



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 423

[CMS-4174-F]

RIN 0938-AT27

Medicare Program; Changes to the Medicare Claims and Medicare Prescription Drug Coverage Determination Appeals Procedures

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations setting forth the appeals process that Medicare beneficiaries, providers, and suppliers must follow in order to appeal adverse determinations regarding claims for benefits under Medicare Part A and Part B or determinations for prescription drug coverage under Part D. These changes help to streamline the appeals process and reduce administrative burden on providers, suppliers, beneficiaries, and appeal adjudicators. These revisions, which include technical corrections, also help to ensure the regulations are clearly arranged and written to give stakeholders a better understanding of the appeals process.

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

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SUPPLEMENTARY INFORMATION:

I. Background

As specified under sections 1869 and 1860D–4 of the Social Security Act (the Act) and the implementing regulations, once Medicare makes a coverage or payment determination under Medicare Parts A, B, or D, affected parties have the right to appeal the decision through four levels of administrative review. If certain requirements, including a minimum amount in controversy (AIC), are met, parties can then appeal the decision to federal district court.

Section 1869 of the Act sets forth the process for appealing Parts A and B claim determinations. For most Part A and B claims, the initial determination is made by a Medicare Administrative Contractor (MAC). If a party is dissatisfied with the initial determination, the party may request a redetermination by the MAC, which is a review by MAC staff not involved in the initial determination. If a party is dissatisfied with the MAC's redetermination, the party may request a Qualified Independent Contractor (QIC) reconsideration consisting of an independent review of the administrative record, including the redetermination. Provided a minimum AIC is met, parties then have the option to appeal to the Office of Medicare Hearings and Appeals (OMHA) where they may receive either a hearing or review of the administrative record by an Administrative Law Judge (ALJ), or a review of the administrative record by an attorney adjudicator. Parties then have the option to appeal to the Medicare Appeals Council (the Council) within the Departmental Appeals Board, where an Administrative Appeals Judge

examines their claim. A party can then appeal the decision to federal district court if certain requirements are met, including a minimum AIC.

The appeals process described previously for Parts A and B claim determinations was initially proposed in the November 15, 2002 **Federal Register** (67 FR 69312), which was promulgated to implement section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554). This process was implemented in an interim final rule with comment period published on March 8, 2005 (the 2005 interim final rule with comment period) (70 FR 11420), which also set forth new provisions to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Correcting amendments to the 2005 interim final rule were published on June 30, 2005 (70 FR 37700) and August 26, 2005 (70 FR 50214), and the final rule was published on December 9, 2009 (74 FR 65296). Subsequent revisions to implement section 201 of the Strengthening Medicare and Repaying Taxpayers Act of 2012 (Pub. L. 112–242) were published on February 27, 2015 (80 FR 10611). These appeals procedures for Part A and B claims are set forth in regulations at 42 CFR part 405, subpart I.

Section 1860D-4 of the Act sets forth the appeals process for Part D coverage determinations. Under Medicare Part D, the Part D plan sponsor issues a coverage determination. If this coverage determination is appealed, the Part D plan sponsor reviews the determination, which is known as a redetermination. If a party is dissatisfied with the redetermination, the party may request a reconsideration by an independent review entity. Similar to the appeals process for Parts A and B claim determinations, provided a minimum AIC is met, parties then have the option to appeal to OMHA where

they may receive either a hearing or review of the administrative record by an ALJ, or a review of the administrative record by an attorney adjudicator. If dissatisfied with OMHA's decision, a party then may appeal to the Council. The Council decision then may be appealed to federal district court if certain requirements are met, including a minimum AIC. These procedures are set forth in regulations at part 423, subparts M and U.

On January 17, 2017, we issued a final rule entitled "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures" (82 FR 4974) (the January 17, 2017 final rule), which revised the Parts A, B, C, and D appeals procedures. The goals of this rulemaking were to streamline the appeals process, increase consistency in decision-making, improve efficiency for both appellants and adjudicators, and provide particular benefit to beneficiaries by clarifying processes and adding provisions for increased assistance when they are unrepresented. On April 16, 2018, we issued a final rule (83 FR 16440) that made additional changes to subparts M and U in order to implement section 704 of the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198), along with other changes.

Through our experience implementing the current appeals process, and through additional research, we have identified several opportunities to streamline the claims appeals process and reduce associated burden on providers, beneficiaries, and appeals adjudicators. We have also identified several technical corrections that should be made to correct cross references, inconsistent definitions, and confusing terminology.

II. Provisions of the Proposed Rule and Summary of and Responses to Public Comments

A. Introduction

In the October 2, 2018 **Federal Register** (83 FR 49513), we published a proposed rule that, if finalized, would make regulatory changes to the Medicare Part A and Part B and Part D appeals processes to help streamline the appeals process and reduce administrative burden on providers, suppliers, beneficiaries, and appeal adjudicators. If finalized, these proposed revisions, which included technical corrections, would also help to ensure the regulations are clearly arranged and written to give stakeholders a better understanding of the appeals process.

We received approximately 15 timely pieces of correspondence on the proposed rule. Commenters included insurance industry associations and organizations, beneficiaries, providers and provider advocacy groups, and health insurance plans. Of the comments received, most commenters supported the rule, specifically the elimination of the requirement that appellants sign appeal requests.

We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments and our final policies are set forth as follows.

B. Discussion of the Proposed Rule

1. Removal of Requirement That Appellants Sign Appeal Requests (§§ 405.944, 405.964, 405.1112, and 423.2112)

Existing regulations at part 405, subpart I, and part 423, subparts M and U,

specify the required elements of requests for Medicare Parts A and B claims appeals and for Medicare Part D coverage determination appeals, respectively. Generally, when a contractor or plan issues a Part A or B initial determination or a Part D coverage determination, it notifies the provider, supplier, and/or beneficiary and offers the opportunity to appeal. If this determination is appealed, the contractor or plan reviews the determination, which, in Medicare Parts A, B and D appeals, is known as a redetermination (see §§ 405.940 and 423.580). This can be followed by a review by an independent contractor consisting of an independent review of the administrative record, including the redetermination, which is known as a reconsideration (§§ 405.960 and 423.600.) If a minimum AIC is met, parties then have the option to appeal to the OMHA where the administrative record may be reviewed by an attorney adjudicator or an ALJ or a hearing may be held by an ALJ (§§ 405.1000 through 405.1058 and 423.1968 through 423.2063). Parties then have the option to appeal to the Council within the Departmental Appeals Board where an Administrative Appeals Judge reviews their claim (§§ 405.1100 through 405.1140 and 423.2100 through 423.2140).

Appeal requests can be made using different standard forms. These standard forms include the following: Medicare Redetermination Request Form (CMS-20027); Medicare Reconsideration Request Form (CMS-20033); Request for Administrative Law Judge Hearing or Review of Dismissal (OMHA-100); and Request for Review of Administrative Law Judge (ALJ) Medicare Decision/Dismissal (DAB-101). A written request that is not made on a standard form is also accepted if it contains certain required elements. For example, see §§ 405.944(b), 405.964(b), 405.1014(a), 405.1112, 423.2014(a), 423.2112.

As discussed previously, all Medicare Parts A, B, and D appeal requests must contain the information specified in our regulations. In addition, for Parts A and B claims appeal requests at the redetermination, reconsideration, and Council review levels (§§ 405.944(b)(4), 405.964(b)(4), and 405.1112(a)), and for Part D coverage determination appeal requests at the Council level (§ 423.2112(a)(4)), the appellants must sign their appeal requests. However, there is no signature requirement when the appellant requests OMHA review of Parts A and B claim determinations, or when the appellant requests a redetermination, reconsideration, or OMHA review of Part D coverage determinations. In addition, there is no requirement that appellants sign appeals requests for appeals of Part C organization determinations.

In order to promote consistency between appeal levels, ensure transparency in developing our appeal request requirements, help ensure that we do not impose nonessential requirements on appellants, reduce the burden on appellants, and improve the appeals process based on our experience, we proposed that appellants in Medicare Parts A and B claim and Part D coverage determination appeals be allowed to submit appeal requests without a signature. Specifically, we proposed to revise §§ 405.944(b)(4), 405.964(b)(4), 405.1112(a), and 423.2112(a)(4) to remove the requirement of the appellant's signature for appeal requests (83 FR 49525 through 49529).

As discussed previously, there is no requirement that appellants sign appeal requests when appealing their cases to OMHA, for the Part C organization determination appeals process, or at the redetermination and reconsideration levels of Part D appeals. However, as we explained in the proposed rule (83 FR 49515), the other requirements for

appeal requests are substantially similar between levels of appeal and appeals processes, or there is a clear reason for the differing requirements. For example, we stated that the requirements for Part A and B appeal requests at the redetermination and reconsideration levels are identical with the exception of the reconsideration requirement that the name of the contractor be listed on the reconsideration appeal request (§§ 405.944 and 405.964). We explained that the rationale for the requirement that the name of the contractor be included on reconsideration appeal requests is that without this information, the independent contractor does not have a method of determining which contractor made the initial determination and redetermination, and is unable to get the case file. Since the contractor doing the redetermination is the same contractor who performed the initial determination, we stated that it is not necessary that this information be included in the redetermination appeal request.

By contrast, we stated in the proposed rule (83 FR 49515) that we do not believe there is a compelling reason to require that a signature be included on redetermination, reconsideration, and Council-level appeal requests, but not on OMHA appeal requests. We explained that removing the requirement that appellants sign their appeal requests, would help promote consistency between appeal request requirements; thus making the appeals process easier for parties to understand.

As discussed in the proposed rule (83 FR 49515), eliminating the requirement that appellants sign their appeal requests would reduce the burden of developing the appeal request and appealing dismissals of appeal requests for lack of a signature to the next level of review (for example, §§ 405.952(b) and 405.972(b)). We stated that allowing adjudicators to review appeal requests without signatures would allow them to focus their

attention on the merits of the appeal, rather than having to dismiss potentially meritorious appeals for a lack of a signature. As a result, we proposed to eliminate the requirement that appellants sign their appeal requests.

We stated in the proposed rule that, when we promulgated the requirement for appellants to sign the appeal requests in regulations, we included a signature on the appeal request to ensure that the person requesting the appeal was a proper party to the appeal. We explained that, through experience, we have found that, in practice, little verification of the signature is possible. To determine if the appeal requestor is a proper party to the appeal, the adjudicator uses the name of the beneficiary and name of the party listed on the appeal request, in addition to the information listed in the case file.

As we explained in the proposed rule (83 FR 49515), the other appeal request requirements consist of fields that are necessary for the adjudicators to properly process the appeal request. As discussed previously, the name of the contractor who made the redetermination is required for the independent contractor to review the case file. In addition, we stated that the Part A and B redetermination appeal request requirement to include the disputed service and/or item enables the contractor to determine the merit of the appellant's claim.

Thus, we stated in the proposed rule that we believe there is no need for a signature on an appeal request at this time and we proposed to eliminate that requirement (83 FR 49515). However, we noted that if we find in the future that there are other reasons that would warrant an appellant's signature on an appeal request (for example, for a good-faith attestation), we would reexamine the possibility of adding the requirement back in. However, we explained that, given that our existing statutory

authority limits our ability to enforce certain attestations, we found the signature requirement unnecessary.

We received several comments on this proposal. Following are summaries of the comments we received and responses to these comments.

Comment: The commenters supported the proposed changes to §§ 405.944, 405.964, 405.1112, and 423.2112 to remove the requirement that appellants sign appeal requests, stating its potential to streamline the appeals process and reduce burden.

Response: We appreciate the commenters' support for elimination of the requirement that appellants sign the appeal request and agree that it will streamline the appeals process and reduce burden.

