DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 476, and 489

[CMS-4204-P]

RIN 0938-AV16

Medicare Program: Appeal Rights for Certain Changes in Patient Status

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement an order from the Federal district court for the District of Connecticut in *Alexander v. Azar* that requires HHS to establish appeals processes for certain Medicare beneficiaries who are initially admitted as hospital inpatients but are subsequently reclassified as outpatients receiving observation services during their hospital stay and meet other eligibility criteria.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER].**

ADDRESSES: In commenting, please refer to file code CMS-4204-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4204-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4204-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: David Danek, david.danek@cms.hhs.gov, for issues related to the retrospective process.

Janet Miller, janet.miller@cms.hhs.gov, for issues related to the prospective process.

Shaheen Halim, shaheen.halim@cms.hhs.gov for issues related to Quality Improvement Organization review.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the

close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Executive Summary

The purpose of this proposed rule is to establish appeals processes to comply with a court order issued in the case *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020), *aff'd sub nom.*, *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022). The proposed processes would apply to certain Medicare beneficiaries who are initially admitted as hospital inpatients but are subsequently reclassified as outpatients receiving observation services during their hospital stay and meet other eligibility criteria.

The proposed processes would consist of the following:

- *Expedited appeals*: We are proposing an expedited appeals process for certain beneficiaries who disagree with the hospital's decision to reclassify their status from inpatient to outpatient receiving observation services (resulting in a denial of coverage for the hospital stay under Part A). Eligible beneficiaries would be entitled to request an expedited appeal regarding that decision prior to discharge from the hospital. Appeals would be conducted by a Beneficiary & Family Centered Care - Quality Improvement Organization (BFCC-QIO).
- *Standard appeals:* We are proposing that beneficiaries who do not file an expedited appeal would have the opportunity to file a standard appeal (that is, an appeal requested by a beneficiary eligible for an expedited appeal, but filed outside of the expedited timeframes) regarding the hospital's decision to reclassify their status from inpatient to outpatient receiving observation services (resulting in a denial of coverage for the hospital stay under Part A). Under

our proposal, these standard appeals will follow similar procedures to the expedited appeals process but without the expedited timeframes to file and for the QIO to make decisions.

- *Retrospective appeals:* We are proposing a retrospective review process for certain beneficiaries to appeal denials of Part A coverage of hospital services (and certain SNF services, as applicable), for specified inpatient admissions involving status changes that occurred prior to the implementation of the prospective appeals process, dating back to January 1, 2009. Consistent with existing claims appeals processes, we are proposing that Medicare Administrative Contractors (MACs) will perform the first level of appeal, followed by Qualified Independent Contractor (QIC) reconsiderations, Administrative Law Judge (ALJ) hearings, review by the Medicare Appeals Council, and judicial review.

II. Background

This proposed rule sets forth new appeals procedures to implement the court order in *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020), *aff'd sub nom.*, *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022). In this order, the court directed the Department of Health and Human Services (HHS) to "permit all members of the … class to appeal the denial of their Part A coverage" and to establish appeal procedures for certain beneficiaries in Medicare Part A and B ("Original Medicare") who are initially admitted to a hospital as an inpatient by a physician but whose status during their stay is changed to outpatient by the hospital, thereby effectively denying Part A coverage for their hospital stay.[1] In some cases, the status change also affects the availability of Part A coverage for a beneficiary's post-hospital extended care services furnished in a skilled nursing facility (SNF). The court imposed additional conditions on the right to appeal as described in detail in this proposed rule.

[1] The terms of the court order refer to denials of Part A coverage. Consistent with the court order, the appeals processes proposed in this rule do not extend to enrollees in Medicare Advantage (MA) plans. Medicare Advantage plan enrollees have existing rights that afford enrollees the right to appeal a plan organization determination where the plan refuses to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization. 42 CFR 422.560 through 422.634. For example, if an MA plan refuses to authorize an inpatient admission, the enrollee may request a standard or expedited plan reconsideration of that organization determination. 42 CFR 422.566(b), 422.568 through 422.572.

The court's order requires new appeal procedures be afforded to the following class: Medicare beneficiaries who, on or after January 1, 2009--

- Have been or will have been formally admitted as a hospital inpatient;
- Have been or will have been subsequently reclassified by the hospital as an outpatient receiving "observation services"[2];
- Have received or will have received an initial determination or Medicare Outpatient Observation Notice (MOON)[3] indicating that the observation services are not covered under Medicare Part A; and
- Either -- (1) were not enrolled in Part B coverage at the time of their hospitalization; or (2) stayed at the hospital for 3 or more consecutive days but were designated as inpatients for fewer than 3 days, unless more than 30 days has passed after the hospital stay without the beneficiary's having been admitted to a skilled nursing facility. Medicare beneficiaries who meet the requirements of the foregoing sentence but who pursued an administrative appeal and received a final decision of the Secretary before September 4, 2011, are excluded from the class.

The court determined that beneficiaries who are members of the class described previously have been deprived of due process and ordered the following:

- Class members shall have an opportunity to appeal the denial of their Part A coverage.
- Class members who have stayed, or will have stayed, at a hospital for 3 or more consecutive days, but who were designated as inpatients for fewer than 3 days, shall have the right to an appeal through an expedited appeals process substantially similar to the existing expedited process for challenging hospital discharges.

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[2] For the purposes of these proposed procedures, a beneficiary is considered an outpatient receiving observation services when the hospital changes a beneficiary's status from inpatient to outpatient while the beneficiary is in the hospital and the beneficiary subsequently receives observation services following a valid order for such services. See proposed 42 CFR 405.931(h).

[3] As explained in 42 CFR 489.21(y), the Medicare Outpatient Observation Notice (MOON) is a written notice furnished by a hospital to Medicare beneficiaries who receive observation services as an outpatient for more than 24 hours. The notice explains why the beneficiary is not an inpatient and also explains the consequences of being an outpatient rather than an inpatient. A copy of the notice is available to download at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202212-0938-016

- Class members shall be permitted to argue that their inpatient admission satisfied the relevant criteria for Part A coverage—for example, that the medical record supported a reasonable expectation of a medically necessary two-midnight stay at the time of the physician's initial inpatient order, in the case of a post–Two Midnight Rule hospital stay—and that the hospital utilization review committee's (URC) determination to the contrary was therefore erroneous. If a class member prevails, then for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, the beneficiary's reclassification as an outpatient that resulted from the URC's erroneous determination shall be disregarded.

- For class members whose due process rights were violated, or will have been violated, prior to the availability of the procedural protections as previously set forth, such beneficiaries shall be afforded a meaningful opportunity to appeal the denial of their Part A coverage, as well as effective notice of this right.

In addition, on December 9, 2022, the district court issued an "Order Clarifying Judgment" with respect to the claims for outpatient hospital services received by beneficiaries who were enrolled in Part B of the program at the time such services were furnished. In this clarifying order, the judge stated that while he intended to provide a meaningful opportunity for class members whose due process rights were violated to appeal the denial of Part A coverage, he also stressed the need to provide a remedy for class members who endured undercompensated stays at skilled nursing facilities. He further stated that, since class members with Part B coverage had much of their past hospital stays paid for by such coverage, he did not intend to require the unwinding of previously approved Part B outpatient hospital claims so they could be reprocessed as Part A claims. The clarification states that if a class member enrolled in Part B coverage at the time of their hospitalization prevails in an appeal of a claim, then an adjustment of payment for the underlying hospital services (including any applicable deductible and

coinsurance amounts) is not required, and Part A payment for covered SNF services may be made without any adjustment to the payment for the underlying hospital services.

In section III.A. of this proposed rule, we describe the proposed procedures that would be available to members of the class described previously (hereinafter, eligible beneficiaries) to appeal denials of Part A coverage of hospital services (and certain SNF services, as applicable), for specified inpatient admissions involving status changes that occurred prior to the implementation of the prospective appeals process, dating back to January 1, 2009. We refer to this as the retrospective appeals process. In section III.B. of this proposed rule, we describe the expedited and standard appeals procedures that would be available prospectively (meaning to beneficiaries whose status is changed after the effective date of this rule and after the implementation and availability of the procedures established by the rule) to eligible beneficiaries who, among other things, are admitted as hospital inpatients and are reclassified by hospitals as outpatients receiving observation services.

