ hearing decision” and adding “ALJ’s or attorney adjudicator’s decision” in its place.

§405.1130 [Amended]

71. Section 405.1130 is amended by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.

§405.1132 [Amended]

72. Section 405.1132 is amended—

a. In paragraphs (a) introductory text, (a)(2), and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (b) by removing the term “MAC’s” and adding “Council’s” in its place.

c. In paragraphs (a) introductory text, (a)(1), and (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

§405.1134 [Amended]

73. Section 405.1134 is amended—

a. In paragraph (a) by removing the term “MAC’s” and adding “Council’s” in its place.

b. In paragraphs (b)(3) and (c) by removing the term “MAC” and adding “Council” in its place.

§405.1136 [Amended]

74. Section 405.1136 is amended—

a. In paragraphs (a)(1) and (2), and (c)(3) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (a)(1) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

c. In paragraphs (a)(2) and (c)(2) by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.

d. In paragraph (c)(3) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§405.1138 [Amended]

75. Section 405.1138 is amended by—

a. Removing the term “MAC” each time it appears and adding “Council” in its place.

b. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§405.1140 [Amended]

76. Section 405.1140 is amended—

a. In the section heading and paragraphs (a)(1) through (3), (b)(1) through (3), (c) heading, (c)(1), (3), and (4), and (d) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In the section heading and paragraphs (a)(1) through (3), (b) heading, (b)(1) through (3), (c)(1) and (4), and (d) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

c. In paragraph (d) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

77. Section 405.1204 is amended by revising paragraphs (c)(4)(iii) and (c)(5) to read as follows:

§405.1204 Expedited reconsiderations.

* * * * *

(c) * * *

(4) * * *

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under §405.1006.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

78. The authority citation for part 422 continues to read as follows:

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§422.561 [Amended]

79. Section 422.561 is amended in the definition of “Appeal” by removing the phrase “Medicare Appeals Council (MAC)” and adding “Medicare Appeals Council (Council)” in its place.

80. Section 422.562 is amended in paragraph (b)(4)(v) by removing the term “MAC” and adding “Council” in its place and by revising paragraphs (c)(1) and (d) to read as follows:

§422.562 General provisions.

* * * * *

(c) * * *

(1) If an enrollee receives immediate QIO review (as provided in §422.622) of a determination of noncoverage of inpatient hospital care the enrollee is not entitled to review of that issue by the MA organization.

* * * * *

(d) *When other regulations apply.* (1) Unless this subpart provides otherwise and subject to paragraph (d)(2) of this section, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate.

(2) The following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in §405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in §405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

81. Section 422.594 is amended by revising paragraph (b)(2) to read as follows:

§422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) * * *

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of §422.600;

* * * * *

82. Section 422.602 is amended by revising paragraph (b) to read as follows:

§422.602 Request for an ALJ hearing.

* * * * *

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with §405.1020 of this chapter.

(2) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary.

* * * * *

83. Section 422.608 is revised to read as follows:

§422.608 Medicare Appeals Council (Council) review.

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, except as provided in §422.562(d)(2).

§422.612 [Amended]

84. Section 422.612 is amended—

a. In the paragraph (a) heading and paragraph (a) introductory text by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

b. In paragraph (a)(1) by removing the term “Board” and adding “Council” in its place.

c. In paragraph (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

§422.616 [Amended]

85. Section 422.616 is amended in paragraph (a) by removing the terms “ALJ” and “MAC” and adding in their place “ALJ or attorney adjudicator” and “Council” respectively.

§422.618 [Amended]

86. Section 422.618 is amended—

a. In paragraph (c)(1) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

b. In paragraph (c)(2) by removing the terms “Medicare Appeals Council”, “Medicare Appeals Council (the Board)”, and “Board” and adding “Council” in their place.

§422.619 [Amended]

87. Section 422.619 is amended—

a. In paragraph (c)(1) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

b. In paragraph (c)(2) by removing the terms “Medicare Appeals Council”, “Medicare Appeals Council (the Board)”, and “Board” and adding “Council” in their place.