After review and consideration of the comments received, and for the reasons discussed previously and in the proposed rule, we are finalizing without modification our proposed revisions to §§ 405.944(b)(4), 405.964(b)(4), 405.1112(a), and 423.2112(a)(4).

2. Change to Timeframe for Vacating Dismissals (§§ 405.952, 405.972, 405.1052, and 423.2052)

The regulations at §§ 405.952(d), 405.972(d), 405.1052(e), and 423.2052(e) allow adjudicators to vacate a dismissal of an appeal request for a Medicare Part A or B claim or Medicare Part D coverage determination within 6 months of the date of the notice of dismissal. We stated in the proposed rule (83 FR 49515) that this allows sufficient time for adjudicators to carefully evaluate their dismissals while taking into account the principle of administrative finality.

As discussed in the proposed rule (83 FR 49515), through experience, we have concluded that the timeframe for vacating a dismissal would be better expressed in

calendar days, rather than months, for two reasons. First, we stated that all timeframes in the regulations under part 405, subpart I, and part 423, subpart U, associated with the filing of appeal requests, adjudication periods, reopening of prior determinations, and other time-limited procedural actions are expressed in calendar days, not months. For example, see §§ 405.942 and 423.2056. Second, we stated that applying a timeframe based on days, rather than months, leads to more consistency in interpretation and actual timeframes. We explained that a timeframe based on months could be subject to varying interpretations, as the number of days in a consecutive 6-month period varies from 181 to 184 days. For example, if an ALJ or attorney adjudicator's dismissal is dated August 31 of one calendar year, advancing the timeframe 6 months to February could be confusing for parties and adjudicators because February does not contain 30 or 31 days. Also, given that February has only 28 or 29 days (in a leap year), any 6-month period that includes February would be shorter than other 6 month periods, leading to some inconsistency in the actual timeframe for vacating a dismissal.

To provide more consistency and predictability for appellants and adjudicators, and better conformity with other timeframes in part 405, subpart I, and part 423, subpart U, we proposed (83 FR 49525 through 49529) to revise the timeframe for vacating a dismissal from 6 months to 180 days in §§ 405.952(d), 405.972(d), 405.1052(e), and 423.2052(e).

We received no comments on these proposals. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing without modification our proposed revisions to §§ 405.952(d), 405.972(d), 405.1052(e), and 423.2052(e).

3. Technical Correction to Regulations to Change Health Insurance Claim Number

(HICN) References to Medicare Numbers (§§ 405.910, 405.944, 405.964, 405.1014, 405.1112, 423.2014, and 423.2112)

Section 501 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), added section 205(c)(2)(C)(xiii) of the Act to prohibit Social Security Numbers (or derivatives) from being displayed on Medicare cards. As a result, CMS issued new Medicare cards, which contain a randomly generated Medicare Beneficiary Identifier (MBI), rather than the Social Security Number-based Health Insurance Claim Number (HICN) that, at the time of the proposed rule, was not on Medicare cards. As discussed in the proposed rule (83 FR 49516), in order to ensure that appellants can easily submit appointment of representative documentation and appeal requests, we would accept this documentation with HICNs or MBIs. Consistent with these efforts, we proposed to remove references to the Social Security Number-based HICN on Medicare cards that are included in the Medicare appeals regulations, and to replace them with references to Medicare number to clarify that either a HICN or MBI can be included on appointment of representative documentation and appeal requests (83 FR 49516). Accordingly, we proposed (83 FR 49527 through 49529) to revise the following provisions of Medicare regulations to remove the words “health insurance claim” from the phrase “Medicare health insurance claim number” so that there is only a reference to “Medicare number”: §§ 405.910(c)(5), 405.944(b)(2), 405.964(b)(2), 405.1014(a)(1)(i), 405.1112(a), 423.2014(a)(1)(i), and 423.2112(a)(4).

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing our proposed revisions without modification to §§ 405.910(c)(5), 405.944(b)(2), 405.964(b)(2),

405.1014(a)(1)(i), 405.1112(a), 423.2014(a)(1)(i), and 423.2112(a)(4).

4. Removal of Redundant Regulatory Provisions Relating to Medicare Appeals of Payment and Coverage Determinations and Conforming Changes (§§ 423.562, 423.576, 423.602, 423.604, 423.1970, 423.1972, 423.1974, 423.1976, 423.1984, 423.1990, 423.2002, 423.2004, 423.2006, 423.2014, 423.2020, 423.2044, 423.2100, and 423.2136)

The January 17, 2017 final rule revised certain Medicare procedures for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries and enrollees. Since the publication of this final rule, we have identified four regulatory provisions in part 423, subpart U, that are redundant. In order to reduce potential confusion, we proposed to remove redundant provisions at §§ 423.1970, 423.1972, 423.1974, and 423.1976 and, where necessary, incorporate appropriate provisions in other sections of the regulations (83 FR 49516 through 49518).

Section 423.1970 of the regulations relating to the rights of enrollees to an ALJ hearing provides—

- In paragraph (a), that, if the amount remaining in controversy after the Independent Review Entity (IRE) reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ;
- In paragraph (b)(1), the methodology for computing the AIC when the basis for appeal is the refusal by the Part D plan sponsor to provide drug benefits;
- In paragraph (b)(2), the methodology for computing the AIC when the basis for appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f); and

- In paragraph (c), the requirements for aggregating appeals to meet the AIC.

Section 423.2002 also contains provisions on the right to an ALJ hearing. This section contains cross-references to the provisions in § 423.1970, and also—

- Establishes a 60-calendar day timeframe for filing a written request for an ALJ hearing following receipt of the written notice of the IRE’s reconsideration; and indicates the AIC requirement must be met to be entitled to an ALJ hearing;

- Provides the circumstances under which an enrollee may request that an ALJ hearing be expedited;

- Establishes a 5-calendar day presumption for receipt of the reconsideration following the date of the written reconsideration, unless there is evidence to the contrary; and

- Provides that, for purposes of the section, requests for hearing are considered as filed on the date they are received by the office specified in the IRE’s reconsideration.

Because §§ 423.1970 and 423.2002 both address the right to an ALJ hearing, and because there is a possibility that confusion may arise from having two sections with the same title in the same CFR subpart, we proposed to remove § 423.1970 (83 FR 49527). We stated that because § 423.1970(a) is redundant of §§ 423.2000(a) and 423.2002(a)(2) in describing that an enrollee has a right to an ALJ hearing when the enrollee is dissatisfied with an IRE reconsideration and meets the AIC requirement, we believe § 423.1970(a) should be eliminated. We proposed to relocate § 423.1970(b) and (c) to new proposed § 423.2006 (“Amount in controversy required for an ALJ hearing and judicial review”) as paragraphs (c) and (d), respectively (83 FR 49527 and 49528).

In addition, we proposed to remove the reference to “CMS” in § 423.1970(b)

(relocated to proposed § 423.2006(c)) to clarify that adjudicators, not CMS, ultimately compute the amount remaining in controversy in determining whether the AIC threshold is met for an ALJ hearing or review of an IRE dismissal, and judicial review (83 FR 49528).

As discussed in the proposed rule (83 FR 49516), we believe having one section titled “Right to an ALJ hearing” at § 423.2002 and another section titled “Amount in controversy required for an ALJ hearing and judicial review” at § 423.2006 is more consistent with the corresponding rules in 42 CFR part 405, subpart I, for appeals of Medicare Part A and Part B initial determinations (§§ 405.1002 and 405.1006). For consistency with § 423.2000(a) and language we proposed to remove from § 423.1970(a), we also proposed to add language to § 423.2002(a) providing that the right to an ALJ hearing is available to enrollees who are dissatisfied with the IRE’s reconsideration determination (83 FR 49527).

In order to further increase consistency with § 405.1006 and consolidate the Medicare Part D appeals rules regarding the AIC, we proposed to incorporate provisions in proposed new § 423.2006(a) and (b) that are similar to those provisions contained at § 405.1006(b) and (c), describing the amounts in controversy required for an ALJ hearing and judicial review, respectively, including the annual adjustment of these amounts. In order to more clearly state the AIC requirements for appeals of Part D prescription drug plan coverage determinations, without the need for multiple statutory and regulatory cross-references, we proposed that new § 423.2006 would include the following (83 FR 49527 and 49528):

- At proposed paragraph (a)(1), a provision similar to § 405.1006(b)(1) that the

required amount remaining in controversy must be \$100 increased by the percentage increase in the medical care component of the Consumer Price Index for All Urban Consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

- At proposed paragraph (a)(2), a provision similar to § 405.1006(b)(2) that, if the figure in § 423.2006(a)(1) is not a multiple of \$10, it is rounded to the nearest multiple of \$10, and that the Secretary will publish changes to the AIC requirement in the **Federal Register** when necessary.

- At proposed paragraph (b), a provision similar to § 405.1006(c) that, to be entitled to judicial review, the enrollee must meet the AIC requirements of this subpart and have an amount remaining in controversy of \$1000 or more, adjusted as specified in proposed § 423.2006(a)(1) and (2).

- At proposed paragraph (c), a provision similar to current § 423.1970(b) explaining how the amount remaining in controversy is calculated.

- At proposed paragraph (d), the text currently found in § 423.1970(c) concerning aggregation of appeals to meet the amount in controversy.

Finally, we proposed to update or remove the cross-references to § 423.1970 in §§ 423.562(b)(4)(iv), 423.576, 423.602(b)(2), 423.1984(c), 423.2002(a) introductory text, (a)(2), and (b)(3), 423.2004(a)(2), and 423.2044(c) and to add a cross-reference to § 423.2006 in § 423.1990(b)(3) in place of the language “established annually by the Secretary” (83 FR 49527 through 49529).

Section 423.1972, titled “Request for an ALJ hearing,” provides the procedures an enrollee must follow when filing a request for hearing as follows:

- Paragraph (a) provides that a written request must be filed with the OMHA office specified in the IRE's reconsideration notice.
- Paragraph (b) provides the timeframe for filing a request.
- Paragraph (c)(1) states that if a request for hearing clearly shows that the AIC is less than that required under § 423.1970, the ALJ or attorney adjudicator dismisses the request.
- Paragraph (c)(2) provides that if, after a hearing is initiated, the ALJ finds that the AIC is less than the amount required under § 423.1970, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

As we stated in the proposed rule (83 FR 49517), with the exception of paragraph (c)(2), all of the provisions in § 423.1972 are duplicative of or incorporate by reference other provisions found in § 423.2002(a) and (d) (Right to an ALJ hearing), § 423.2014(d)(2) and (e) (Request for an ALJ hearing or a review of an IRE dismissal), § 423.2020 (Time and place for a hearing before an ALJ), and § 423.2052(a)(2) (Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal). In order to eliminate the redundancy and potential confusion, we proposed to remove § 423.1972 in its entirety (83 FR 49527). As a part of this proposed change, we also proposed to update or remove the cross-references to § 423.1972 in §§ 423.604, 423.1984(c), 423.2014(d) introductory text and (e)(1), and 423.2020(a). We stated in the proposed rule (83 FR 49517) that we do not believe it is necessary to retain § 423.1972(c)(2) in another location because ALJs have broad authority to regulate the course of the hearing. We further noted that, in the rare circumstances described in § 423.1972(c)(2) where an ALJ does not make a finding regarding the AIC until after a

hearing is initiated, the ALJ may discontinue the hearing and issue a dismissal under §§ 423.2002(a)(2) and 423.2052(a)(2).

Section 423.1974, titled “Council review,” provides that 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. We stated in the proposed rule (83 FR 49517) that this provision is similar to § 423.2100, titled “Medicare Appeals Council review: general.” To eliminate the redundancy, we proposed (83 FR 49529) to remove the language of § 423.1974 and incorporate it in § 423.2100(a). This language would replace the language in § 423.2100(a). We also proposed (83 FR 49527) to update or remove the cross-references to § 423.1974 in §§ 423.562(b)(4)(v) and 423.1984(d).