Once we publish a final rule regarding the procedures for these new appeals, we intend to specify the implementation date for filing appeal requests for retrospective and prospective appeals. When the prospective process is fully implemented, eligible beneficiaries who are hospitalized and receive notice of their appeal rights and wish to pursue an appeal will be expected to utilize the prospective procedures (proposed 42 CFR 405.1210 through 405.1212). Eligible beneficiaries who are hospitalized and entitled to an appeal under these procedures prior to the implementation date of the prospective process will be able to utilize the retrospective appeals process, subject to the filing limitation proposed in § 405.932(a)(2)(i)(B).

Accordingly, we are proposing new retrospective and prospective appeals processes to implement the court's order as detailed in this proposed rule.

III. Provisions of the Proposed Regulations

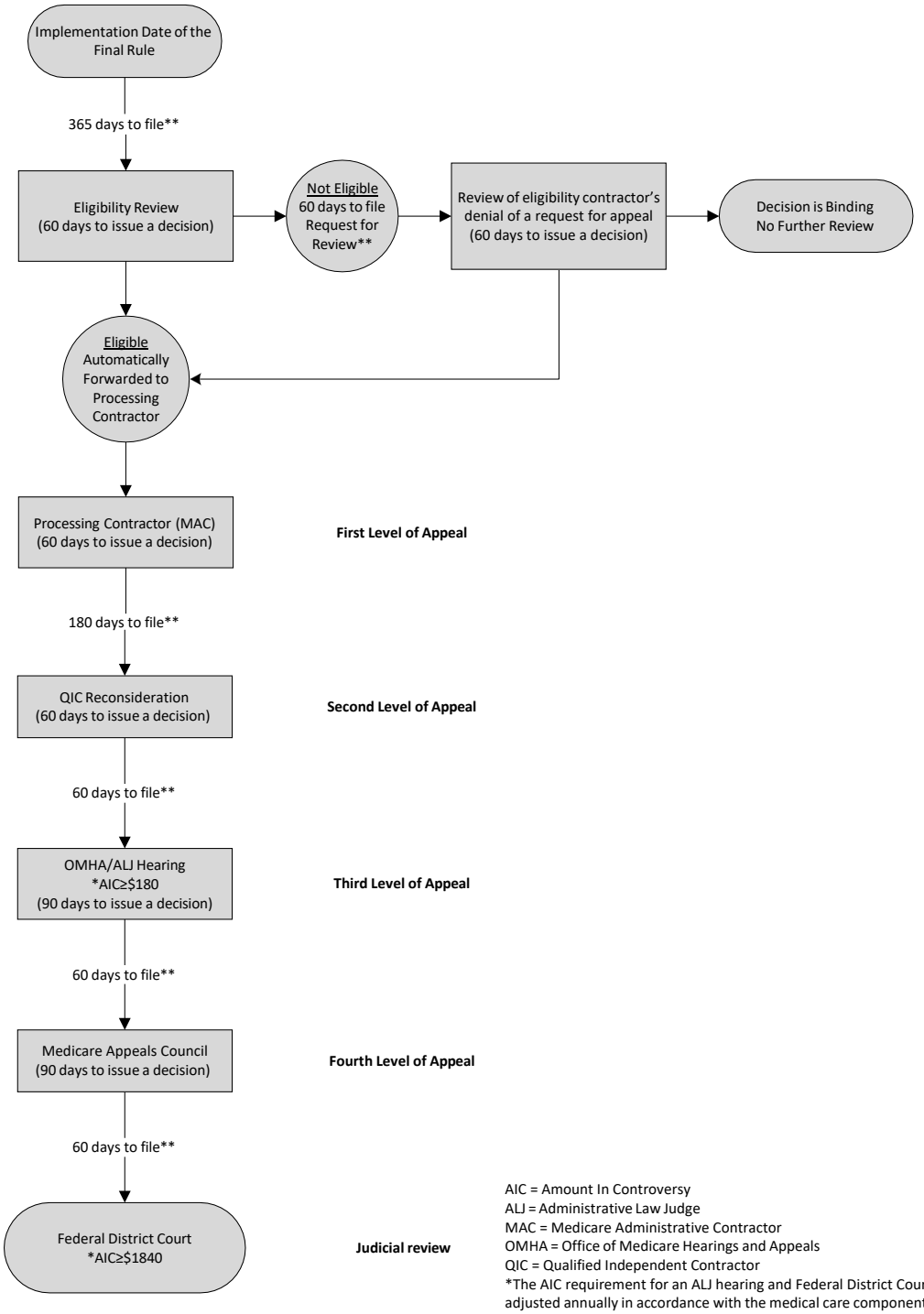
A. *Retrospective Appeals*

1. Overview

The retrospective appeals required by the court order constitute a new process under the Medicare program, as the appeals would be based on alleged entitlement to coverage for services that were not actually billed to the program on a claim. That is, under existing claims appeals processes for the Original Medicare program, a beneficiary is asking for a determination on whether specific items and services billed on a claim for payment should have been covered and paid, not whether items and services should have been billed or whether there should have been coverage when there is no claim. Sections 205(a), 1871, and 1872 of the Social Security Act (the Act) provide the Secretary authority to establish regulations to carry out the administration of the insurance programs under Title XVIII of the Act.[4] The new retrospective appeals procedures required under the court order do not fit into the existing claims appeals process for Original Medicare claims established under section 1869 of the Act. However, in our view, these new procedures would have similarities to the longstanding claims appeals procedures with which Medicare beneficiaries are familiar. Accordingly, we are proposing new procedures to govern the retrospective appeals process in proposed 42 CFR 405.931 through 405.938 that would be based, in large part and to the extent appropriate, on the existing claims appeals procedures in the existing provisions in 42 CFR part 405 Subpart I (as authorized under section 1869 of the Act). We provide more detail about the proposed procedures at each level of the administrative appeals process following this overview, and we have included flowcharts to depict the overall proposed appeals process for retrospective reviews (in Figure 1) and prospective reviews (in Figure 2).

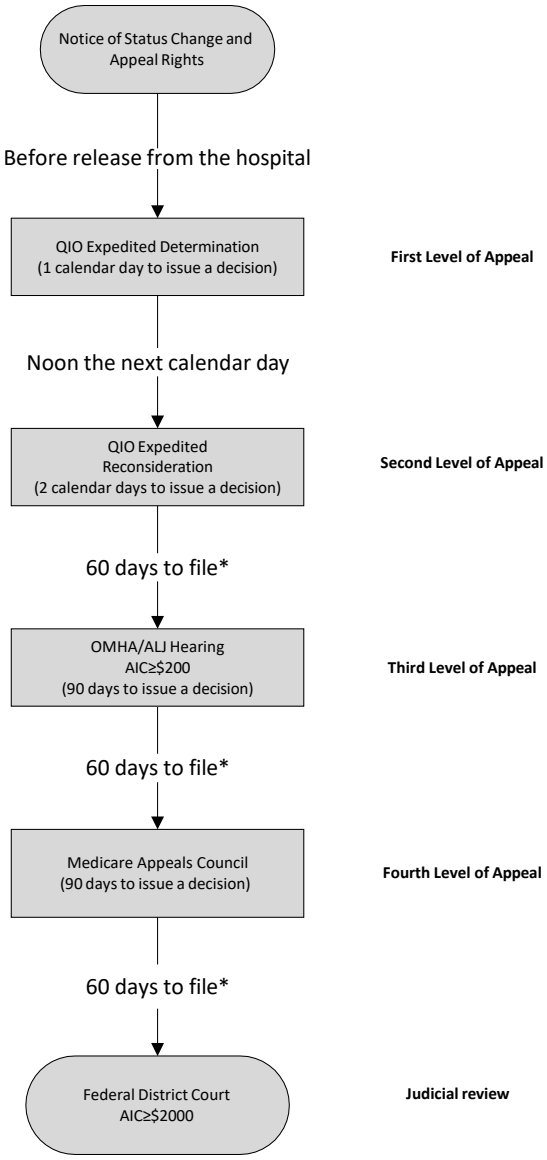
[4] Section 205(a) of the Act, incorporated into Title XVIII by section 1872 of the Act, provides that the Secretary "shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this title, which are necessary or appropriate to carry out such provisions[.]" Section 1871 of the Act states that the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.