§422.622 [Amended]

88. In §422.622, paragraph (g)(2) is amended by removing the phrase “may appeal to an ALJ, the MAC, or a federal court” and adding “may appeal to OMHA for an ALJ hearing, the Council, or a Federal court” in its place.

§422.626 [Amended]

89. In § 422.626, paragraph (g)(3) is amended by removing the phrase “to an ALJ, the MAC, or a Federal court” and adding “to OMHA for an ALJ hearing, the Council, or a Federal court” in its place.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

90. The authority citation for part 423 continues to read as follows:

AUTHORITY: Sections 1102, 1106, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh).

91. Section 423.558 is amended by revising paragraph (b) to read as follows:

§ 423.558 Scope.

* * * * *

(b) The requirements regarding reopenings, ALJ hearings and ALJ and attorney adjudicator decisions, Council review, and judicial review are set forth in subpart U of this chapter.

§423.560 [Amended]

92. Section 423.560 is amended in the definition of “Appeal” by removing the term “Medicare Appeals Council (MAC)” and adding “Medicare Appeals Council (Council) in its place.

93. Section 423.562 is amended by revising paragraphs (b)(4)(v) and (vi) to read as follows:

§423.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in §423.1974.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination, in whole or in part, the right to judicial review of the decision if the amount in controversy meets the requirements in §423.1976.

* * * * *

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review

94. The heading of subpart U is revised to read as set forth above.

95. Section 423.1968 is revised to read as follows:

§423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

96. Section 423.1970 is amended by revising paragraphs (c)(1)(ii) and (iii) and (c)(2)(ii) and (iii) to read as follows:

§423.1970 Right to an ALJ hearing.

* * * * *

(c) * * *

(1) * * *

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with §423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) * * *

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with §423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

97. Section 423.1972 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

§423.1972 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the OMHA office specified in the IRE's reconsideration notice.

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the timeframe as provided in §423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of receipt of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with §423.2020

(2) For purposes of this section, the date of receipt of the reconsideration determination is presumed to be 5 calendar days after the date of the written reconsideration determination, unless there is evidence to the contrary.

(c) * * *

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under §423.1970, the ALJ or attorney adjudicator dismisses the request.

* * * * *

98. Section 423.1974 is revised to read as follows:

§423.1974 Council review.

An enrollee who is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal as provided in §423.2102.

§423.1976 [Amended]

99. Section 423.1976 is amended—

a. In the (a) paragraph heading and paragraph (a) introductory text by removing the term “ALJ's” and adding “ALJ's or attorney adjudicator's” in its place.

b. In paragraphs (a)(1) and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

§423.1978 [Amended]

100. In § 423.1978, paragraph (a) is amended by removing the phrase “ALJ or the MAC” and adding “ALJ or attorney adjudicator or the Council” in its place.

101. Section 423.1980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(2) and (4), (d) heading, (d)(2) and (3), (e) heading, and (e)(2) and (3) to read as follows:

§423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

* * * * *

(4) Consistent with §423.1978(d), the Part D plan sponsor’s, IRE’s, ALJ’s or attorney adjudicator’s, or Council’s decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with §423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with §423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.

* * * * *

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with §423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with §423.1986.

§423.1982 [Amended]

102. Section 423.1982 is amended—

a. In paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

b. In paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term “MAC” and adding “Council” in its place.

103. Section 423.1984 is amended by revising paragraphs (d) and (e) to read as follows:

§423.1984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in §423.1974 and §423.2100 through §423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

* * * * *

104. Section 423.1990 is amended—

a. In paragraphs (a)(2), (b)(1) introductory text, (b)(1)(ii), and (b)(4) by removing the term “MAC” each time it appears and adding “Council” in its place

b. In paragraph (d)(2)(ii) by removing the term “MAC’s” and adding “Council’s” in its place.

c. In paragraph (b)(1)(i) by removing the phrase “final decision” and adding “decision” in its place and by removing the phrase “order of the ALJ” and adding “order of the ALJ or an attorney adjudicator” in its place.

d. In paragraph (b)(1)(ii) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

e. In paragraphs (c)(3), (4), and (5) by removing the term “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

f. By revising paragraph (d)(1).

g. In paragraph (d)(2)(i) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

h. By revising paragraph (h).