Section 423.1976, titled “Judicial review,” provides the following:

- In paragraph (a), that an enrollee may request judicial review of an ALJ’s or attorney adjudicator’s decision if the Council denied the enrollee’s request for review and the AIC meets the threshold requirement established annually by the Secretary.
- In paragraph (b), that the enrollee may request judicial review of a Council decision if it is the final decision of CMS and the AIC meets the threshold established in paragraph (a)(2).
- In paragraph (c), that, in order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act.

As we stated in the proposed rule (83 FR 49517), with the exception of paragraph (a), these provisions are largely duplicative of other provisions contained in § 423.2136,

also titled “Judicial review.” To eliminate this redundancy, we proposed to remove the provisions of § 423.1976 and revise § 423.2136 as follows:

- Section 423.2136(a) would be redesignated as § 423.2136(a)(1). The cross-reference to § 423.1976 would be removed, and language from § 423.1976(b) would be incorporated in § 423.2136(a)(1)(i) and (ii) and revised by replacing “CMS” with “the Secretary” for consistency with the language in section 1876(c)(5)(B) of the Act and § 423.2140, and replacing “paragraph (a)(2) of this section” with “§ 423.2006” which we proposed to add to the regulations to address the AIC requirements.

- Language at § 423.1976(a) would be revised to incorporate a reference to § 423.2006 and the authorizing language from § 423.2136(a) (proposed § 423.2136(a)(1)) and moved to new § 423.2136(a)(2).

- We also proposed to update or remove the cross-references to § 423.1976 in §§ 423.562(b)(4)(vi), 423.576, and 423.2136(b)(1). We sought comment on these proposed changes.

In summary, we proposed to remove or relocate language as shown in the following table:

Current Section	Proposed New Section	Proposed Action	Rationale
§ 423.1970(a)	N/A	Remove	Similar language exists in §§ 423.2000(a) and 423.2002(a)(2)
§ 423.1970(b)	§ 423.2006	Remove and incorporate revised language at proposed new § 423.2006(c)	Increases consistency with § 405.1006
§ 423.1970(c)		Remove and incorporate at proposed new § 423.2006(d)	
N/A	§ 423.2006(a)	Add language concerning AIC computation not previously outlined in part 423	
N/A	§ 423.2006(b)		
§ 423.1972(a)	N/A	Remove	Similar language exists in §§ 423.2002(a) and
§ 423.1972(b)			

Current Section	Proposed New Section	Proposed Action	Rationale
§ 423.1972(c)(1)			(d), 423.2014(d)(2) and (e), 423.2020, and 423.2052(a)(2) and reduces redundancy
§ 423.1972(c)(2)	N/A	Remove	Unnecessary.
§ 423.1974	N/A	Remove and incorporate into § 423.2100(a)	Reduces redundancy
§ 423.1976(a)	N/A	Remove and incorporate revised language at new § 423.2136(a)(2)	
§ 423.1976(b)		Remove and incorporate revised language at proposed new § 423.2136(a)(1)	
§ 423.1976(c)	N/A	Remove	Similar language exists in § 423.2136(b)(1)

We received no comments on the proposals described previously. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revisions without modification.

5. Change to Timeframe for Council Referral (§§ 405.1110 and 423.2110)

The regulations at §§ 405.1110(a) and (b)(2) and 423.2110(a) and (b)(2) give CMS or its contractors 60 calendar days after the date or issue date, respectively, of OMHA’s decision or dismissal to refer the case to the Council. In the case of Part A and Part B appeals, CMS or its contractors are sent the decision notice when they are a party to the hearing or soon after the hearing occurred. For Part D appeals, as specified in § 423.2046(a)(1), the decision notice is sent to the enrollee, plan sponsor, and IRE.

As we discussed in the proposed rule (83 FR 49518), our regulations generally include regulatory timeframes that start when CMS or its contractors receive the decision notice, rather than the date the decision notice was issued. For example, § 405.1010(b)(3), which addresses the timing of when CMS or its contractor may elect to participate in an ALJ hearing, provides that CMS or its contractor must send notice of its intent to participate, if no hearing is scheduled, no later than 30 calendar days after

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 explained that the rationale for starting the timeframe in § 405.1010(b)(3) after receipt of the notice was to ensure that CMS or its contractors have sufficient time to conduct a thorough evaluation of the facts and the case.

For the same reason, we proposed to revise the timeframe in §§ 405.1110(a) and (b)(2) and 423.2110(a) and (b)(2) for CMS or its contractors to refer a case to the Council such that the timeframe would begin after the ALJ's or attorney adjudicator's decision or dismissal is received (83 FR 49527 and 49529). We stated that starting the timeframe after CMS or its contractor receives OMHA's written decision or dismissal would help ensure that CMS and its contractors have sufficient time to decide whether the case is the type of case that should be referred to the Council for review. In addition, we stated that this proposed change would help ensure that even if CMS and its contractors receive a delayed notice, they would have sufficient time to decide whether the case should be referred to the Council.

In order to ensure consistent implementation of this proposal, we also proposed to add new §§ 405.1110(e) and 423.2110(e) to provide that 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 (83 FR 49529). We explained that this would help facilitate the Council's determination on the timeliness of the referral by establishing a date by which the Council may presume that CMS or its contractor received the decision from OMHA. We stated that this 5-day mailing presumption is consistent with the presumption included in §§ 405.1102(a)(2)

and 423.2102(a)(3) with respect to the timeframe for requesting Council review following an ALJ's or attorney adjudicator's decision or dismissal (83 FR 49518).

For these reasons, we proposed to revise the Council referral timeframes in §§ 405.1110(a) and (b)(2) and 423.2110(a) and (b)(2), and proposed to add §§ 405.1110(e) and 423.2110(e) as discussed previously (83 FR 49529).

Following is a summary of the comment we received and our response to this comment.

Comment: A commenter expressed concern that changing the timeframe to begin after the decision is received could further delay the Council's ultimate decision on the case, if the Council accepts the referral.

Response: We acknowledge that this change in timeframe could result in a delayed decision by the Council on the case. However, we believe that CMS and its contractors need sufficient time to do a thorough review of each appeal. We believe that the need for CMS and its contractors to conduct a thorough review outweighs any concerns that may arise from a slight delay that appellants may experience in receiving their decision by the Council, if the Council ultimately accepts the referral.

Accordingly, after review and consideration of the comment received, and for the reasons discussed previously and in the proposed rule, we are finalizing without modification our proposed revisions to §§ 405.1110(a) and (b)(2) and 423.2110(a) and (b)(2), and our proposals to add §§ 405.1110(e) and 423.2110(e).

6. Technical Correction to Regulation regarding Duration of Appointed Representative in a Medicare Secondary Payer Recovery Claim (§ 405.910)

The regulation at § 405.910 sets forth rules addressing the appointment of

representatives in a Medicare Parts A and B claims appeals, including for secondary payer recovery claims. Specific rules regarding the duration of time that an appointment of representative instrument is valid are provided under § 405.910(e).

On February 27, 2015, we published a final rule entitled “Medicare Program; Right of Appeal for Medicare Secondary Payer Determinations Relating to Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers’ Compensation Laws and Plans (80 FR 10611). In that final rule, we added paragraph (e)(4) to § 405.910 in order to provide applicable plans with the benefit of the existing rule for Medicare secondary payers regarding the duration of appointment for an appointed representative. Within this added provision, we included a citation to § 405.906(a)(1)(iv), as the regulation establishing party status for applicable plans. As we stated in the proposed rule (83 FR 49518), this citation is an incorrect cross-reference; and the correct cross-reference is § 405.906(a)(4). We proposed to revise § 405.910(e)(4) to correct the cross-reference (83 FR 49525). We stated in the proposed rule that this proposed correction would not alter any existing processes or procedures within the Medicare claims appeals process.

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revision without modification to § 405.910(e)(4).

7. Technical Correction to Actions That Are Not Initial Determinations (§ 405.926)

The regulation at § 405.926 sets forth actions that are not considered initial determinations subject to the administrative appeals process under part 405, subpart I. On October 4, 2016, we issued a final rule entitled “Medicare and Medicaid Programs;

Reform of Requirements for Long-Term Care Facilities” (81 FR 68688 through 68872) that moved the definition of “transfer and discharge” in § 483.12 to the definitions under § 483.5. Accordingly, we updated the cross-reference to “§ 483.5” within § 405.926(f) to the cross-reference to “§ 483.5(n)”. However, as we stated in the proposed rule (83 FR 49519), the citation of § 483.5(n) is an incorrect cross-reference.

To correct this error, we proposed to revise § 405.926(f) to remove the incorrect reference to “§ 483.5(n)” and replace it with the cross-reference “§ 483.5 definition of ‘transfer and discharge’” (83 FR 49525). We stated that this proposed technical correction would serve to correct an incorrect citation. We further explained that it would not alter any existing processes or procedures within the Medicare claims appeals process (83 FR 49518).

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revision without modification to § 405.926(f).

8. Changes to Enhance Implementation of Rule Streamlining the Medicare Appeals Procedures (§§ 405.970, 405.1006, 405.1010, 405.1014, 405.1020, 405.1034, 405.1046, 405.1052, 405.1056, 423.1014, 423.1990, 423.2002, 423.2010, 423.2016, 423.2032, 423.2034, 423.2036, 423.2052, and 423.2056)

Since we published the January 17, 2017 final rule, we have identified several provisions that, upon further review, pose unanticipated challenges with implementation, which are explained in this section. In addition, there are other regulatory provisions that we believe require additional clarification and the correction of technical errors and omissions. In the proposals listed in this section, we sought to help ensure the provisions

are implemented as intended, provide clarification, and correct technical errors and omissions. Our proposed changes were as follows.

a. Amount in Controversy (AIC) (§ 405.1006)

Section 405.1006 addresses the AIC required for an ALJ hearing and judicial review, and § 405.1006(d) provides the methodology for computing the AIC. In general, the AIC is computed as the amount that the provider or supplier bills for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services, and further reduced by any deductible and/or coinsurance amounts that may be collected for the items or services. In the January 17, 2017 final rule, we created several exceptions to this general computation methodology for situations where we believed an alternative methodology would more accurately describe the amount actually in dispute. Among these alternatives was the calculation methodology specified in § 405.1006(d)(4), which states that when an appeal involves an identified overpayment, the AIC is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim. For appeals involving an estimated overpayment amount determined through the use of statistical sampling and extrapolation, § 405.1006(d)(4) further provides that the AIC is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter.

As discussed in the proposed rule (83 FR 49519), when we created this exception, we did not account for the possibility that the amount of the overpayment or estimated overpayment specified in the demand letter might change throughout the administrative appeals process if, for example, an adjudicator finds that some of the items or services for

which an overpayment was demanded are covered and payable, or alternatively, if an adjudicator raises a new issue that results in the denial of additional items or services. We explained that, even outside the administrative appeals process, the amount of an overpayment may be revised by a CMS contractor (for example, following a discussion period with the contractor that initially determined the overpayment). Although some of these situations may result in the issuance of a revised demand letter, such a letter may not always be issued during the pendency of the appeals process.

To account for situations where the amount of an overpayment specified in the demand letter does not reflect subsequent adjustments to the amount remaining in controversy, we proposed to revise § 405.1006(d)(4) to state that when an appeal involves an identified overpayment, the AIC is the amount of the overpayment specified in the demand letter, or the amount of the revised overpayment if the amount originally demanded changes as a result of a subsequent determination or appeal, for the items or services in the disputed claim (83 FR 49525). For appeals involving an estimated overpayment amount determined through the use of statistical sampling and extrapolation, we further proposed to revise § 405.1006(d)(4) to state that the AIC is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter, or as subsequently revised (83 FR 49525).