FIGURE 1: PROPOSED RETROSPECTIVE REVIEW PROCESS



AIC = Amount In Controversy
ALJ = Administrative Law Judge
MAC = Medicare Administrative Contractor
OMHA = Office of Medicare Hearings and Appeals
QIC = Qualified Independent Contractor
*The AIC requirement for an ALJ hearing and Federal District Court is adjusted annually in accordance with the medical care component of the consumer price index. The chart reflects the amounts for calendar year 2024 and is subject to change each calendar year.
**Filing deadlines are from date of receipt of the notice/decision (presumed to be 5 days from the date of the notice unless evidence to the contrary).

FIGURE 2: PROPOSED EXPEDITED (PROSPECTIVE) APPEALS PROCESS



AIC = Amount In Controversy ALJ = Administrative Law Judge
OMHA = Office of Medicare Hearings and Appeals

In § 405.931(b)(2), we are proposing to define the term "eligibility contractor" to mean the contractor that would serve as a single point of contact for incoming retrospective appeal requests. As proposed in § 405.932(a) through (e), the eligibility contractor would determine if the request for appeal is valid, including whether the request is timely and contains the required elements for an appeal. In addition, we are proposing that the eligibility contractor would determine whether the individual submitting the request (or the individual for whom a request is submitted, in the case of a request filed by a representative) meets the definition of a class member as defined by the court, and is, thus, an eligible party entitled to an appeal under the terms of the court order. The eligibility contractor would then either deny or approve each appeal request received and notify the individual (or their representative) of the determination. For those requests that are denied (that is, the beneficiary has not demonstrated s/he meets the definition of a class member and is not eligible for an appeal, or the appeal request is not otherwise valid), we are proposing in § 405.932(e) that the individual filing the request (or their representative) would have an opportunity to correct any errors and/or demonstrate why the appeal request should be approved. An individual's request to review a denial must be received by the eligibility contractor within 60 calendar days of the individual's receipt of the denial notice under proposed § 405.932(e)(2). For appeal requests that are approved (that is, the beneficiary satisfies the requirements for class membership -- and thus, is determined to be an eligible party -- and the request is valid), the eligibility contractor would forward those requests to the processing contractor to conduct the first level appeal.

In § 405.931(b)(3), we are proposing that the processing contractor would perform the first level of appeal. The processing contractor would be the MAC that currently has jurisdiction over Part A claims for the hospital at which the beneficiary was initially admitted prior to being subject to a status change. As proposed in § 405.932(f) through (i), processing contractors would generally follow existing procedures that govern redeterminations (42 CFR 405.940 through 405.958), as appropriate, except as we have otherwise proposed in § 405.932.

In § 405.934, we are proposing that eligible parties (or their representatives) who are dissatisfied with the processing contractor's appeal decision would have the opportunity to request a reconsideration to be performed by a QIC. We are proposing that the QICs would generally utilize existing procedures that govern reconsiderations (42 CFR 405.960 through 405.978), as appropriate, except as we have otherwise proposed in § 405.934.

Following a reconsideration, in § 405.936 we are proposing that eligible parties (or their representatives) who are dissatisfied with the reconsideration would be able to request a hearing before an Administrative Law Judge (ALJ) (or review by an attorney adjudicator) if the claims under appeal meet the amount in controversy requirement.[5] In § 405.936(c), we are proposing a new method of calculating the amount in controversy that reflects the differences between these new appeals and typical claims appeals under existing procedures. In addition, under proposed § 405.938, eligible parties (or their representatives), would be able to request review by the Medicare Appeals Council (hereinafter, Council). As with the first two levels of appeal, we are proposing that these new appeals before an ALJ (or attorney adjudicator) and the Council would generally follow existing procedures in 42 CFR 405.1000 through 1140, as appropriate, except as we have otherwise proposed in §§ 405.936 through 405.938. Eligible parties would also be able to request judicial review under the existing provisions in 42 CFR 405.1136.

In § 405.932(a)(2), we are proposing to limit the time to file a request for a retrospective appeal to 365 calendar days following the implementation date of the final rule. We have provided notice of the pending appeals process for class members since July 2022 on both Medicare.gov and CMS.gov and we will continue to update those websites with information as this rulemaking proceeds and as we begin to implement the final rule. Thus, when this rulemaking is concluded and procedures are finalized, effective, and operational, we believe we

[5] The amount in controversy requirement for CY 2024 is $180 for a hearing before an Administrative Law Judge, and $1,840 for judicial review. See https://www.govinfo.gov/content/pkg/FR-2023-09-29/pdf/2023-21500.pdf.

would have afforded eligible beneficiaries ample time to gather necessary documentation in anticipation of filing appeal requests.

2. Party Status, Authorized Representatives, and Appointed Representatives

The court order instructs HHS to establish new appeals procedures for certain beneficiaries, specifically, beneficiaries who are members of the defined class, as previously described in the overview and in proposed § 405.931(b). The court's decision noted that some class members suffered financial or other consequences as a result of the change in their status from inpatient to outpatient receiving observation services, including having to pay for the costs of post-hospital extended care services in a SNF out of pocket because they did not satisfy the statutory requirement for SNF coverage of having a 3 consecutive day qualifying inpatient stay (see section 1861(i) of the Act). In addition, other class members had to pay for their hospital services themselves because they lacked Medicare Part B coverage. The court directed HHS to afford class members a right to appeal certain denials of Part A coverage which are defined later is this section. The court ordered an appeal process be made available to those class members who did not have such a process available if their hospital stays, dating back to January 1, 2009, met the conditions of the order. Accordingly, in § 405.931(b)(1) we are proposing to define an eligible party as an individual who meets the definition of a class member in *Alexander v. Azar*. In that case, the court adopted the following class definition: a Medicare beneficiary who, on or after January 1, 2009—

- Was formally admitted as a hospital inpatient;
- While in the hospital was subsequently reclassified as an outpatient receiving observation services (as defined in § 405.931(h));
- Has received an initial determination (as defined in § 405.920) or a Medicare Outpatient Observation Notice (MOON) (as described in § 489.20(y)) indicating that the observation services are not covered under Medicare Part A; and
- Either—

++ Was not enrolled in the Supplementary Medical Insurance program (that is, Medicare Part B coverage) at the time of beneficiary's hospitalization; or

++ Stayed at the hospital for 3 or more consecutive days but was designated as an inpatient for fewer than 3 days, unless more than 30 calendar days has passed after the hospital stay without the beneficiary's having been admitted to a SNF.

An eligible party would be entitled to request an appeal under the proposed retrospective process.

In contrast, the court's decision did not include providers as class members entitled to additional appeals procedures and did not require HHS to afford new appeal rights to providers in these new appeals proceedings. Accordingly, in § 405.931(b) and (c), we are proposing to limit party status in these new appeals to beneficiaries who meet the definition of a class member as specified in the court order.