The revisions read as follows:

§423.1990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

105. Section 423.2000 is amended by revising the section heading and paragraphs (a), (b) through (e), and (g) to read as follows:

§423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator:

General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in §423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in §423.2010.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

* * * * *

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

§423.2002 [Amended]

106. Section 423.2002 is amended—

a. In paragraph (a) introductory text by removing the phrase “may request” and adding “has a right to” in its place.

b. In paragraph (c) by removing the phrase “The ALJ” and adding “OMHA” in its place.

c. In paragraph (e) by removing the word “entity” and adding “office” in its place.

107. Section 423.2004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

§423.2004 Right to a review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE’s dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

(1) The enrollee files a written request for review within 60 calendar days after receipt of the notice of the IRE’s dismissal.

* * * * *

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's dismissal.

(b) If the ALJ or attorney adjudicator determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with §423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE's dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE's dismissal in accordance with §423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE's dismissal in accordance with §423.2052(b).

108. Section 423.2008 is revised to read as follows:

§423.2008 Parties to the proceedings on a request for an ALJ hearing.

The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

109. Section 423.2010 is revised to read as follows:

§423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The

ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made*—(1) *No notice of hearing*. If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing*. If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request*. CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed.

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent within the same time frames specified in paragraph (d)(3)(i)(A) and (B) of this section to the enrollee.

(iii) If CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of its position paper or written testimony to the enrollee or fails to submit its position paper or written testimony within the time frames described in this section, the position paper or written testimony will not be considered in deciding the appeal.

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

(i) If no hearing is scheduled or the request to participate was made after the hearing occurred, the written notice of an invalid request to participate must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a non-expedited hearing is scheduled, the written notice of an invalid request to participate must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

110. Section 423.2014 is revised to read as follows:

§423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(ii) The name, address, and telephone number of the appointed representative, as defined at §423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(2) The enrollee must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the enrollee will be provided with an opportunity to complete the request, and if an adjudication time frame applies it does not begin until the request is complete. If the enrollee fails to provide the information necessary to complete the request within the time frame provided, the enrollee's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(d) *When and where to file.* Consistent with §423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, the request is not treated as untimely, and any applicable time frame specified in §423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) Consistent with §423.1972(b), if the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or review of an IRE dismissal with the office specified in the notice of reconsideration or dismissal.

(4) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of an IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of an IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If

good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of an IRE dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in §405.942(b)(2) and (3) of this chapter.

(5) If a request for hearing is not timely filed, any applicable adjudication period in §423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(6) A determination granting a request to extend the filing deadline is not subject to further review.

111. Section 423.2016 is revised to read as follows:

§423.2016 Timeframes for deciding an appeal of an IRE reconsideration.

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a)(1) of this section begins on the date that a timely filed request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(3) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal*. An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in §423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) *Grant of a request*. If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request*. If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs

(a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the matters at issue ordered by a court or tribunal of competent jurisdiction;

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

112. Section 423.2018 is revised to read as follows:

§423.2018 Submitting evidence.

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing in accordance with §423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in §423.2016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing pursuant to §423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in §423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

113. Section 423.2020 is amended by—

- a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).
- b. Adding paragraphs (g)(3)(vii) and (viii).
- c. Revising paragraphs (h), (i) heading, and (i)(1), (2), (4), and (5).
- d. Adding paragraph (j).

The revisions and additions read as follows:

§423.2020 Time and place for a hearing before an ALJ.

* * * * *

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented enrollees.* The ALJ will direct that the appearance of an unrepresented enrollee who filed a request for hearing be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented enrollee.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by represented enrollees.* The ALJ will direct that the appearance of an individual, other than an unrepresented enrollee who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by video-teleconferencing if he or she determines that video-teleconferencing is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing,

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with §423.2038(b).