Following is a summary of the comment we received and our response to this comment.

Comment: A commenter expressed concern that CMS and MACs do not always issue demand letters when the amount of an overpayment changes. The commenter requested that CMS require MACs to issue revised demand letters whenever an appeal

decision is made that would increase or decrease the amount of an identified overpayment, and to clarify what the AIC would be if no revised demand letter is issued.

Response: The commenter's request to require MACs to issue revised demand letters whenever an appeal decision is made that would increase or decrease the amount of an identified overpayment is beyond the scope of the proposed rule, and thus we are not addressing it in this final rule.

With regard to the commenter's request to clarify what the AIC would be if no revised demand letter is issued, as we explained in the preamble to the proposed rule (83 FR 49519), the amount of an overpayment or estimated overpayment specified in a demand letter might change throughout the administrative appeals process as a result of appeals determinations, or outside the appeals process (for example, following a discussion period with the contractor that initially determined the overpayment). We further explained that, although some of these situations may result in the issuance of a revised demand letter, such a letter may not always be issued during the appeals process. It is for this reason that we proposed to revise §405.1006(d)(4) to account for situations in which the amount of the overpayment or estimated overpayment specified in the demand letter (original or revised) no longer accurately reflects the AIC for an appeal. In these circumstances, an OMHA adjudicator would consider the amount of the overpayment or estimated overpayment specified in the most recent demand letter, factoring in any additional denied items or services, payment reductions, or payments awarded subsequent to the issuance of the demand letter. For purposes of determining whether an appeal meets the minimum AIC required for an ALJ hearing or review of a dismissal, we believe the demand letter, coupled with other available billing or payment information, would

provide appellants and adjudicators with the necessary information to determine, or at least approximate, the effect of subsequent determinations or appeals and the amount of the revised overpayment. For estimated overpayments determined through the use of statistical sampling and extrapolation, because these estimated overpayments tend to far exceed the minimum AIC, we believe it would generally be unnecessary to calculate the exact amount of the revised estimate.

After review and consideration of the comments received, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revisions without modification to §405.1006(d)(4).

b. Submissions by CMS and CMS Contractors (§§ 405.1010 and 405.1012)

In § 405.1010(b)(1), we state that if CMS or a CMS contractor elects to participate in the proceedings on a request for hearing before receipt of a notice of hearing, or when notice of hearing is not required, it 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, or if the appeal is not assigned, to a designee of the Chief ALJ. We discussed in the January 17, 2017 final rule that the requirement to notify the parties who were sent a copy of the notice of reconsideration helps ensure that the potential parties to a hearing, if a hearing is conducted, would receive notice of the intent to participate (82 FR 5016). However, the final regulation at § 405.1010(b)(1) does not account for requests for reconsideration that are escalated from the QIC level to the OMHA level of appeal without a notice of reconsideration having been issued.

As discussed in the proposed rule (83 FR 49519), in order to help ensure that the potential parties to a hearing would receive notice of CMS' or the contractor's intent to

participate and address reconsideration escalations from the QIC to OMHA, we proposed to revise § 405.1010(b)(1) to require that, for escalated requests for reconsideration, notice of the intent to participate would also be sent to any party that filed a request for reconsideration or was found liable for the services at issue subsequent to the initial determination, which we believe is consistent with circumstances under which a party would receive notice of a hearing under § 405.1020. (Section 405.1020(c)(1) also provides that a notice of hearing is sent to all parties that participated in the reconsideration. However, we stated we did not believe this provision is necessary in circumstances where the QIC has not issued a reconsideration because, in practice, there is generally no opportunity for participation in these circumstances by parties other than the party that filed the request for reconsideration.) For the same reason, we also proposed to revise § 405.1010(c)(3)(ii)(A), which currently requires that copies of CMS or contractor position papers or written testimony that are submitted before receipt of a notice of hearing must be sent to the parties who were sent a copy of the notice of reconsideration (83 FR 49525 and 49526). We proposed to revise § 405.1010(c)(3)(ii)(A) to instead provide that copies are sent to the parties that are required to be sent a copy of the notice of intent to participate in accordance with § 405.1010(b)(1). We noted that no corresponding revisions to § 423.2010 are needed because escalation is not available in Medicare Part D appeals (83 FR 49519).

In § 405.1010(b)(3)(ii), we state that if CMS or a CMS contractor elects to participate after a hearing is scheduled, it must send written notice of its intent to participate no later than 10 calendar days “after receiving the notice of hearing.” As discussed in the proposed rule (83 FR 49519 and 49520), upon reviewing the revised

rules, we noticed an inconsistency between this language and the language in § 405.1012(a)(1), which requires CMS or a CMS contractor electing to be a party to a hearing to send written notice of its intent to be a party no later than 10 calendar days “after the QIC receives the notice of hearing.” We explained in the January 17, 2017 final rule (82 FR 5020) that the timeframe in § 405.1012(a)(1) was based on receipt of the notice of hearing by the QIC because notices of hearing are currently sent to the QIC in accordance with § 405.1020(c). We stated that we believe these requirements should be consistent and the timeframes should begin on the same date, regardless of whether CMS or a CMS contractor is electing to be a party or participant. We also stated that we believe that the regulations should provide flexibility for CMS to designate another contractor, other than the QIC, to receive notices of hearing under § 405.1020(c) if that contractor is then tasked with disseminating the notice of hearing to other CMS contractors. Therefore, and as discussed in this section with regard to notices of hearing, we proposed to revise § 405.1020(c)(1) to provide for this flexibility (83 FR 49526).

For conformity with proposed revised § 405.1020(c)(1) and to resolve the existing inconsistency in §§ 405.1010(b)(3)(ii) and 405.1012(a)(1), we proposed to revise both sections to provide that written notice of the intent to participate or intent to be a party must be submitted no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing (83 FR 49526). We noted that no corresponding revision is needed to the part 423, subpart U, rules because notices of hearing are sent to both the Medicare Part D plan sponsor and the IRE (83 FR 49520).

In § 405.1010(c)(3)(i), we state that CMS or a CMS contractor that filed an

election to participate must submit any position papers or written testimony within 14 calendar days of its 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. In the January 17, 2017 final rule (82 FR 5017), we discussed that the requirement to submit any written testimony within 14 calendar days of the election to participate if no hearing has been scheduled helps to ensure that 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.

Although § 405.1010(c)(3)(i) allows an ALJ to extend the 5-calendar day submission timeframe for cases in which a hearing is scheduled, the regulation text may be unclear as to whether the same discretion is afforded to ALJs or attorney adjudicators with respect to the 14-calendar day submission timeframe for cases in which no hearing has been scheduled. Our intent was to apply this discretionary extension in both circumstances, as evidenced by the corresponding regulation at § 423.2010(d)(3)(i), which allows an ALJ or attorney adjudicator to grant additional time to submit a position paper or written testimony both in cases where a hearing has been scheduled and in cases where no hearing has been scheduled (82 FR 5019). Accordingly, to clarify our intent and help ensure consistency between part 405 and part 423, we proposed to revise § 405.1010(c)(3)(i) to clarify that an ALJ or attorney adjudicator may also extend the 14-calendar day timeframe for submission of position papers and written testimony in cases in which no hearing has been scheduled (83 FR 49525 and 49526).

In § 405.1012(b), we state that if CMS or a CMS contractor elects to be a party to

the hearing, it must send written notice of its intent to the ALJ and to “the parties identified in the notice of hearing.” Upon reviewing the revised rules, we noticed an inconsistency between this language and the language in § 405.1010(b)(2), which states that if CMS or a CMS contractor elects to participate after receipt of a notice of hearing, it must to send written notice of its intent to participate to the ALJ and “the parties who were sent a copy of the notice of hearing.” Although the standard for who must receive notice is the same, the way in which it is articulated is different, which we believe may lead to confusion. To prevent potential confusion and help ensure consistency in the regulations, we proposed to revise § 405.1012(b) by replacing the language “identified in the notice of hearing” with “who were sent a copy of the notice of hearing” (83 FR 49526). As we noted in the proposed rule, no corresponding revision is needed to the part 423, subpart U, rules because only the enrollee is a party to a Medicare Part D appeal and CMS, the IRE, and the Part D plan sponsor may only request to be nonparty participants (83 FR 49520).

Finally, § 405.1012(e)(1) states the circumstances under which an ALJ or attorney adjudicator may determine that a CMS or contractor election to be a party to a hearing made under § 405.1012 is invalid. Because § 405.1012(a) only permits CMS or a contractor to elect to be a party after the QIC receives a notice of hearing, and only an ALJ may schedule and conduct a hearing, we believe the determination as to whether an election made under § 405.1012 is valid should be left to the assigned ALJ. Therefore, we proposed in § 405.1012(e)(1) to replace the phrase “ALJ or attorney adjudicator” with “ALJ” (83 FR 49526). As we noted, no corresponding revision is needed to the part 423, subpart U, rules because only the enrollee is a party to a Medicare Part D appeal and

CMS, the IRE, and the Part D plan sponsor may only request to be nonparty participants (83 FR 49520).

Following is a summary of the comment we received and our response to this comment.

Comment: One commenter opposed the proposal to permit a contractor, other than the QIC, to receive notices of hearing because the commenter believed that allowing flexibility for CMS to designate another contractor to receive notices of hearing would undermine QIC accountability, as the commenter believed that the QIC that rendered the decision on appeal should be a party to the hearing. The commenter further stated that the proposal to allow CMS to designate another contractor, other than the QIC, to receive notices of hearing rather than the QIC would waste time, add complexity, and prejudice providers by allowing CMS to select a different contractor shortly before the hearing. The commenter also noted that the current time frame for CMS or a CMS contractor to submit a position paper or written testimony when a hearing is scheduled (no later than 5 calendar days prior to a hearing if a hearing has been scheduled, unless the time frame is extended by an ALJ) does not afford appellants enough time to review and address any new issues raised in the position paper or written testimony. The commenter also pointed out that on page 49520 of the preamble to the proposed rule, we inadvertently stated that we proposed to revise §405.1012(b)(2), but that paragraph does not exist.

Response: We do not agree with the commenter that our proposal to allow CMS the flexibility to designate another contractor, other than the QIC, to receive notices of hearing would undermine QIC accountability, add complexity to the hearing process, or unfairly prejudice providers. It is possible that the commenter misunderstood our

proposal as a proposal to replace the QIC who adjudicated the appeal with another contractor as a party to the hearing; however, this was not what we proposed. Rather, we proposed that CMS have flexibility to replace the QIC in its administrative role of distributing hearing requests.

Providing CMS with the flexibility to designate a different contractor to receive the notice of hearing does not add complexity to the hearing process. When a hearing is scheduled under the current regulations, OMHA sends the notice of hearing to a single CMS contractor. That contractor is then responsible for disseminating notice of the hearing to other CMS contractors, such as the MAC that issued the redetermination. This proposal, which we are finalizing, will allow CMS to assign the administrative responsibility of notifying the appropriate entities to a contractor other than the QIC. The QIC will still receive notice of the hearing, and would still have the opportunity to elect to participate in or be a party to the appeal, as applicable. Only CMS contractors that were involved with the claims, determinations, and decisions on appeal, or their successors, are notified of a hearing under the current process, and only those entities would be notified under the process we are finalizing.