As we believe some beneficiaries who are members of the class may require assistance with their appeal requests, we are proposing to apply existing rules regarding appointed representatives and authorized representatives (see §§ 405.902 and 405.910) to these new appeals.[6] There may also be some situations in which a class member has died since their hospitalization and, as applicable, admission to a SNF. Our existing rules in § 405.906(a)(1) permit certain successors in interest to file appeals on behalf of a deceased beneficiary. Thus, in § 405.931(d)(3) we are proposing to apply those rules to deceased class members who would have been eligible to request an appeal under the proposed procedures for retrospective appeals. However, contrary to existing claims appeals procedures, in § 405.931(d)(1)(i) we are proposing to exclude providers from representing beneficiaries in these new appeals, and we are proposing to prohibit the assignment of appeal rights to providers as well. Since the decision to change a

[6] Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal. Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary involved in the appeal (for example, a beneficiary's legal guardian, surrogate decision-maker for an incapacitated beneficiary, or an SSA-appointed representative payee). The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process and does not need a further appointment.

patient's status is made by the hospital, we have concerns that the interests of a class member could conflict with the interests of a hospital or SNF, and we are concerned that a class member's challenge to their denial of Part A coverage resulting from a change in status from inpatient to outpatient receiving observation services may not be appropriately represented by the hospital that initiated that change, determined that outpatient services were appropriate for the beneficiary, and in most cases, previously received payment for outpatient services. We have similar concerns regarding representation by SNFs that already received payment for the SNF services at issue. Unlike most existing claims appeals, where the primary issue under review is the denied coverage and payment for items and/or services billed on a claim, the issue on appeal under these procedures is whether services meet the relevant criteria for coverage and payment under the inpatient hospital benefit under Part A of the program rather than under the Part B outpatient benefit where payment was, in most cases,[7] previously made to the hospital, and the consequences of that decision on coverage of SNF services. Moreover, as we are implementing procedures required under the court's order under the Secretary's rulemaking authority in sections 205(a), 1871, and 1872 of the Act, we believe the provisions of section 1869 of the Act guide, but do not explicitly govern, the appeals procedures for the new retrospective appeals ordered by the court and proposed in this proposed rule.

We are proposing to include a definition of "unrepresented beneficiary" applicable to appeals under proposed §§ 405.931 through 405.938. In the existing claims appeals process in 42 CFR part 405 Subpart I, certain procedural requirements do not apply to an unrepresented beneficiary. However, that term is not defined in existing regulations. Therefore, in § 405.931(d)(5), we propose to define an unrepresented beneficiary as a beneficiary who is an eligible party and: (1) has not appointed a representative under § 405.910; or (2) has an

[7] We acknowledge that payment by Medicare would not have been made in appeals brought by a beneficiary who was not enrolled in Part B at the time of hospitalization. In those situations, the beneficiary would have been responsible for payment for outpatient services furnished by the hospital.

authorized representative as defined in § 405.902;[8] or (3) has appointed as its representative, a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney; or (4) in the case of a deceased beneficiary, the appeal request is filed by an eligible party who meets the conditions set forth in § 405.906(a)(1).

We are also proposing to incorporate certain existing policies that would apply in the new appeals procedures for the convenience of appellants and adjudicators. For example, in § 405.931(f), we propose that the date of receipt of a notice or decision sent by the eligibility contractor, processing contractor or other appeals adjudicator is presumed to be 5 calendar days following the date on the notice unless there is evidence to the contrary. In addition, in § 405.931(g) we propose that for the purposes of determining whether a beneficiary has a qualifying inpatient stay for SNF eligibility and for eligibility as a class member, days are counted consistent with existing policy in § 409.30 (that is, 3 consecutive calendar days starting with the admission day but not counting the discharge day).

In proposed § 405.931(h), we explain that for the purposes of determining eligibility for an appeal under these procedures, a beneficiary is considered an outpatient receiving observation services when the hospital changes a beneficiary's status from inpatient to outpatient while the beneficiary is in the hospital and the beneficiary subsequently receives observation services following a valid order for such services.

3. Appeal Requests and Determinations of Eligibility by the Eligibility Contractor

In § 405.932, we are proposing to channel all retrospective appeal requests from eligible parties through a single point of contact, the eligibility contractor. We are proposing, in § 405.932(a)(2) for a retrospective appeal, that the appeal request filed by an eligible party (or

[8] Typically, an authorized representative will be a legal guardian, representative payee or someone acting under state law on behalf of a beneficiary (for example, a family member with a durable power of attorney). Often these authorized representatives are family members or other individuals who are unfamiliar with the technical requirements of the existing claim appeals process. We believe it is reasonable to treat appeals filed by authorized representatives under these proposed procedures, like other existing claim appeals filed by family members (that is, as if the appeal was filed by an unrepresented beneficiary).

their representative) must be received by the eligibility contractor within 365 calendar days from the implementation date specified when this rule is finalized.[9] Details regarding the deadline to file an appeal and where such appeals should be filed would be posted to Medicare.gov once the retrospective appeals process is operational. A single point of contact will relieve beneficiaries of the burden of determining which contractor is currently responsible for claims processed many years ago in order to file their appeal request. In addition, due to the complexity of the requirements for determining eligibility as a class member for an appeal, we believe having a single point of contact would promote consistency in such determinations and would provide a better overall experience for eligible beneficiaries pursuing their appeal rights.

We anticipate eligible parties (or their representatives) will provide relevant information to demonstrate their eligibility as a member of the class afforded appeal rights in the court order as proposed in § 405.932(a) through (c), including medical records that may serve to document certain conditions of eligibility under the court order. Medical records would also assist in determining whether the beneficiary received observation services following the reclassification from inpatient to outpatient receiving observation services. However, we understand the challenges beneficiaries and their representatives may face in obtaining and producing such information in situations where significant time may have passed since a beneficiary was hospitalized. Therefore, we are proposing in § 405.932(c)(2), that the eligibility contractor would work with MACs, eligible parties, and providers, whenever necessary, to attempt to obtain the information needed to make such determinations. In our existing claims appeals process, contractors routinely seek records from providers to assist beneficiaries filing appeals when the beneficiary is unable to provide records needed to adjudicate the appeal.

In § 405.932(b), we are proposing that eligible parties (or their representatives) provide,

[9] For example, under these proposed procedures, if the final rule specifies an implementation date of April 1, 2025, an eligible party who was hospitalized after January 1, 2009 (through the implementation date of the prospective appeals process) would have until March 31, 2026, to file a request for appeal with the eligibility contractor. Details regarding the filing location will be specified once the retrospective process is operational.

in writing, certain minimum basic information in their appeal request, so the eligibility and processing contractors may identify the prior claims filed for the hospital stay and SNF services, as applicable, that serve as the basis for the retrospective appeal. These required elements for an appeal request (which are similar to existing requirements for requesting a redetermination under § 405.944) include the beneficiary's name, Medicare number (the number on the beneficiary's Medicare card), name of the hospital and the dates of hospitalization, and the name of the skilled nursing facility and the dates of stay (as applicable). If the appeal includes SNF services not covered by Medicare, the written request must also include an attestation to the out-of-pocket payment(s) made by the beneficiary for such SNF services and must include documentation of payments made to the SNF for such services. CMS would prepare a model form that appellants may use to file requests for a retrospective appeal under these provisions. Once the appeal process is operational, this notice would be available online at Medicare.gov to download and complete and would be available to request in printed or accessible form by calling 1-800-MEDICARE.

We are also proposing in § 405.932(b)(2) that eligible parties attest to their out-of-pocket costs (other than customary cost sharing paid to a third-party payer or insurer) paid for SNF services not covered by Medicare because the statutory requisite, 3 consecutive day inpatient hospital stay, was not met. (We note that for the purposes of determining coverage of SNF services under section 1861 of the Act, inpatient hospital days are counted in accordance with longstanding, existing policy in § 409.30, that is, a patient must have a qualifying inpatient stay of at least 3 consecutive calendar days starting with the admission day but not counting the discharge day. See proposed § 405.931(g).)