(1) As specified in §423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to

appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

(e) * * *

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause.

* * * * *

(g) * * *

(3) * * *

(vii) The enrollee or enrollee's representative has a prior commitment that cannot be changed without significant expense.

(viii) The enrollee or enrollee's representative asserts he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in §423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee who filed the request for hearing objects to a telephone or video-teleconferencing hearing, the enrollee or the enrollee's

representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time and/or place he or she wants an in-person or video-teleconferencing hearing to be held.

* * * * *

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with §423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in §423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with §423.2022(a)(2).

114. Section 423.2022 is revised to read as follows:

§423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in §423.2020(c) at their last known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in the enrollee's favor and that were specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with §423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the enrollee fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that

the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at §423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the enrollee and in accordance with OMHA procedures.

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with §423.2020(e).

115. Section 423.2024 is amended in paragraph (a) by removing the phrase “The ALJ hearing office” and adding “OMHA” in its place and revising paragraph (c) to read as follows:

§423.2024 Objections to the issues.

* * * * *

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

116. Section 423.2026 is revised to read as follows:

§423.2026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator may not adjudicate an appeal if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with §423.2100 through §423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with §423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

117. Section 423.2030 is revised to read as follows:

§423.2030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with §423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the enrollee or representative to stop such behavior, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with §423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard appeal, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in §423.2016 is extended in accordance with §423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with §423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with §423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with §423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with §423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

118. Section 423.2032 is revised to read as follows:

§423.2032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor.

(b) *New issues—(1) When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS, the IRE, or the Part D plan sponsor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS, the IRE, or the Part D plan sponsor for the first time to the ALJ. The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue relating to a determination or appealed matter specified in the request for hearing, including a favorable portion of a determination or appealed matter specified in the request for hearing, if its resolution could have a material impact on the appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to pending appeal if the coverage determination was adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with §423.2014(e).

119. Section 423.2034 is revised to read as follows:

§423.2034 Requesting information from the IRE.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues can be provided only by CMS, the IRE, and/or the Part D plan sponsor. Prior to issuing a request for information to the IRE, OMHA will confirm whether an electronic copy of the missing redetermination or reconsideration is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS, the IRE, and/or the Part D plan sponsor” means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor website or information in an official CMS or HHS publication.

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with §423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

§423.2036 [Amended]

120. Section 423.2036 is amended—

a. In paragraph (b)(1) introductory text by removing the phrase “send the ALJ” and adding “submit to OMHA” in its place.

b. In paragraph (b)(1)(ii) by removing the phrase “The ALJ hearing office” and adding “OMHA” in its place.

c. By removing paragraph (d).

d. By redesignating paragraph (g) as new paragraph (d).

e. In paragraphs (f)(2), (f)(3) introductory text, and (f)(3)(i), (ii), and (iii) by removing the term “MAC” and adding “Council” in its place.

f. In paragraph (f)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

121. Section 423.2038 is revised to read as follows:

§423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or

payment may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

122. Section 423.2040 is revised to read as follows:

§423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice, if the enrollee consents to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of receiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

123. Section 423.2042 is revised to read as follows:

§423.2042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conference and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including but not limited to duplicative evidence submitted by the enrollee.

(3) An enrollee may request and receive a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, an enrollee may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with §423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

(3) If the enrollee requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the enrollee is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the enrollee obtains consent from the individual.

124. Section 423.2044 is revised to read as follows:

§423.2044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§423.2020 and 423.2022.

(b) *Consolidated decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

- (i) A consolidated decision and record; or
- (ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the enrollee or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with §423.1970 and the enrollees have all authorized disclosure of information to the other enrollees.

125. Section 423.2046 is revised to read as follows:

§423.2046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing—(1) General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

(2) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

- (i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;
- (ii) The procedures for obtaining additional information concerning the decision; and
- (iii) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under §423.566.