Under current §§405.1010 and 405.1012, CMS or any of its contractors may elect to participate in the proceedings on a request for an ALJ hearing, and one of these entities may also elect to be a party to the proceedings if a hearing is scheduled and the appellant is not an unrepresented beneficiary. Neither the QIC nor any other CMS contractor is required to be a party (or a non-party participant) to a hearing. To join the proceedings as a party, a CMS contractor must affirmatively elect party status during the appropriate timeframe, and must notify the other parties identified in the notice of hearing of its intent

to be a party to the hearing. Section 405.1012(a)(1), (b). Additionally, under §405.1012(a)(2), an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to a hearing and cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing. Our proposal does not undermine QIC accountability, as current §405.1012 already provides flexibility for CMS or any CMS contractor, not just the QIC, to elect to join an appeal as a party, with the limitation that only the first entity to file its election after the notice of hearing is issued may attend the oral hearing. Our proposal to permit the designation of a contractor, other than the QIC, to perform the administrative role of disseminating hearing requests, would not change the ability of CMS or any of its contractors to elect to be a party to an OMHA appeal.

As for the commenter's concern about the current time frame for CMS or CMS contractor submission of position papers or written testimony when a hearing is scheduled, this comment is beyond the scope of the proposed rule, and we will not be addressing it in this final rule.

Finally, we thank the commenter for alerting us to the typographical error we inadvertently made in the preamble to the proposed rule by referring to §405.1012(b)(2) instead of §405.1012(b) in one place in the discussion. The proposed regulation text of the proposed rule (83 FR 49526) correctly reflected our proposal to modify §405.1012(b).

After review and consideration of the comments received, and for the reasons discussed previously and in the proposed rule, we are finalizing these proposed changes without modification to §§405.1010(b)(1), (b)(3)(ii), (c)(3)(i), and (c)(3)(ii)(A) and 405.1012(a)(1), (b), and (e)(1) .

c. Extension Requests (§§ 405.1014 and 423.2014)

Prior to the January 17, 2017 final rule, § 405.1014(c)(2) provided that any request for an extension of the time to request a hearing must be in writing, give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration. In the January 17, 2017 final rule, this provision was relocated to § 405.1014(e)(2) and revised, in part, to state that any request for an extension of the time to request a hearing or review of a QIC dismissal must be filed with the request for hearing or request for review. This change was motivated by questions from appellants concerning whether a request for an extension should be filed without a request for hearing so that a determination could be made on the extension request before the request for hearing was filed (82 FR 5038). However, in our attempt to provide clarity to appellants, we created a requirement that, in its strictest interpretation, would foreclose an appellant from requesting an extension of the time to request a hearing or review after a request for hearing is filed. The need for such a request to be made may arise when an appellant—particularly an unrepresented beneficiary—is not aware that a request for hearing is untimely at the time of filing. In these situations, OMHA frequently asks the appellant to provide an explanation for the untimely filing and, if the OMHA adjudicator finds good cause for the untimely filing, the time period for filing is extended in accordance with § 405.1014(e)(3).

In order to remedy this situation, we proposed to revise § 405.1014(e)(2) to provide that requests for extension must be filed with the request for hearing or request for review, or upon notice that the request may be dismissed because it was not timely filed (83 FR 49520, 49521, and 49526). We also proposed a corresponding revision to

§ 423.2014(e)(3) for extension requests filed by Medicare Part D enrollees (83 FR 49520, 49521, and 49528).

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revisions without modification to §§ 405.1014 and 423.2014.

d. Notice of Hearing (§ 405.1020)

In § 405.1020(c)(1), we require that a notice of hearing be 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. However, this rule does not account for requests for reconsideration that are escalated from the QIC level to the OMHA level of appeal without a reconsideration having been issued.

To help ensure that the QIC, and other CMS contractors who receive notice of scheduled hearings through the QIC, receive notice of all scheduled hearings, we proposed to revise § 405.1020(c)(1) to require that notice be sent to the QIC that issued the reconsideration or from which the request for reconsideration was escalated (83 FR 49521 and 49526). As discussed in section II.H.2. of the proposed rule with regard to CMS and CMS contractor submissions, we proposed, and are finalizing a change to the regulation, to provide future flexibility for CMS to designate another contractor to receive notices of hearing by revising § 405.1020(c)(1) to state, in part, that the notice of

hearing may instead be sent to another contractor designated by CMS to receive it. We noted that no corresponding revisions are needed in § 423.2020(c)(1) because escalation is not available in Medicare Part D appeals, and notices of hearing are sent to both the Medicare Part D plan sponsor and the IRE (83 FR 49521).

We received a comment on this proposal, which we have summarized and addressed as follows.

Comment: A commenter opposed the proposal to allow CMS to designate another contractor, other than the QIC, to receive notices of hearing, because the contractor that rendered the decision appealed should be a party to the hearing, not a third party that was not previously involved in the appeal. The commenter expressed concern that last minute designations by CMS would unfairly prejudice providers.

Response: We do not agree with the commenter that our proposal to allow flexibility for CMS to designate another contractor to receive notices of hearing will unfairly prejudice providers. As clarified in an earlier response, the contractor designated to receive notices of hearing will not replace the QIC that issued the reconsideration as a potential party to the hearing, or prevent the QIC from participating in an appeal. Under current §§405.1010 and 405.1012, CMS or any of its contractors may elect to participate in the proceedings on a request for an ALJ hearing, and one of these entities may also elect to be a party to the proceedings if a hearing is scheduled and the appellant is not an unrepresented beneficiary. The CMS-designated recipient of the notice of hearing under proposed §405.1020(c)(1), whether it continues to be the QIC that issued the reconsideration or another contractor that CMS designates to receive the notice of hearing, will disseminate the notice of hearing to any other CMS contractor involved in

reviewing the claim at issue or an appeal thereof. The proposal, which we are finalizing, merely provides CMS with flexibility to designate a different contractor to receive notices of hearing on CMS's behalf and disseminate notice of the hearing to the QIC and other CMS contractors.

For the reasons discussed previously and in the proposed rule, we are finalizing this proposed change without modification to §405.1020(c)(1).

e. Request for an In-Person or Video Teleconference (VTC) Hearing (§§ 405.1020 and 423.2020)

Section 405.1020(i)(1) and (5) provides that if an unrepresented beneficiary who filed the request for hearing objects to a video-teleconference (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, an ALJ may grant the unrepresented beneficiary's or other party's request for an in-person or VTC hearing if it satisfies the requirements in § 405.1020(i)(1) through (3), with the concurrence of the Chief ALJ or a designee and upon a finding of good cause. Prior to the January 17, 2017 final rule, § 405.1020(i) dealt exclusively with a party's request for an in-person hearing and § 405.1020(i)(5) required concurrence of the Managing Field Office ALJ and a finding of good cause for an ALJ to grant the request. (As we discussed in the January 17, 2017 final rule (82 FR 5046), the position of Managing Field Office ALJ was replaced by the position of Associate Chief ALJ, and we replaced the reference to "Managing Field Office ALJ" in § 405.1020(i)(5) with "Chief ALJ or a designee" to provide greater flexibility in the future as position titles change.) Managing Field Office ALJ concurrence and a finding of good cause were not required prior to the

January 17, 2017 final rule for requests for a VTC hearing because VTC was the default method of hearing.

As we discussed in the proposed rule (83 FR 49521), when we revised § 405.1020(i) in the January 17, 2017 final rule to reflect the change from VTC to telephone hearing as the default method for appearances by parties other than unrepresented beneficiaries, we neglected to restrict the requirement for the concurrence of the Chief ALJ or designee to requests for in-person hearing, in accordance with § 405.1020(b)(1)(ii) and (b)(2)(ii). In addition, we neglected to clarify that, because VTC is the default hearing method for unrepresented beneficiaries, a finding of good cause is not required when an unrepresented beneficiary who filed the request for hearing objects to an ALJ's offer to conduct a hearing by telephone and requests a VTC hearing. Accordingly, we proposed to revise § 405.1020(i)(5) to clarify that concurrence of the Chief ALJ or designee is only required if the request is for an in-person hearing, and that a finding of good cause is not required for a request for VTC hearing made by an unrepresented beneficiary who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone. We also proposed corresponding revisions to § 423.2020(i)(5) for objections filed by Medicare Part D enrollees.

As further discussed in the proposed rule, in reviewing the January 17, 2017 final rule, we also noted potential confusion about whether § 405.1020(e) or (i) applies to objections to the place of a hearing when the objection is accompanied by a request for a VTC or an in-person hearing. While an objection to a hearing being conducted by telephone or VTC may broadly qualify as an objection to the place of the hearing under § 405.1020(e), our intent was for § 405.1020(i) to apply to such an objection when the

objection is accompanied by a request for a different hearing format, because § 405.1020(i) is specific to an objection to the scheduled hearing format and request for an alternate hearing format. To mitigate the potential confusion as to which provisions applies, we proposed to revise § 405.1020(e) by adding paragraph (e)(5) to make clear that it applies only when the party's or enrollee's objection does not include a request for an in-person or VTC hearing (83 FR 49521 through 49526). We also proposed a corresponding revision to § 423.2020(e) concerning a Medicare Part D enrollee's objection to the time and place of hearing (83 FR 49528).

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the revision proposed previously without modification.

f. Dismissal of a Request for a Hearing (§§ 405.1052 and 423.2052)

Section 405.1052(a) describes the situations under which an ALJ may dismiss a request for hearing (other than withdrawals of requests for hearing, which are described in § 405.1052(c)). Although paragraph (a) pertains only to ALJ dismissals, paragraphs (a)(3), (a)(4)(i), and (a)(5) and (6) contain inadvertent references to attorney adjudicators.

- Paragraph (a)(3) states that an ALJ may dismiss a request for hearing when 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).

- Paragraph (a)(4)(i) provides that when determining whether the beneficiary's surviving spouse or estate has a remaining financial interest, the ALJ or attorney adjudicator considers whether 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. (As discussed in section II.H.10 of the proposed rule, we proposed to change the reference to “limitation of liability” to “limitation on liability.”)

- Paragraph (a)(5) states that an 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 part 405, subpart I, 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.

- Paragraph (a)(6) states that 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.

As discussed in the January 17, 2017 final rule (82 FR 4982), our intent in finalizing the attorney adjudicator proposals was to provide authority for attorney adjudicators to dismiss a request for hearing only when an appellant withdraws his or her request for an ALJ hearing, and not under any other circumstances. We further explained that attorney adjudicators could not dismiss a request for hearing due to procedural issues or make a determination that would result in a dismissal of a request for an ALJ hearing (other than a determination that the appellant had withdrawn the request for hearing) (82 FR 5008 and 5009). Therefore, we proposed to revise § 405.1052(a)(3), (a)(4)(i), and (a)(6) to remove the reference to attorney adjudicators and paragraph (a)(5) to remove the first reference to an attorney adjudicator (83 FR 49526). We also proposed

corresponding corrections to § 423.2052(a)(3), (5), and (6) for dismissals of Part D requests for hearing (83 FR 49529).

Prior to the January 17, 2017 final rule, § 405.1052(b) required that notice of a dismissal of a request for hearing be sent to all parties at their last known address. We explained in that rule that the requirement to send notice of the dismissal to all parties was overly inclusive and caused 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 (82 FR 5086). Therefore, we revised this provision (and moved it to § 405.1052(d)) to state that OMHA mails or otherwise transmits a written notice of a dismissal of a request for hearing or review to all parties who were sent a copy of the request for hearing or review at their last known address.

However, as we discussed in the proposed rule (83 FR 49522), in our effort to better tailor the list of recipients, we neglected to specify that notice is also sent to the appellant—who must receive notice of the dismissal, but would not have received a copy of its own request for hearing or review—and to account for CMS or a CMS contractor who elected to be a party to the appeal. We believe that CMS or a CMS contractor that is a party to an appeal has an interest in the outcome of the appeal and should be notified if the request for hearing or review is dismissed. Section 405.1046 helps ensure that CMS or CMS contractors who are a party to a hearing receive notice of the decision by requiring that the decision be sent to all parties at their last known address. In order to help ensure CMS and CMS contractors are afforded similar notice of dismissals, and that the appellant is notified of a dismissal of its request for hearing or review, we proposed to revise § 405.1052(d) to require that notice be sent to the appellant, all parties who were

sent a copy of the request for hearing or review at their last known address, and to CMS or a CMS contractor that is a party to the proceedings on a request for hearing (83 FR 49526). We stated that no corresponding revision to § 423.2052 is needed because only the enrollee is a party to a Medicare Part D appeal and receives notice of the dismissal (83 FR 49522).