In cases where a third-party payer or insurer covered all of the cost of SNF services of an eligible party, we are proposing that such services be excluded from consideration in the retrospective appeals process. (Payments for SNF services made by a family member would not be considered payment by a third-party payer but would be considered out-of-pocket payment

for the eligible party.) In light of the clarification to the court order indicating that the new appeal processes are intended to provide a remedy for class members who already endured uncompensated or undercompensated stays at skilled nursing facilities, we do not believe the court order requires the readjudication of such paid services under a Medicare appeal process if payment for that care is provided by another insurer.[10] Moreover, readjudicating these claims potentially puts Medicare trust fund dollars at risk for making duplicate payments to providers for previously compensated care, as Medicare does not have authority to compel refunds with respect to payments made by third-party payers to providers. In addition, focusing our efforts on situations involving payments for denied services made by beneficiaries (or their families) focuses resources for appeals for beneficiaries (or their families) that paid out of pocket for the cost of care.

We are proposing in § 405.932(d) that the eligibility contractor would be responsible for determining the validity of requests for appeal under these provisions, that is, whether the request is filed by an eligible party, is timely filed, and contains the required elements for a valid request specified in § 405.932(b)(1) and (2). The eligibility contractor would issue a decision to approve or deny such requests. In proposed § 405.932(d)(1)(ii), we would require the eligibility contractor to issue a written decision within 60 calendar days of receipt of a valid appeal request from the eligible party (or their representative). We propose in § 405.932(d)(2) that approved requests (meaning those meeting both eligibility and filing requirements), would be forwarded to the processing contractor (the MAC with jurisdiction over the hospital claim), and the processing contractor would perform the appeal. Under proposed § 405.932(d)(3), requests that are not eligible for an appeal or do not meet the requirements under proposed in §§ 405.931 and 405.932 would be denied. However, we are proposing that individuals receiving a notice of denial of an

[10] However, if an eligible party paid out of pocket for some or all of the SNF services, including situations where a denial by a third-party insurer resulted in the beneficiary making out of pocket payments for some or all of the SNF services, then those SNF services that resulted in out of pocket payments would be eligible for an appeal under these proposed processes.

appeal request would have an opportunity to request a review of the denial by the eligibility contractor in order to provide additional clarification, or correct any deficiencies in the filing, under the provisions proposed in § 405.932(e). Our proposed approach to handling requests that are ineligible for an appeal differs slightly from how similar appeal requests are handled under existing claims appeals procedures in § 405.952. Under existing rules, such requests are dismissed, and dismissals may be reviewed and vacated by the adjudicator who issued the dismissal or appealed to the next level adjudicator to determine if the dismissal was appropriate. However, given the complexity of the eligibility requirements, the age of the service in question and in many cases, the lack of a claim to review, in our view the most effective and efficient approach to resolving eligibility concerns is to keep these disputes with the eligibility contractor, requiring review by an individual not involved with the initial denial determination.

4. Conduct of Appeals by Processing Contractors

Currently, MACs perform the first level of administrative appeal for Medicare claims (see 42 CFR 405.940 through 405.958). We are proposing a similar process for these new appeals, utilizing existing procedures, as appropriate, with MACs performing the first level of retrospective appeals under this rule. Specifically, we are proposing that the MAC that currently has jurisdiction over Part A claims from the relevant hospital would be responsible for conducting the retrospective appeal as the processing contractor. Where we believe the procedures for the new retrospective appeals would need to differ from existing claims appeals procedures, we are proposing new processes. For example, in § 405.931(b)(1) and (c), we are proposing that party status for these appeals be limited to the eligible class members (or their authorized representatives).

In § 405.932(f)(1), we are proposing that if the processing contractor determines there is necessary information missing from the appeal case file, the processing contractor would attempt to obtain the information from the provider and/or the eligible party (or their representative), as applicable. We are proposing that the processing contractor afford entities up to 60 calendar

days to submit requested information. If the requested information is not submitted in the specified timeframe, we propose that the processing contractor would make a decision based on the information available.

In proposed § 405.932(f)(3), we are requiring processing contractors to issue a written decision within 60 calendar days of receipt of a valid appeal request from the eligibility contractor. However, in cases where the processing contractor needs additional information to conduct the appeal from the eligible party (or their representative) or a provider, in § 405.932(f)(1), we are proposing that the time between the request for such information and when it is received (up to 60 calendar days) would not count towards the 60-day adjudication timeframe. If the requested information is not sent to the processing contractor, then we are proposing that the time afforded by the contractor for submission of the information would not count towards the adjudication timeframe. In effect, the 60-day timeline on which the processing contractor must make its decision will be tolled during the period between the date the processing contractor requests information from the provider and/or the eligible party and the later of the date that information is received or the deadline by which the information is requested has passed.

Under proposed § 405.932(f) and (g), based on the information available, the processing contractors would determine whether the hospital admission, and as applicable, SNF services, satisfied the relevant criteria for Part A coverage at the time of the admission, notwithstanding subsequent reclassification by the hospital, and whether the hospital services, and as applicable, SNF services, should have been covered under Part A. If the processing contractor determines that the hospital admission and, as applicable, SNF services satisfied the relevant criteria for Part A coverage at the time services were furnished, it would render a favorable decision and would send written notice to the eligible party (or their representative). The notice would explain the rationale for, and effect of, the decision, similar to existing notices for redeterminations.

In § 405.932(g)(4), when applicable, we are proposing that processing contractors would

send notice of a favorable decision to the SNF that furnished services to the beneficiary in order to inform the SNF of the reason for the decision and the effect of the decision. In addition, under § 405.932(g)(2) and (6), processing contractors would send SNFs notice of a partially favorable decision where the beneficiary's hospital inpatient admission would have met the criteria for Part A coverage, but the SNF services subsequently received by the beneficiary do not meet the relevant criteria for Part A coverage (for example, if the services are determined not medically reasonable and necessary under §1862(a)(1)(A) of the Act). The notice of a partially favorable decision sent to a SNF informs the SNF of the reason the hospital services were determined to meet the relevant criteria for Part A coverage, and the reasons the SNF services were determined not to be covered under Part A. We are proposing that the processing contractor also explain that the notice is being sent to the SNF for informational purposes only, and that only the eligible party (or the eligible party's representative) may appeal the decision to the QIC under proposed § 405.934. An eligible party may appeal a partially favorable decision with respect to coverage of SNF services to the QIC under proposed § 405.934 in the same manner as unfavorable decisions with respect to Part A coverage of the hospital services. In addition, in § 405.932(g)(5), with respect to an appeal filed by a beneficiary not enrolled in Medicare Part B at the time of hospitalization, we are proposing that processing contractors would send notice of a favorable decision to the hospital to inform the hospital of the reason for the decision and the effect of the decision.

Providers are reminded that under sections 1814 and 1866 of the Act, §§489.20 and 489.21, and the terms of the provider agreement, providers may not collect any amounts for covered services other than applicable coinsurance and deductible. Accordingly, in the case of a favorable appeal decision that involves SNF services paid for by the beneficiary, we are proposing in § 405.932(g)(4) and (h)(2)(i) that SNFs would be required to refund any payments collected from the beneficiary for the covered SNF services (see 42 CFR part 489 Subpart D regarding the requirements for handling of incorrect collections). Similarly, in the case of a

favorable appeal decision rendered for a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization, we are proposing in § 405.932(g)(5) and (h)(2)(ii) that hospitals would be required to refund any payments collected for the outpatient hospital services.

Furthermore, we believe that the Medicare statute requires a provider of services to submit new claims in order to determine the amount of benefits due for covered services and to receive payment under Part A of the program. Under section 1814(a)(1) of the Act, and 42 CFR 424.33, and 42 CFR 424.51, payment for Part A services furnished to an individual may be made only to a provider of services eligible to receive payment under section 1866 of the Act after a request for payment (a claim) is filed with Medicare by the provider. The clarifying order issued by the court stated that the program is not required to unwind previously filed Part B outpatient hospital claims in order to make payment for covered SNF services in the case of a favorable decision (meaning for the purposes of effectuating a favorable decision, any existing Part B outpatient hospital claim will not be reopened or revised by the MAC to reflect an appeal decision that the class member's hospital admission satisfied the relevant criteria for Part A coverage at the time of the admission, and the hospital will not be required to submit a claim for inpatient services under Medicare Part A[11]). However, the clarification only applies to beneficiary class members who were enrolled in Medicare Part B at the time of hospitalization. Thus, in the case of a beneficiary class member who was not enrolled in Medicare Part B at the time of hospitalization, we are proposing in § 405.932(h)(2)(ii) that following a favorable appeal decision and making any required refund for payments received for covered services, the hospital may submit a new Part A inpatient claim to Medicare in order to determine the appropriate amount of benefits and for Medicare to make payment for inpatient hospital services under Part A. We are also proposing in § 405.932(h)(2)(ii) that the claim must be submitted by the hospital within 180 calendar days after the hospital receives its notice of a favorable appeal decision for

[11] We note that a previously paid claim is still subject to reopening under § 405.980 for other reasons unrelated to the appeal decision (for example, if payment for the claim was procured by fraud or similar fault).

the eligible party.