(b) *Decisions on requests for review of an IRE dismissal—(1) General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of an IRE dismissal, or the dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the IRE's dismissal. OMHA mails or otherwise transmits a copy of the decision to the enrollee.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by an enrollee and must include—

- (i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

- (ii) The procedures for obtaining additional information concerning the decision; and
- (iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to the enrollee at his or her last known address.

126. Section 423.2048 is revised to read as follows:

§423.2048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding unless—

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in §423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in §423.1980;

(3) The expedited access to judicial review process at §423.1990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in §423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in §423.1980.

§423.2050 [Amended]

127. Section 423.2050 is amended—

a. In the section heading by removing the phrase “an ALJ” and adding “OMHA” in its place.

b. In the text of the section by removing the phrase “pending before an ALJ” and adding “pending before OMHA” in its place, and by removing the term “the ALJ” and adding “OMHA” in its place.

c. In the section heading and the text of the section by removing the term “MAC” each time it appears and adding “Council” in its place.

128. Section 423.2052 is revised to read as follows:

§423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing

for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(2) The person requesting a hearing has no right to it under §423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in §423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(5) The ALJ or attorney adjudicator dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the enrollee's

rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The enrollee abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an enrollee has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(7) The enrollee's request is not complete in accordance with §423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under §423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in §423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with §423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be

made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

129. Section 423.2054 is revised to read as follows:

§423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under §423.2108(b), or vacated by the ALJ or attorney adjudicator under §423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under §423.2052(e).

130. Section 423.2056 is added to read as follows:

§423.2056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination in accordance with §423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in §423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with §423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to the IRE, or its successor, to re-adjudicate the request for reconsideration.

(c) *Requested remand—(1) Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding an IRE's dismissal of a request for reconsideration.* Consistent with §423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(e) *Consideration of change in condition.* The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination to be considered in the appeal.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph are not available for and do not apply to remands that are issued under paragraph (d) of this section.

131. Section 423.2058 is added to read as follows:

§423.2058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with §423.2056(g).

§423.2062 [Amended]

132. Section 423.2062 is amended—

a. In the section heading and paragraphs (a) and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (a) by removing the term “ALJs” and adding “ALJs and attorney adjudicators” in its place.

c. In paragraph (b) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

133. Section 423.2063 is revised to read as follows:

§423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare program, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the CMS Administrator. Consistent with §401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with §401.109 of this chapter are binding on all CMS components, and all HHS components that adjudicate matters under the jurisdiction of CMS.

134. Section 423.2100 is revised to read as follows:

§423.2100 Medicare Appeals Council review: general.

(a) Consistent with §423.1974, the enrollee may request that the Council review an ALJ's or attorney adjudicator's decision or dismissal.

(b) When the Council reviews an ALJ's or attorney adjudicator's written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

135. Section 423.2102 is revised to read as follows:

§423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) An enrollee may request Council review of a decision or dismissal issued by an ALJ or attorney adjudicator if the enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's written decision or dismissal.

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in §423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's or attorney adjudicator's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's written decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) An enrollee requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at §405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to an IRE, or an ALJ's or attorney adjudicator's affirmation of an IRE's dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

§423.2106 [Amended]

136. Section 423.2106 is amended by—

- a. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.
- b. Removing the term “ALJ’s” each time it appears and adding “ALJ’s or attorney adjudicator’s” in its place.
- c. Removing the term “MAC” each time it appears and adding “Council” in its place.
- d. Removing the term “MAC’s” and adding “Council’s” in its place.

§423.2108 [Amended]

137. Section 423.2108 is amended by—

- a. In paragraphs (a) through (c) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.
- b. In paragraphs (a) and (d)(2)(iii) by removing the term “ALJ’s” each time it appears and adding “ALJ’s or attorney adjudicator’s” in its place.
- c. In the section heading and paragraphs (a) through (c), (d)(1), (d)(2) introductory text, (d)(3) introductory text, and (d)(3)(ii) by removing the term “MAC” each time it appears and adding “Council” in its place.
- d. In paragraph (a) by removing the term “MAC’s” and adding “Council’s” in its place.
- e. In the heading and text of paragraph (b) by removing the phrase “ALJ’s dismissal” and adding “ALJ’s or attorney adjudicator’s dismissal of a request for a hearing” in its place.