We received no comments on the proposals described previously.

Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the revisions proposed previously without modification.

g. Remanding a Dismissal of a Request for Reconsideration (§§ 405.1056, 405.1034, 423.2034, and 423.2056)

Section 405.1056(a)(1) provides that 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 timeframe 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. Section 405.1056(a)(2) provides that 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. In § 405.1056(d), 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.

As we stated in the proposed rule (83 FR 49522), occasionally, an ALJ or attorney adjudicator may need to remand a request for review of a dismissal of a reconsideration

request for reasons similar to those specified in § 405.1056(a)(1) and (2) because the ALJ or attorney adjudicator is unable to obtain an official copy of the dismissal determination, or because the QIC does not furnish the case file for an appealed dismissal. We explained that, by restricting the bases for remand under § 405.1056(a)(1) and (2) to appeals of reconsiderations, we inadvertently made these reasons unavailable for remands of requests for review of a dismissal under § 405.1056(d). Therefore, we proposed to revise § 405.1056(d) by redesignating existing paragraph (d) as paragraph (d)(1), and adding paragraph (d)(2) to state that an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of the section if an official copy of the notice of dismissal or case file cannot be obtained from the QIC (83 FR 48527). We also proposed corresponding revisions to § 423.2056(d) for Medicare Part D remands of a request for review of an IRE's dismissal of a request for reconsideration (83 FR 49529). We stated that this proposed change would necessitate two additional revisions.

First, §§ 405.1056(g) and 423.2056(g), which discuss reviews of remands by the Chief ALJ or designee, state that the review of remand procedures are not available for and do not apply to remands that are issued under § 405.1056(d) or § 423.2056(d), respectively. In the January 17, 2017 final rule, we explained that this limitation was due to the fact that remands issued on review of a QIC's or IRE's dismissal of a request for reconsideration (that is, based on a determination that the QIC's or IRE's dismissal was in error) are more akin to a determination than a purely procedural mechanism (82 FR 5069 through 5070). Because remands issued under new proposed §§ 405.1056(d)(2) and 423.2056(d)(2) would be procedural remands, we proposed to revise §§ 405.1056(g)

and 423.2056(g) by replacing the references to paragraph (d) with a reference to paragraph (d)(1), so that remands issued under paragraph (d)(2) would be subject to the review of remand procedures in paragraph (g) (83 FR 49522, 49527, and 49529).

Second, we proposed to revise §§ 405.1034(a)(1) and 423.2034(a)(1) to provide that the request for information procedures in these paragraphs apply not only to requests for official copies of redeterminations and reconsiderations, but also to requests for official copies of dismissals of requests for redetermination or reconsideration (83 FR 49522 and 49526).

We received a comment on this proposal. Following is a summary of the comment we received and our response to this comment.

Comment: One commenter opposed the proposal to revise §§ 405.1056(d) and 423.2056(d) to allow an ALJ or attorney adjudicator to remand a request for review of a dismissal if an official copy of the notice of dismissal or case file cannot be obtained from the QIC because the commenter believed it would reduce CMS contractors' accountability for recordkeeping and timely transmission of case file information, while creating additional burden and delays for appellants. The commenter further stated that the proposal to revise §§ 405.1056(d) and 423.2056(d) to allow an ALJ or attorney adjudicator to remand decisions if an official copy of the case file cannot be obtained would have the effect of increasing, not decreasing, the number of pending appeals, and that "if CMS or its contractors cannot maintain appropriate records, then an adverse finding should be reversed."

Response: We do not agree with the commenter that our proposal to revise §§ 405.1056(d) and 423.2056(d) to permit an OMHA adjudicator to remand a request for

review of a dismissal when OMHA is unable to obtain the case file or an official copy of a notice of dismissal would reduce CMS contractor accountability, create additional burden or cause undue delays for appellants, or significantly add to the number of pending appeals. OMHA and CMS have joint operating procedures in place for transmitting case files. Currently, in the rare circumstance in which the QIC or IRE does not respond to a request for a case file, OMHA sends a second request. Requests for hearing are remanded only if the QIC or IRE does not respond to the second request, or does respond but is unable to furnish the requested case file. Similarly, when an official copy of a redetermination or reconsideration is missing from the case file, §§405.1034(a)(1) and 423.2034(a)(1) require that OMHA verify whether an electronic copy of the redetermination or reconsideration is available in the official system of record, and if so accept the electronic copy as an official copy. If an electronic copy is not available in the system of record, an OMHA adjudicator is required to request the missing information from the QIC or IRE, or its successor, while retaining jurisdiction over the case. Then, only if the QIC or IRE does not furnish the requested redetermination or reconsideration within the time frame specified in §405.1034 or §423.2034 is a remand authorized under §405.1056(a)(1) or §423.2056(a)(1).

In proposed §§405.1056(d) and 423.2056(d), authorizing remands when an official copy of the notice of dismissal or a case file for an appealed dismissal of a request for reconsideration cannot be obtained from the QIC or IRE, OMHA would apply the same procedures that currently apply under §§405.1034(a) and 423.2034(a) for missing redeterminations, reconsiderations, and case files for appealed reconsiderations and the same joint operating procedures that are already in place for requesting case files.

We further proposed to revise §§405.1034(a)(1) and 423.2034(a)(1) to require that OMHA first confirm whether an official copy of a missing notice of dismissal is available in the official system of record before issuing a request for information to the QIC or IRE (83 FR 49526 and 49528). Thus, the same safeguards that currently apply to prevent unnecessary requests for information and remands in appeals of reconsiderations would also apply to requests for review of a dismissal, and would help ensure appellants are not subjected to increased burdens or delays that may be associated with a remand. Rather than reducing accountability, we believe the possibility that a case may be remanded would increase accountability and encourage the QIC or IRE to furnish complete case files for requests for review of a dismissal upon receipt of the initial OMHA case file request.

In the rare circumstances where a missing dismissal or case file could not be obtained by OMHA because the QIC or IRE does not respond to OMHA's case file request, or because an electronic copy of the missing notice of dismissal is not available in the official system of record and the QIC or IRE does not respond to OMHA's request under §405.1034(a) or §423.2034(a), or because the QIC or IRE cannot locate the requested case file or dismissal, we believe a remand to the QIC or IRE that issued the dismissal would be the most efficient means to reconstruct the record or, if necessary, re-adjudicate the request for reconsideration. The commenter's suggestion that OMHA issue a fully favorable determination and reverse the denial is not appropriate, as it would require CMS or a plan to pay previously denied claims or authorize previously denied requests for coverage without regard to their merits. HHS is charged with maintaining Medicare program integrity against waste, fraud, and abuse, and has a statutory

obligation to ensure that non-meritorious claims that do not meet statutory criteria for payment are not paid (see, for example, sections 1814, 1835, 1862(a), and 1893 of the Act).

After review and consideration of the comments received, for the reasons discussed previously and in the proposed rule, we are finalizing these proposed changes without modification to §§405.1034(a)(1), 405.1056(d) and (g), 423.2034(a)(1), and 423.2056(d) and (g).

h. Notice of a Remand (§ 405.1056)

Section 405.1056(f) provides that OMHA mails or otherwise transmits written notice of a remand of a request for hearing or request for review to all of the parties who were sent a copy of the request for hearing or review, at their last known address, and to CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. However, as discussed in the proposed rule (83 FR 49522), § 405.1056(f) does not require that notice be sent to the appellant, who would not have received a copy of its own request for hearing or review. For the same reasons described previously with regard to notices of dismissal, we proposed to revise § 405.1056(f) to require that notice be sent to the appellant, all parties who were sent a copy of the request for hearing or review at their last known address, and to CMS or a contractor that elected to be a participant in the proceedings or party to the hearing (83 FR 49522, 49523, and 49527). We stated that no corresponding revision to part 423, subpart U, is needed because § 423.2056(f) already provides that notice is sent to the enrollee, who is the only party to a Part D appeal.

In addition, § 405.1056(f) provides that the notice of remand states that there is a

right to request that the Chief ALJ or a designee review the remand. However, § 405.1056(g) states that the review of remand procedures are not available for and do not apply to remands that are issued under § 405.1056(d) (which, as noted in section II.H.D.7. of the proposed rule, we proposed to redesignate as § 405.1056(d)(1)). To resolve this discrepancy and help ensure that parties receive accurate information regarding the availability of the review of remand procedures, we proposed to revise § 405.1056(f) to clarify that the notice of remand states that there is a right to request that the Chief ALJ or a designee review the remand, unless the remand was issued under § 405.1056(d)(1) (83 FR 49527). We also proposed corresponding changes to § 423.2056(f) (83 FR 49529).

We received no comments on the proposals described previously. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revisions without modification to §§ 405.1056(f) and 423.2056(f).

i. Requested Remands (§ 423.2056)

Section 423.2056(b) provides that 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 readjudicate the request for reconsideration. However, as discussed in the proposed rule (83 FR 49523), when we finalized this provision in the January 17, 2017 final rule, we did not account for situations in which no redetermination was issued because the Medicare Part D plan sponsor failed to meet the timeframe for a standard or expedited redetermination, as provided in § 423.590. We stated that, in these situations, § 423.2056(b) does not provide a basis for remand because

the failure of the Part D plan sponsor to provide a redetermination within the specified timeframe constitutes an adverse redetermination decision, and the Part D plan sponsor is required to forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe in accordance with § 423.590(c) (for requests for standard redeterminations) and (e) (for requests for expedited redeterminations). Accordingly, we proposed to revise § 423.2056(b) to clarify that this reason for remand does not apply when the request for redetermination was forwarded to the IRE in accordance with § 423.590(c) or (e) without a redetermination having been conducted (83 FR 49529).

We received no comments on this proposal. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the proposed revision without modification to § 423.2056(b).

j. Other Technical Changes

In the January 17, 2017 final rule, we amended regulations throughout 42 CFR part 405, subparts I and J, part 422, subpart M, part 423, subparts M and U, and part 478, subpart B, by replacing certain references to ALJs, ALJ hearing offices, and unspecified entities with a reference to OMHA or an OMHA office. We explained that these changes were being made 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 (82 FR 4992). However, as discussed in the proposed rule (83 FR 49523), we neglected to revise two existing references to ALJs in § 405.970(c)(2) and one existing reference to an ALJ in § 405.970(d). To correct our oversight, we proposed to revise § 405.970(c)(2) and (d) by replacing each instance of the phrase “to an ALJ” with “to OMHA” to clarify that appeals are escalated to OMHA, rather than an individual ALJ

(83 FR 49525).

In the January 17, 2017 final rule, in order to reduce confusion with MACs, we revised references to the Medicare Appeals Council throughout part 405, subpart I, part 422, subpart M, and part 423, subparts M and U, by replacing “MAC” with “Council” (82 FR 4993). However, we stated in the proposed rule (83 FR 49523) that we neglected to change one reference to “MAC” in § 423.1990(d)(2)(ii). Accordingly, we proposed to revise § 423.1990(d)(2)(ii) by replacing “MAC” with “Council” (83 FR 49527).