In addition, if a favorable appeal decision includes eligible SNF services that are covered, in § 405.932(h)(2)(i), we are proposing that following a refund of amounts collected from the beneficiary, the SNF may then submit a claim (or claims) for such services to Medicare in order to determine the appropriate amount of benefits, and for Medicare to make payment for the covered SNF services. The SNF claim, following a favorable appeal decision (that is, the hospital admission satisfied the relevant criteria for Part A coverage as an inpatient at the time of admission and the SNF services met relevant Part A coverage criteria), would be processed without regard to the hospital's erroneous reclassification of the beneficiary as an outpatient receiving observation services. We are also proposing in § 405.932(h)(2)(i) that the SNF submit the claim within 180 calendar days after receiving the notice of a favorable appeal decision for the eligible party. CMS would issue operating instructions related to the submission of new claims by a SNF and a hospital when this rulemaking is finalized and effective.

If the processing contractor determines that the hospitalization did not meet applicable Part A inpatient coverage requirements, we are proposing in § 405.932(g)(3) the MAC would send notice of its unfavorable decision to the eligible party (or their representative). If the processing contractor determines that the hospital admission meets applicable Part A inpatient coverage requirements, but the SNF services eligible for the appeal do not meet applicable coverage requirements, we are also proposing in § 405.932(g)(2) that the processing contractor would send notice of its partially favorable decision to the eligible party (or their representative). The notice of an unfavorable or partially favorable decision would inform the eligible party (or their representative) of the right to request a reconsideration with a QIC under proposed § 405.934 and would provide detailed information about the requirements for filing the request and where the request must be filed.

5. Conduct of Reconsiderations by Qualified Independent Contractors

In § 405.934(a), we are proposing that the second level of retrospective appeals be performed by QICs. As with the first level of appeal, we are proposing that the second level of retrospective appeal generally follow existing procedures for reconsiderations outlined in §§ 405.960 through 405.978, as appropriate, except as specified in the provisions proposed in this rule. Under proposed § 405.934(a), eligible parties (or their representative) who are dissatisfied with a MAC's unfavorable decision in proposed § 405.932(g)(2) may file a request for reconsideration with the QIC within 180 calendar days of receipt of the MAC's notice. The MAC's decision would specify the elements required for the request for reconsideration, and we propose that those elements would be the same as the existing requirements for a reconsideration set forth in § 405.964. Requests for reconsideration under § 405.934 that are untimely or incomplete would be handled consistent with existing procedures for dismissals in § 405.972.

Consistent with the conduct of reconsiderations under existing procedures in § 405.968, the QICs shall review all evidence furnished during the first level of appeal and any additional evidence submitted with the request for reconsideration. Under proposed § 405.934(c), the QIC determines if the inpatient admission, and as applicable, SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the QIC issues notice of its decision to the eligible party (or their representative).

We are proposing in § 405.934(c)(3) that the QIC mail or otherwise transmit notice of its decision within 60 calendar days of receipt of the request for reconsideration. We are also proposing to apply existing procedures in § 405.970 regarding the calculation of decision-making timeframes, and the provisions regarding the escalation of cases for a QIC's failure to meet such timeframes, as appropriate, to these new appeals. In proposed § 405.934(c)(4), the notice of a favorable decision sent by the QIC to the eligible party (or their representative) would include an explanation of the decision and information regarding the effect of the decision, as well as other information similar to that found in existing reconsideration notices under § 405.974.

In § 405.934(c)(5), when applicable, we are proposing that QICs would send notice of a favorable reconsideration to the SNF that furnished services to the beneficiary in order to inform the SNF of the reason for its decision and the effect of the decision. In addition, in § 405.934(c)(6), with respect to an appeal filed by a beneficiary not enrolled in Medicare Part B at the time of hospitalization, we are proposing that the QIC would send notice of a favorable decision to the hospital to inform the hospital of the reason for its decision and the effect of the decision. In addition, we are proposing that the QIC would send the SNF notice of a partially favorable decision where the inpatient admission meets the criteria for Part A coverage, but the SNF services do not meet the relevant criteria for Part A coverage (for example, if the services are determined not medically reasonable and necessary under section 1862(a)(1)(A) of the Act). The notice of a partially favorable decision sent to a SNF would inform the SNF of the reason the hospital services were determined to meet the relevant criteria for Part A coverage, and the reason the SNF services were determined not to be covered under Part A. We are proposing that the QIC also explain that the notice is being sent to the SNF for informational purposes only, and that only the eligible party may appeal the decision to an ALJ under § 405.936. An eligible party would have the right to appeal such a partially favorable decision with respect to the coverage of SNF services under proposed § 405.936 in the same manner as unfavorable decisions with respect to Part A coverage of the hospital services.

Consistent with the processes following a favorable first level of appeal decision, as previously described, in the case of a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization, we are proposing in § 405.934(d)(2)(ii) that following a favorable appeal decision and making any required refund for payments received for covered services, the hospital may submit a new Part A inpatient claim to Medicare in order to determine the appropriate amount of benefits, and for Medicare to make payment for inpatient hospital services. We are also proposing in § 405.934(d)(2)(ii) that the claim must be submitted by the hospital within 180

calendar days after the hospital receives its notice of favorable reconsideration for the eligible party.

In addition, if a favorable appeal decision includes eligible SNF services that are covered, in § 405.934(d)(2)(i), we are proposing that following a refund of amounts collected from the beneficiary, the SNF may then submit a claim (or claims) for such services in order to determine the appropriate amount of benefits, and that Medicare would make payment for the covered SNF services. We are also proposing in § 405.934(d)(2)(ii) that the SNF submit the claim within 180 calendar days after receiving the notice of a favorable appeal decision for the eligible party.

If the QIC determines that the hospitalization did not meet applicable Part A inpatient coverage requirements, we are proposing in § 405.934(c)(2) that the QIC would send notice of its unfavorable decision to the eligible party (or their representative). If the QIC determines that the hospital admission meets applicable Part A inpatient coverage requirements, but the SNF services eligible for the appeal do not meet applicable coverage requirements, we are also proposing in § 405.934(c)(2) that the QIC would send notice of its partially favorable decision to the eligible party (or their representative). The notice of an unfavorable or partially favorable decision would inform the eligible party (or their representative) of the right to request a hearing before an ALJ (or review by an attorney adjudicator) under proposed § 405.936 and would provide detailed information about the requirements for filing the request and where the request must be filed.

6. Conduct of Hearings Before Administrative Law Judges and Decisions by Administrative Law Judges or Attorney Adjudicators

Currently, the third level of claims appeals are performed by ALJs and attorney adjudicators within the HHS Office of Medicare Hearings and Appeals (OMHA). As with the first two levels of appeal, we are proposing in § 405.936(b) that the third level of retrospective appeal generally follow existing procedures for claims appeals in §§ 405.1000 through 405.1063, as appropriate, except as specified in the provisions proposed in this rule. Under proposed

§ 405.936(a), eligible parties (or their representative) who are dissatisfied with either a QIC's dismissal of a request for reconsideration, or an unfavorable reconsideration in proposed § 405.934(c)(2), may file a request in writing with the OMHA within 60 calendar days of receipt of the QIC's notice. The reconsideration notice would specify the elements required for the request for hearing, and we propose that these elements would mirror existing requirements for appeal requests in § 405.1014(a)(1). We are also proposing that untimely or incomplete requests would be handled under existing procedures for dismissals in § 405.1014(e) and § 405.1052.