138. Section 423.2110 is revised to read as follows:

§423.2110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the

Council for it to consider reviewing under this authority any time within 60 calendar days after the date of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

§423.2112 [Amended]

139. Section 423.2112 is amended—

a. In paragraphs (a)(1), (b), and (c) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

b. In paragraph (b) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

c. In paragraphs (a)(1) and (3) and (c) by removing the term “MAC” and adding “Council” in its place.

§423.2114 [Amended]

140. Section 423.2114 is amended in the introductory text and paragraph (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

§423.2116 [Amended]

141. Section 423.2116 is amended by—

a. Removing the term “MAC” each time it appears and adding “Council” in its place.

b. Removing the term “MAC’s” and adding “Council’s” in its place.

c. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§423.2118 [Amended]

142. Section 423.2118 is amended by—

- a. Removing the term “MAC” each time it appears and adding “Council” in its place.
- b. Removing the term “MAC’s” and adding “Council’s” in its place.
- c. Removing the phrase “ALJ hearing” and adding “ALJ’s or attorney adjudicator’s action” in its place.
- d. Removing the phrase “the exhibits list” and adding “any index of the administrative record” in its place.
- e. Removing the term “CD” and adding “audio recording” in its place.

§423.2120 [Amended]

143. Section 423.2120 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

§423.2122 [Amended]

144. Section 423.2122 is amended—

- a. In the section heading and paragraphs (a) paragraph heading, (a)(1) through (3), (b) introductory text, (b)(1) and (2), and (c)(1) through (4) by removing the term “MAC” each time it appears and adding “Council” in its place.
- b. In paragraphs (a) heading and (a)(1) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.
- c. In paragraph (a)(1) by removing the term “ALJ level” and adding “OMHA level” in its place.
- d. In paragraph (a)(1) by removing the term “hearing decision” and adding “ALJ’s or attorney adjudicator’s decision” in its place.
- e. In paragraphs (a)(1) and (2) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

f. In paragraph (a)(2) by removing the term “hearing record” and adding “administrative record” in its place.

g. In paragraph (c)(3) by removing the term “MAC’s” and adding “Council’s” in its place.

§423.2124 [Amended]

145. Section 423.2124 is amended by removing the term “MAC” each time it appears and adding “Council” in its place.

§423.2126 [Amended]

146. Section 423.2126 is amended—

a. Amending the section heading and paragraphs (a) heading, (a)(1) through (3), (a)(4) heading, (a)(4)(i) and (ii), (a)(5) heading, (a)(5)(i) and (ii), and (b) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraphs (a) heading, (a)(1) through (3), (a)(4) heading, and (a)(5)(ii) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

c. In paragraph (a)(2) by removing the term “MAC’s and adding “Council’s” in its place.

d. In paragraph (a)(5)(ii) by adding “if applicable” after the word “rehearing”.

§423.2128 [Amended]

147. Section 423.2128 is amended—

a. In the section heading and paragraphs (a), (b), and (c) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In paragraph (a) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

c. In paragraph (b) by removing the phrase “ALJ hearing decision” and adding “ALJ or attorney adjudicator decision” in its place.

§423.2130 [Amended]

148. Section 423.2130 is amended by removing the term “MAC’s” each time it appears and adding “Council’s” in its place.

§423.2134 [Amended]

149. Section 423.2134 is amended in paragraphs (b)(3) and (c) by removing the term “MAC” and adding “Council” in its place.