In § 423.2010(d)(1), we stated that CMS, IRE, and/or Part D plan sponsor participation in an appeal 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. As discussed in the proposed rule (83 FR 49523), this provision is similar to § 405.1010(c)(1), which describes the scope of CMS and CMS contractor participation in Medicare Part A and Part B appeals and provides, in part, that such participation does not include calling witnesses or cross-examining the witnesses of a party to the hearing. We stated in the proposed rule (83 FR 49523) that, when finalizing § 423.2010(d)(1) in the January 17, 2017 final rule, which we based on § 405.1010(c)(1), we inadvertently retained the phrase “to the hearing” after “enrollee”. We stated that we believe this phrase is unnecessary in this context and reads awkwardly, and proposed to revise § 423.2010(d)(1) to remove it (83 FR 49523 and 49528).

Prior to the January 17, 2017 final rule, § 423.2016(b)(1) provided that an ALJ may consider the standard for granting an expedited hearing met if a lower-level adjudicator has granted a request for an expedited hearing. We revised this paragraph in

the January 17, 2017 final rule to account for the possibility that a request for an expedited appeal could be granted by an attorney adjudicator. However, as we stated in the proposed rule (83 FR 49523), we neglected to correct the existing reference to a lower-level adjudicator having granted a request for an expedited hearing. Because lower-level adjudicators do not conduct hearings, we proposed to revise § 423.2016(b)(1) by replacing “hearing” with “decision” (83 FR 49528).

Section 423.2032(c) describes the circumstances in which a coverage determination on a drug that was not specified in a request for hearing may be added “to pending appeal.” As we discussed in the proposed rule, we inadvertently omitted the word “a” and proposed to revise § 423.2032(c) by removing the phrase “to pending appeal” and adding “to a pending appeal” in its place (83 FR 49523 and 49528).

Prior to the January 17, 2017 final rule, § 423.2036(g) stated, in part, that an ALJ may ask the witnesses at a hearing any questions relevant to the issues “and allow the enrollee or his or her appointed representative, as defined at § 423.560.” As discussed in the proposed rule (83 FR 49523), in the January 17, 2017 final rule, we redesignated this paragraph as paragraph (d), but neglected to correct the missing language at the end of the sentence. For consistency with § 405.1036(d), we proposed to revise § 423.2036(d) by adding “, to do so” at the end of the paragraph, before the period (83 FR 49529).

Section 423.2036(e) discusses what evidence is admissible at the hearing, and states that an ALJ may not consider evidence on any change in condition of a Part D enrollee after a coverage determination, and further provides that if an enrollee wishes for such evidence to be considered, the ALJ must remand the case to the Part D IRE as set forth in § 423.2034(b)(2). Prior to the January 17, 2017 final rule, § 423.2034(b)(2)

stated that an ALJ will remand a case to the appropriate Part D IRE if the ALJ determines that the enrollee wishes evidence on his or her change in condition after the coverage determination to be considered in the appeal. As discussed in the proposed rule (83 FR 49523), in the January 17, 2017 final rule, we moved this provision to § 423.2056(e), but neglected to update the cross-reference to it in § 423.2036(e). Accordingly, we proposed to revise § 423.2036(e) to replace the reference to “§ 423.2034(b)(2)” with the reference “§ 423.2056(e)” (83 FR 49529).

In §§ 405.952(b)(4)(i), 405.972(b)(4)(i), 405.1052(a)(4)(i) and (b)(3)(i), and 405.1114(c)(1), when discussing determinations as to whether a beneficiary’s surviving spouse or estate has a remaining financial interest in an appeal, we refer to limitation on liability under section 1879 of the Act as “limitation of liability.” To increase consistency with the language used in the statute and help reduce confusion as to which standard is being applied, we proposed to replace the phrase “limitation of liability” with “limitation on liability” in each of these sections (83 FR 49525 through 49527).

As we stated in the proposed rule (83 FR 49524), we identified one provision in part 405, subpart I, and two provisions in part 423, subpart U, where we used incorrect terminal punctuation at the end of a paragraph that is part of a list. To correct our errors, we proposed to revise §§ 405.1046(a)(2)(ii), 423.2002(b)(1), and 423.2010(b)(3)(ii) by replacing the period at the end of each paragraph with a semicolon (83 FR 49526 through 49528).

Lastly, we proposed to revise the authority citations for parts 405 and 423 to meet the current Office of the Federal Register regulatory drafting guidance (83 FR 49524, 49525, and 49527). As we stated in the proposed rule (83 FR 49524), the guidance

requires that we use only the United States Code (U.S.C.) citations for statutory citations unless the citation does not exist.

We received no comments on the proposed technical changes discussed previously. Accordingly, for the reasons discussed previously and in the proposed rule, we are finalizing the revisions proposed previously without modification.

III. Collection of Information Requirements

This final rule revises the appeals process regarding claims for benefits under Medicare Parts A and B and for Medicare prescription drug coverage determinations under Part D. Since appeals are an information collection requirement that is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). The burden for preparing and filing an appeal is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 et seq.). Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

IV. Regulatory Impact Statement

We have examined the impact of this 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 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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other 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 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule would not

have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. 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 are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This rule would have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” OMB’s

interim guidance, issued on April 5, 2017,

[https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf)

[OMB.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf), explains that “EO 13771 deregulatory actions are not limited to those defined as significant under EO 12866 or OMB’s Final Bulletin on Good Guidance Practices.”

This final rule, is considered an EO 13771 deregulatory action. Consistent with Executive Order 13771 requirements, when discounted from 2016 to infinity at 7 percent, this final rule would annually save \$9,497,685.00 a year.

The final policy to remove the requirement that appellants sign appeal requests would result in a slight reduction of burden to appellants by allowing them to spend less time developing their appeal request and appealing dismissals of appeal requests for lack of a signature to the next level of review. Using the data from the number of appeal requests received, we estimate that approximately 4,465,000 appeal requests per year require a signature. We estimate that it takes 1 minute to sign the appeal request.

Therefore, the reduction in administrative time spent would be $4,465,000 \times .016 \text{ hour} = 71,440.00 \text{ hours}$.

We used an adjusted hourly wage of \$34.66 based on the Bureau of Labor Statistics May 2016 website for occupation code 43-9199, “All other office and administrative support workers,” which gives a mean hourly salary of \$17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, results in \$34.66 an hour. The consequent cost savings would be $71,440.00 \times \$34.66 = \$2,476,110.40$ for time spent signing the appeal requests.

Based on a sampling of the number of appeal requests that are dismissed for not containing a signature, we estimated that 284,486 appeal requests are dismissed per year

for not containing a signature on them, and 5 minutes to request that the adjudicator vacate the dismissal or appeal the dismissal. For appellants, the reduction in administrative time spent would be $284,486 \times .083 \text{ hours} = 23,612 \text{ hours}$ with a consequent savings of $23,612 \text{ hours} \times \$34.66 \text{ per hour} = \$818,404.00$. The total amount saved for appellants would be $\$3,294,514.40$, which consists of $\$2,476,110.40$ for time spent signing the appeal requests added to $\$818,404.00$ for time saved appealing the dismissed appeal requests.

When the cost of contractors dismissing appeal requests for the lack of signature is factored in, the cost savings becomes $\$11,757,600$. This cost is calculated by multiplying the number of appeal requests dismissed at the MAC and QIC levels multiplied by the cost that we pay the contractors to adjudicate a dismissal. The average cost for a MAC to dismiss an appeal request would be $\$25 \times 200,000 \text{ appeals dismissed for a lack of signature per year, which equates to } 5,000,000$. The average cost for a QIC to dismiss an appeal request would be $\$80 \times 84,470 \text{ appeal requests dismissed for a lack of signature per year, which equates to a savings of } \$6,757,600$. When these two costs are added together the cost savings becomes $\$11,757,600$.

We did not receive comments on the burden estimates outlined in the proposed rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 423

Administrative practice and procedures, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND
DISABLED**

1. The authority citation for part 405 is revised to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

§ 405.910 [Amended]

2. Section 405.910 is amended—
 - a. In paragraph (c)(5) by removing the phrase “health insurance claim”; and
 - b. In paragraph (e)(4) by removing the reference “§ 405.906(a)(1)(iv)” and adding the reference “§ 405.906(a)(4)” in its place.

§ 405.926 [Amended]

3. Section 405.926 is amended in paragraph (f) by removing the reference “§§ 483.5(n) and 483.15” and adding the reference “§ 483.5 definition of ‘transfer and discharge’ and § 483.15” in its place.

§ 405.944 [Amended]

4. Section 405.944 is amended—
 - a. In paragraph (b)(2) by removing the phrase “health insurance claim”; and
 - b. In paragraph (b)(4) by removing the phrase “and signature”.

§ 405.952 [Amended]

5. Section 405.952 is amended—
 - a. In paragraph (b)(4)(i) by removing the phrase “limitation of liability” and

adding the phrase “limitation on liability” in its place; and

b. In paragraph (d) by removing the phrase “6 months” and adding the phrase “180 calendar days” in its place.

§ 405.964 [Amended]

6. Section 405.964 is amended—

a. In paragraph (b)(2) by removing the phrase “health insurance claim”; and

b. In paragraph (b)(4) by removing the phrase “and signature”.

§ 405.970 [Amended]

7. Section 405.970 is amended in paragraphs (c)(2) and (d) by removing the phrase “to an ALJ” each time it appears and adding the phrase “to OMHA” in its place.

§ 405.972 [Amended]

8. Section 405.972 is amended—

a. In paragraph (b)(4)(i) by removing the phrase “limitation of liability” and adding the phrase “limitation on liability” in its place; and

b. In paragraph (d) by removing the phrase “6 months” and adding the phrase “180 calendar days” in its place.

9. Section 405.1006 is amended by revising paragraph (d)(4) to read as follows:

§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(d) * * *

(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, or the amount of the revised overpayment if the amount originally demanded changes as a result of a subsequent determination or appeal, 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, or as subsequently revised.

* * * * *

10. Section 405.1010 is amended by revising paragraphs (b)(1), (b)(3)(ii), (c)(3)(i), and (c)(3)(ii)(A) to read as follows:

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

* * * * *

(b) * * *

(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—

(i) 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

(ii) The parties who were sent a copy of the notice of reconsideration or, for escalated requests for reconsideration, any party that filed a request for reconsideration or was found liable for the services at issue subsequent to the initial determination.

* * * * *

(3) * * *

(ii) If a hearing is scheduled, no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(c) * * *

(3) * * *

(i) Unless the ALJ or attorney adjudicator grants additional time to submit the position paper or written testimony, 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.

(ii) * * *

(A) The parties that are required to be sent a copy of the notice of intent to participate in accordance with paragraph (b)(1) of this section, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal;
or

* * * * *

§ 405.1012 [Amended]

11. Section 405.1012 is amended--

a. In paragraph (a)(1) by removing the phrase “after the QIC receives the notice of hearing” and adding the phrase “after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing” in its place;

b. In paragraph (b) by removing the phrase “identified in the notice of hearing” and adding the phrase “who were sent a copy of the notice of hearing” in its place; and

c. In paragraph (e)(1) by removing the phrase “ALJ or attorney adjudicator” and adding the term “ALJ” in its place.

§ 405.1014 [Amended]

12. Section 405.1014 is amended—

a. In paragraph (a)(1)(i) by removing the phrase “health insurance claim”; and

b. In paragraph (e)(2) by removing the phrase “with the request for hearing or request for review of a QIC dismissal” and adding the phrase “with the request for hearing or request for review of a QIC dismissal, or upon notice that the request may be dismissed because it was not timely filed,” in its place.

13. Section 405.1020 is amended by—

a. Revising paragraph (c)(1);

b. Adding paragraph (e)(5); and

c. Revising paragraph (i)(5).

The revisions and addition read as follows:

§ 405.1020 Time and place for a hearing before an ALJ.

* * * * *

(c) * * *

(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 or from which the request for reconsideration was escalated, or another contractor designated to receive the notice of hearing by CMS; 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.