As we previously noted, in some respects, the nature of the appeals required by the court order dictate a new implementation approach that cannot utilize existing procedures. For example, ordinarily under current claims appeals procedures, adjudicators review claims that contain denied items or services to determine whether items and/or services billed on a Medicare claim are covered and whether payment may be made. In addition, under § 405.1006, billed charges on claims submitted to Medicare serve as the basis for determining the amount in controversy required for an appeal at the third level of appeal and for judicial review in federal district court. However, under this proposed process, with respect to the relevant hospital stay, there is no inpatient hospital claim and no denial of billed services.

For retrospective appeals, we are proposing to incorporate the existing amount in controversy requirement required for a hearing before an ALJ or judicial review in federal court consistent with section 1869(b)(1)(E) of the Act and § 405.1006.[12] However, with respect to the methodology for calculating the amount in controversy, we cannot utilize the existing method for claims appeals in § 405.1006(d)(1) to calculate such amount. The procedures in existing regulations require the use of actual charges from the disputed claim(s) billed to Medicare, and in the scenario giving rise to appeal rights in the court order, no Part A inpatient claim will have

[12] For calendar year 2024, the minimum amount in controversy for a hearing at the OMHA level is $180, and for judicial review the minimum amount in controversy is $1,840. These amounts are calculated annually in accordance with section1869(b)(1)(E) of the Act, and notice of the minimum amounts for the following calendar year is published in the Federal Register and is available on https://www.cms.gov/medicare/appeals-grievances/fee-for-service/third-level-appeal.

been filed. Without a Part A inpatient claim, there are no billed charges for the denied Part A coverage to serve as the basis for calculating the amount in controversy. Other methods in § 405.1006(d) for calculating the amount in controversy are designed for appeals that are factually different than these new appeals, and thus, we do not believe it would be appropriate to adopt other existing calculation methods to apply them here.

In the case of a beneficiary who was enrolled in Medicare Part B at the time of hospitalization, we believe it would be appropriate to utilize the billed charges on a claim filed by the hospital for Part B outpatient hospital services as the basis for calculating the amount in controversy for these new appeals. Since we do not have a Part A inpatient claim for the hospital services furnished to the beneficiary, we do not have available to us the costs of the denied Part A services that are at issue in the appeal to serve as the basis for the amount in controversy. While the billed charges for outpatient services will differ from those that would have been billed on an inpatient claim, we believe it is reasonable to use the billed charges on the approved outpatient claim for the purposes of determining the amount in controversy, and in § 405.936(c)(2) we propose including those charges in calculating the amount in controversy for a hearing before an ALJ and for judicial review in federal district court. We emphasize that, as explained in section III.A.4 of this proposed rule, for beneficiaries enrolled in Part B at the time of hospitalization, we will not make an adjustment of payment related to the previously submitted Part B outpatient hospital claim (including any deductible and coinsurance amounts) when effectuating a favorable appeal decision. Nevertheless, we are proposing that the billed charges for the outpatient hospital services would be included in determining whether the amount in controversy requirement is met because we do not have available to us the costs of the denied Part A hospital services at issue in the appeal and because we believe that for purposes of determining the amount in controversy it is appropriate to attribute a dollar amount to the hospital services at issue, even if ultimately we would not adjust the payment for the hospital services.

For any billed SNF services that are included in the appeal, the billed charges on a claim submitted by the SNF would be utilized in calculating the amount in controversy. However, in cases where a claim was not submitted by the SNF because the services were not covered, the amount the beneficiary was charged for SNF services, as reflected in an itemized statement received by the beneficiary or evidence of payments made by the beneficiary to the SNF, would be used in determining the amount in controversy.

Thus, we are proposing in § 405.936(c)(2) that the billed charges on the Part B outpatient claim and the billed charges for any SNF claim at issue in the appeal, or the billed charges paid by the beneficiary in the absence of a claim, would serve as the amount in controversy for hearings before an ALJ and for judicial review in federal district court. Furthermore, as the cost sharing for a Part A inpatient claim will be different than the cost sharing for the Part B outpatient claim, we are not reducing the amount in controversy by any applicable cost sharing, or other payments made for the Part B outpatient hospital claim as we do for existing calculation methods. Nor are we factoring in any cost sharing or payments made related to the SNF claim, as applicable, to reduce the amount in controversy.

For beneficiaries who are eligible parties because they were not enrolled in Medicare Part B at the time of their hospitalization, in most situations, we do not believe hospitals would have submitted a claim to the program for Part B outpatient services. Therefore, for beneficiaries who were not enrolled in Part B at the time of hospitalization and did not have a claim submitted to Medicare on their behalf for hospital outpatient services, we are proposing in § 405.936(c)(3) to calculate the amount in controversy by using the hospital's billed charges to the beneficiary for such outpatient services. We believe the hospital's charges to the beneficiary, as reflected in an itemized statement received by the beneficiary, or evidence of payments made to the hospital, are a reasonable estimation of the financial impact of the denial of Part A coverage to the beneficiary and the amount at issue in the appeal. In addition, the billed charges for SNF services, if any,

paid by the beneficiary would also be used in computing the amount in controversy for appeals involving beneficiaries not enrolled in Medicare Part B at the time of hospitalization.

Consistent with the conduct of appeals before ALJs and attorney adjudicators under existing procedures in §§ 405.1028 through 405.1030, we are proposing that ALJs and attorney adjudicators review all evidence furnished during the first two levels of appeal and any additional evidence submitted by the beneficiary with the request for hearing or request for review of a dismissal. Under proposed § 405.936(d), the ALJ or attorney adjudicator determines if the inpatient admission, and as applicable, SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, and then issues notice of the decision to the eligible party (or their representative). In proposed § 405.936(d)(2), we explain that the notice of an unfavorable decision or partially favorable decision (that is, a decision where Part A coverage is approved for the hospital admission, but Part A coverage is not approved for applicable SNF services that are at issue in the appeal) would be sent to the eligible party (or their representative). In proposed § 405.936(d)(3), the notice of a favorable decision sent to the eligible party (or their representative) would include an explanation of the decision and information regarding the effect of the decision, as well as other information similar to that found in existing notices under § 405.1046.

In § 405.936(d)(4), when applicable, we are proposing that the ALJ or attorney adjudicator would send notice of a favorable reconsideration to the SNF that furnished services to the beneficiary in order to inform the SNF of the reason for the decision and the effect of the decision. In addition, in § 405.936(d)(5), with respect to an appeal filed by a beneficiary not enrolled in Medicare Part B at the time of hospitalization, we are proposing that the ALJ or attorney adjudicator would send notice of a favorable decision to the hospital to inform the hospital of the reason for the decision and the effect of the decision. In the case of a partially favorable decision, we are proposing in § 405.936(d)(2) that notice would be sent to the SNF as an informational copy, and in proposed § 405.936(d)(6) we specify the elements included in the

notice sent to the SNF. The notice of a partially favorable decision sent to a SNF would inform the SNF of the reason the hospital services were determined meet the relevant criteria for Part A coverage, and the reason the SNF services were determined not to be covered under Part A. We are proposing that the ALJ or attorney adjudicator also explain that the notice is being sent to the SNF for informational purposes only, and that only the eligible party may appeal the decision to the Council under § 405.938.

In § 405.936(d)(7), we are proposing to utilize the existing procedures in § 405.1016 regarding the calculation of timeframes within which ALJs and attorney adjudicators must issue decisions, including applicable waivers and extensions to the adjudication timeframe, and the option for an eligible party (or their representative) to escalate an appeal for failure to issue a decision in the applicable timeframe.