§423.2136 [Amended]

150. Section 423.2136 is amended—

a. In paragraphs (a) and (c)(3) by removing the term “MAC” and adding “Council” in its place.

b. In paragraph (c)(2) by removing the term “MAC’s” and adding “Council’s” in its place.

c. In paragraph (c)(3) by removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§423.2138 [Amended]

151. Section 423.2138 is amended by—

a. Removing the term “MAC” each time it appears and adding “Council” in its place.

b. Removing the term “ALJ” and adding “ALJ or attorney adjudicator” in its place.

§423.2140 [Amended]

152. Section 423.2140 is amended—

a. In the section heading and paragraphs (a)(1) through (3), (b)(1), (b)(2) introductory text, (b)(2)(ii), (b)(3) and (4), (c) heading, (c)(1), (3), and (4), and (d) by removing the term “MAC” each time it appears and adding “Council” in its place.

b. In the section heading and paragraphs (a)(1) through (3), (b) heading, (b)(1), (b)(2) introductory text, (b)(2)(i), (b)(3) and (4), (c)(1) and (4), and (d) by removing the term “ALJ” each time it appears and adding “ALJ or attorney adjudicator” in its place.

c. In paragraph (d) by removing the term “ALJ’s” and adding “ALJ’s or attorney adjudicator’s” in its place.

PART 478—RECONSIDERATIONS AND APPEALS

153. The authority citation for part 478 continues to read as follows:

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 478.40 [Amended]

154. In § 478.14, paragraph (c)(2) is amended by removing the phrase “part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B” and adding “part 405, subpart I of this chapter for determinations under Medicare Part A and Part B” in its place.

155. Section 478.40 is amended by revising paragraphs (a) and (c) to read as follows:

§478.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least \$200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may request a hearing by an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).

* * * * *

(c) *Governing provisions.* (1) The provisions of subpart I of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart or specified in paragraph (c)(2) of this section. Except as provided in paragraph (c)(2) of this section, references in subpart I to initial determinations made by a Medicare contractor and reconsiderations made by a QIC should be read to mean initial determinations and reconsidered determinations made by a QIO.

(2) The following part 405 regulations, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in §405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in §405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the

introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

156. Section 478.42 is revised to read as follows:

§478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under §478.40 must submit a written request to the OMHA office identified in the notice of the QIO reconsidered determination.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in §478.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be 5 calendar days after the date on the notice, unless there is evidence to the contrary.

(3) A request is considered filed on the date it is received by OMHA.

157. Section 478.44 is revised to read as follows:

§478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with §405.1006(d) and (e) of this chapter. When two or more appellants submit a request for hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with §405.1006(d) and (e) of this chapter.

(b) If the ALJ or attorney adjudicator determines that the amount in controversy is less than \$200, the ALJ, without holding a hearing, or attorney adjudicator notifies the parties that the

parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least \$200.

(c) At the end of the 15-day period, if an ALJ determines that the amount in controversy is less than \$200, the ALJ, without holding a hearing dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

158. Section 478.46 is revised to read as follows:

§478.46 Medicare Appeals Council and judicial review.

(a) The circumstances under which the Medicare Appeals Council (Council) will review an ALJ's or attorney adjudicator's decision or dismissal are the same as those set forth at §§405.1102 ("Request for Council review when ALJ or attorney adjudicator issues decision or dismissal") and 405.1110 ("Council reviews on its own motion") of this chapter.

(b) If \$2,000 or more is in controversy, a party may obtain judicial review of a Council decision, or an ALJ's or attorney adjudicator's decision if a request for review by the Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Council decision or denial.

159. Section 478.48 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

§478.48 Reopening and revision of a reconsidered determination or a decision.

* * * * *

(b) *ALJ or attorney adjudicator and Council Reopening—Applicable procedures.* The ALJ or attorney adjudicator, or the Council, whichever made the decision, may reopen and revise

the decision in accordance with the procedures set forth in §405.980 of this chapter, which concerns reopenings and revised decisions under subpart I of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or attorney adjudicator, or the Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

Approved: December 22, 2016.

Sylvia Burwell,

Secretary,

Department of Health and Human Services

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