* * * * *

(e) * * *

(5) If the party's objection to the place of the hearing includes a request for an in-person or VTC hearing, the objection and request are considered in paragraph (i) of this section.

* * * * *

(i) * * *

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, 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. Good cause is not required for a request for VTC hearing made by an unrepresented beneficiary who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

* * * * *

14. Section 405.1034 is amended by revising paragraph (a)(1) to read as follows:

§ 405.1034 Requesting information from the QIC.

(a) * * *

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims, and official copies of dismissals of a request for redetermination or reconsideration, 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, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

* * * * *

§ 405.1046 [Amended]

15. Section 405.1046 is amended in paragraph (a)(2)(ii) by removing the period at the end of the paragraph and adding a semicolon in its place.

16. Section 405.1052 is amended by revising paragraphs (a)(3), (a)(4)(i), (a)(5) and (6), (b)(3)(i), (d), and (e) 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) * * *

(3) The party did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 405.1014(e).

(4) * * *

(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 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 on liability provisions based on the denial of the services at issue.

* * * * *

(5) The ALJ 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 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.

* * * * *

(b) * * *

(3) * * *

(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 on liability provisions based on the denial of the services at issue.

* * * * *

(d) Notice of dismissal. OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the appellant, all parties who were sent a copy of the request for hearing or review at their last known address, and to CMS or a CMS contractor that is a party to the proceedings on a request for hearing. 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 180 calendar days of the date of the notice of dismissal.

17. Section 405.1056 is amended by revising paragraphs (d), (f), and (g) to read as follows:

§ 405.1056 Remands of requests for hearing and requests for review.

* * * * *

(d) Remanding a QIC's dismissal of a request for reconsideration. (1)

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.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the QIC, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

* * * * *

(f) Notice of remand. OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the appellant, 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, unless the remand was issued under paragraph (d)(1) of this section.

(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)(1) of this section.

18. Section 405.1110 is amended—

a. In paragraph (a) by removing the phrase “after the date” and adding the phrase “of receipt” in its place;

b. In paragraph (b)(2) by removing the term “issued” and adding the term “received” in its place; and

c. Adding paragraph (e).

The addition reads as follows:

§ 405.1110 Council reviews on its own motion.

* * * * *

(e) Referral timeframe. 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.

§ 405.1112 [Amended]

19. Section 405.1112 is amended in paragraph (a)—

a. By removing the phrase “health insurance claim”; and

b. By removing the phrase “and signature”.

§ 405.1114 [Amended]

20. Section 405.1114 is amended in paragraph (c)(1) by removing the phrase “limitation of liability” and adding the phrase “limitation on liability” in its place.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

21. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

§ 423.562 [Amended]

22. Section 423.562 is amended—

a. In paragraph (b)(4)(iv) by removing the reference “§ 423.1970” and adding the reference “§ 423.2006” in its place;

b. In paragraph (b)(4)(v) by removing the reference “§ 423.1974” and adding the reference “§ 423.2100” in its place; and

c. In paragraph (b)(4)(vi) by removing the reference “§ 423.1976” and adding the reference “§ 423.2006” in its place.

§ 423.576 [Amended]

23. Section 423.576 is amended by removing the references “§ 423.580 through § 423.604” and “§ 423.1970 through § 423.1976” and adding the references “§§ 423.580 through 423.604” and “§§ 423.2000 through 423.2140” in their places, respectively.

§ 423.602 [Amended]

24. Section 423.602 is amended in paragraph (b)(2) by removing the reference “§ 423.1970” and adding the reference “§ 423.2006” in its place.

§ 423.604 [Amended]

25. Section 423.604 is amended by removing the reference “§ 423.1972” and adding the reference “§ 423.2014” in its place.

§ 423.1970 [Removed and reserved]

26. Section 423.1970 is removed and reserved.

§ 423.1972 [Removed and reserved]

27. Section 423.1972 is removed and reserved.

§ 423.1974 [Removed and reserved]

28. Section 423.1974 is removed and reserved.

§ 423.1976 [Removed and reserved]

29. Section 423.1976 is removed and reserved.

§ 423.1984 [Amended]

30. Section 423.1984 is amended—

a. In paragraph (c) by removing the reference “§ 423.1970 through § 423.1972 and § 423.2000 through § 423.2063” and adding the reference “§§ 423.2000 through 423.2063” in its place; and

b. In paragraph (d) by removing the reference “§ 423.1974 and § 423.2100 through § 423.2130” and adding the reference “§§ 423.2100 through 423.2130” in its place.

§ 423.1990 [Amended]

31. Section 423.1990 is amended—

a. In paragraph (b)(3) by removing the phrase “established annually by the Secretary” and adding the phrase “specified in § 423.2006” in its place; and

b. In paragraph (d)(2)(ii) by removing the term “MAC” and adding the term “Council” in its place.

32. Section 423.2002 is amended—

- a. By revising paragraphs (a) introductory text and (a)(2);
- b. In paragraph (b)(1) by removing the period at the end of the paragraph and adding a semicolon in its place; and
- c. By revising paragraph (b)(3).

The revisions read as follows.

§ 423.2002 Right to an ALJ hearing.

(a) An enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ if—

* * * * *

(2) The enrollee meets the amount in controversy requirements of § 423.2006.

(b) * * *

(3) The enrollee meets the amount in controversy requirements of § 423.2006.

* * * * *

§ 423.2004 [Amended]

33. Section 423.2004 is amended in paragraph (a)(2) by removing the reference “§ 423.1970” and adding the reference “§ 423.2006” in its place.

34. Section 423.2006 is added to read as follows:

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

(a) ALJ review. To be entitled to a hearing before an ALJ, an enrollee must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be \$100, increased by the percentage increase in the medical care component of the

Consumer Price Index for All Urban Consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (a)(1) of this section is not a multiple of \$10, it is rounded to the nearest multiple of \$10. The Secretary will publish changes to the amount in controversy requirement in the **Federal Register** when necessary.

(b) Judicial review. To be entitled to judicial review, the enrollee must meet the amount in controversy requirements of this subpart at the time it requests judicial review. For review requests, the required amount remaining in controversy must be \$1,000 or more, adjusted as specified in paragraphs (a)(1) and (2) of this section.

(c) Calculating the amount remaining in controversy. (1) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, the projected value of those benefits is used to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(2) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), the projected value of the drugs subject to the drug management program is used to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year.

(d) Aggregating appeals to meet the amount in controversy--(1) Enrollee. Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(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) Multiple enrollees. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(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.

§ 423.2010 [Amended]

35. Section 423.2010 is amended—

a. In paragraph (b)(3)(ii) by removing the period at the end of the paragraph and adding a semicolon in its place; and

b. In paragraph (d)(1) by removing the phrase “to the hearing”.

36. Section 423.2014 is amended by revising paragraphs (a)(1)(i), (d) introductory text, and (e)(1) and (3) to read as follows:

§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) * * *

(1) * * *

(i) The name, address, telephone number, and Medicare number of the enrollee.

* * * * *

(d) When and where to file. The request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

* * * * *

(e) * * *

(1) 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.

* * * * *

(3) The request must be filed with the office specified in the notice of reconsideration or dismissal, 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 request for review of an IRE dismissal, or upon notice that the request may be dismissed because it was not timely filed.

* * * * *

§ 423.2016 [Amended]

37. Section 423.2016 is amended in paragraph (b)(1) by removing the term “hearing” and adding the term “decision” in its place.

38. Section 423.2020 is amended by—

- a. Revising paragraph (a);
- b. Adding paragraph (e)(5); and
- c. Revising paragraph (i)(5).

The revisions and addition read as follows:

§ 423.2020 Time and place for a hearing before an ALJ.

(a) General. The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

* * * * *

(e) * * *

(5) If the enrollee’s objection to the place of the hearing includes a request for an in-person or video-teleconferencing hearing, the objection and request are considered in paragraph (i) of this section.

* * * * *

(i) * * *

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, 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. Good cause is not required for a request for

video-teleconferencing hearing made by an unrepresented enrollee who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

* * * * *

§ 423.2032 [Amended]

39. Section 423.2032 is amended in paragraph (c) by removing the phrase “to pending appeal” and adding the phrase “to a pending appeal” in its place.

40. Section 423.2034 is amended by revising paragraph (a)(1) to read as follows:

§ 423.2034 Requesting information from the IRE.

(a) * * *

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues, and official copies of dismissals of a request for redetermination or reconsideration, 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, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

* * * * *

§ 423.2036 [Amended]

41. Section 423.2036 is amended—

a. In paragraph (d) by removing the reference “§ 423.560” and adding the phrase “§ 423.560, to do so” in its place; and

b. In paragraph (e) by removing the reference “§ 423.2034(b)(2)” and adding the reference “§ 423.2056(e)” in its place.

§ 423.2044 [Amended]

42. Section 423.2044 is amended in paragraph (c) by removing the reference “§ 423.1970” and adding the reference “§ 423.2006” in its place.

§ 423.2052 [Amended]

43. Section 423.2052 is amended—

a. In paragraph (a)(3) by removing the phrase “or attorney adjudicator”;

b. In paragraph (a)(5) by removing the phrase “The ALJ or attorney adjudicator dismisses” and adding the phrase “The ALJ dismisses” in its place;

c. In paragraph (a)(6) by removing the phrase “or attorney adjudicator”; and

d. In paragraph (e) by removing the phrase “6 months” and adding the phrase “180 calendar days” in its place.

44. Section 423.2056 is amended by revising paragraphs (b), (d), (f), and (g) to read as follows:

§ 423.2056 Remands of requests for hearing and requests for review.

* * * * *

(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 readjudicate the request for reconsideration, unless the request for redetermination was forwarded to the IRE in accordance with § 423.590(c) or (e) without a redetermination having been conducted.

* * * * *

(d) Remanding an IRE’s dismissal of a request for reconsideration. (1)

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.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the IRE, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

* * * * *

(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, unless the remand was issued under paragraph (d)(1) of this section.

(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 (g) are not available for and do not apply to remands that are issued in paragraph (d)(1) of this section.

45. Section 423.2100 is amended by revising paragraph (a) to read as follows:

§ 423.2100 Medicare Appeals Council review: general.

(a) 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.

* * * * *

46. Section 423.2110 is amended—

- a. In paragraph (a) introductory text by removing the phrase “after the date” and adding the phrase “of receipt” in its place;
- b. In paragraph (b)(2) introductory text by removing the term “issued” and adding the term “received” in its place; and
- c. Adding paragraph (e).

The addition reads as follows.

§ 423.2110 Council review on its own motion.

* * * * *

(e) Referral timeframe. 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.

§ 423.2112 [Amended]

47. Section 423.2112 is amended in paragraph (a)(4)—

- a. By removing the phrase “health insurance claim”; and
- b. By removing the phrase “and signature”.

48. Section 423.2136 is amended by revising paragraphs (a) and (b)(1) to read as follows.

§ 423.2136 Judicial review.

(a) General rule--(1) Review of Council decision. To the extent authorized by sections 1876(c)(5)(B) and 1860D-4(h) of the Act, an enrollee may obtain a court review of a Council decision if—

- (i) It is a final decision of the Secretary; and
- (ii) The amount in controversy meets the threshold requirements of § 423.2006.

(2) Review of ALJ's or attorney adjudicator's decision. To the extent authorized by sections 1876(c)(5)(B) and 1860D-4(h) of the Act, the enrollee may request judicial review of an ALJ's or attorney adjudicator's decision if—

- (i) The Council denied the enrollee's request for review; and
- (ii) The amount in controversy meets the threshold requirements of § 423.2006.

(b) * * *

(1) Any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

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CMS-4174-F

Dated: March 19, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2019-09114 Filed: 5/3/2019 11:15 am; Publication Date: 5/7/2019]