Consistent with the processes at the first two levels of appeal, as previously described, in the case of a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization, we are proposing in § 405.936(e)(2)(ii) that following a favorable appeal decision and making any required refund for payments received for covered services, the hospital may submit a new Part A inpatient claim to Medicare in order to determine the appropriate amount of benefits, and for Medicare to make payment for inpatient hospital services. We are also proposing in § 405.936(e)(2)(ii) that the claim must be submitted by the hospital within 180 calendar days after the hospital receives its notice of favorable decision for the eligible party.

In addition, if a favorable appeal decision includes eligible SNF services that are covered, in § 405.936(e)(2)(i), we are proposing that following a refund of amounts collected from the beneficiary, the SNF may then submit a claim (or claims) for such services in order to determine the appropriate amount of benefits, and for Medicare to make payment for the covered SNF services. We are also proposing in § 405.936(e)(2)(i) that the SNF submit the claim within 180 calendar days after receiving the notice of a favorable appeal decision for the eligible party.

If the ALJ or attorney adjudicator determines that the hospital admission did not meet applicable Part A inpatient coverage requirements, we are proposing in § 405.936(d)(2) and (d)(3)(vii) the ALJ or attorney adjudicator would send notice of the unfavorable decision to the eligible party (or their representative). If the ALJ or attorney adjudicator determines that the hospital admission meets applicable Part A inpatient coverage requirements, but the SNF services eligible for the appeal do not meet applicable coverage requirements, we are also proposing in § 405.936(d)(2) that the ALJ or attorney adjudicator would send notice of its partially favorable decision to the eligible party (or their representative). The notice of an unfavorable or partially favorable decision would inform the eligible party (or their representative) of the right to request review by the Council under proposed § 405.938 and would provide detailed information about the requirements for filing the request and where the request must be filed.

In proposed § 405.936(e) and (f), we explain the effect of an ALJ or attorney adjudicator decision as binding on the eligible party unless it is further appealed or reopened. The reopening of an ALJ or attorney adjudicator decision would be processed under existing procedures in § 405.980(d) and (e). The effect of an ALJ or attorney adjudicator decision is consistent with the effect of decisions at other levels in the appeals process, as previously described. We are proposing that an eligible party (or their representative) who is dissatisfied with an unfavorable decision by an ALJ or attorney adjudicator may request review by the Council under proposed § 405.938(a), and the ALJ or attorney adjudicator decision notice would provide detailed information about the process for filing such a request.

7. Conduct of Review by the Medicare Appeals Council

Under § 405.938, we are proposing that retrospective reviews at the fourth level of appeal would be conducted by the Council and would generally follow existing procedures for claims appeals in §§ 405.1100 through 405.1130, except as specified in the provisions proposed in this rule. Under proposed § 405.938(a), eligible parties (or their representative) who are dissatisfied

with either a dismissal of a request for hearing by an ALJ or attorney adjudicator, or an unfavorable ALJ or attorney adjudicator decision in proposed § 405.936(d)(2) may file a request in writing with the Council within 60 calendar days of receipt of the notice from the ALJ or attorney adjudicator. The request must include the elements specified in the notice issued by the ALJ or attorney adjudicator, and we propose to use the existing requirements for requests for Council review in § 405.1112. We are proposing that untimely or incomplete requests would be handled under existing procedures in §§ 405.1100 through 405.1116.

We are proposing that the Council would review appeal requests and requests for review of dismissal actions under existing procedures in §§ 405.1100 through 405.1132, as applicable. Under proposed § 405.938(c)(1), the Council makes a decision or remands the case to an ALJ or attorney adjudicator. We are proposing in § 405.938(c)(2) that the Council may adopt, modify, or reverse the decision of an ALJ or attorney adjudicator, consistent with existing Council procedures. In § 405.938(c)(3), we are proposing the Council would send notice of its decision, or its remand to an ALJ or attorney adjudicator, to the eligible party (or their representative), and we propose that a decision would contain information regarding the effect of a favorable decision. In the case of an unfavorable or partially favorable decision, we are proposing that the Council include information about filing a request for judicial review under existing procedures in § 405.1136. We also explain in proposed § 405.938(c)(3) that a partially favorable decision issued by the Council refers to a determination that the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage. Notice of a partially favorable decision is sent to the eligible party (or their representative), and to the SNF that furnished services under appeal, but for informational purposes only.

In addition, we are proposing in § 405.938(c)(4), when applicable, the Council would send notice of a decision favorable to an eligible party to the hospital and the SNF that furnished services. The notice would explain the effect of the decision as specified in proposed

§ 405.938(d), including the provider's obligation to refund payments collected for services determined to be covered following the appeal. The notice would also explain, as applicable, the process for a SNF or a hospital to submit a claim for the covered services to determine the amount of benefits due following the refund of payments previously collected.

In § 405.938(c)(5), we are proposing to utilize the existing procedures in § 405.1100 regarding the calculation of timeframes within which the Council must issue decisions, including applicable waivers and extensions to the adjudication timeframe[13], and the option for an eligible party (or their representative) to escalate an appeal for failure to issue a decision in the applicable timeframe.

In proposed § 405.938(e) and (f), we explain that a Council decision is considered final and binding on the eligible party unless it is reopened and revised, or in the case of an unfavorable decision, a Federal district court issues a decision modifying the Council decision. The reopening of a Council decision would be processed under existing procedures in § 405.980(d) and (e). The effect of a favorable Council decision is consistent with the effect of decisions at other levels in the appeals process, as previously described. We are proposing in § 405.938(e)(1) that an eligible party (or their representative) who meets the requirements to escalate a case under § 405.1132 or is dissatisfied with an unfavorable decision by the Council, may request judicial review consistent with existing procedures in §§ 405.1132 through 405.1136. Based on its existing procedures, the Council's decision notice would provide detailed information about the process for filing such a request.

8. Judicial Review

[13] For example, under § 405.1106(a), if a party submits a timely filed request for Council review with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. In other words, if an ALJ decision specifies that a party must submit a request for Council review with the Council, and the party mistakenly files their request with, for example, OMHA, then the Council's adjudication time period does not begin until the Council receives the request for review from OMHA.

We are proposing in § 405.938(f)(1) that eligible parties dissatisfied with a final decision of the Council whose claims meet the amount in controversy requirement in proposed § 405.936(c) may request judicial review in Federal district court under the existing procedures in § 405.1136. In addition, under proposed § 405.938(f)(2), an eligible party (or their representative) who satisfies the amount in controversy requirement in proposed § 405.936(c) and is entitled to escalate a case from the Council to Federal district court upon satisfying the criteria set forth in § 405.1132, may request judicial review under the existing procedures in § 405.1136.

B. *Prospective Appeal Rights*

1. Overview

This proposed rule would also establish and implement a new notice requirement and an expedited appeals process, on a prospective basis, for certain beneficiaries whose status was changed from inpatient to outpatient receiving observation services while they were still in the hospital. The proposed expedited appeals process parallels the process in effect for inpatient hospital discharge appeals set forth at 42 CFR 405.1205 through 1206, with some differences. In its order dated March 26, 2020, the court indicated that HHS should use a process for the expedited appeals that is "substantially similar" to the existing process for expedited hospital discharge appeals at §§ 405.1205 through 405.1208; under that hospital discharge appeals process, beneficiaries receive a notice of their rights and may request an expedited determination by a Quality Improvement Organization (QIO) about the hospital's decision to discharge the beneficiary. While the processes are largely similar, a notable difference is that the issue under appeal in this proposed process relates to the change of status from an inpatient to an outpatient receiving observation services. This change of status may affect cost sharing for the hospital stay as well as whether any post hospital care in a skilled nursing facility would be covered by Medicare.

CMS contracts with QIOs, pursuant to Title XI, Part B of the Act and section 1862(g) of

the Act, to perform certain statutorily required functions and contractual quality improvement and other activities for the purposes of improving the quality of care furnished to Medicare beneficiaries with respect to Medicare covered items and services. The QIO Program is part of the HHS' national quality strategy for providing quality and patient centered care to Medicare beneficiaries. Section 1154(a)(1) of the Act establishes certain review functions of QIOs, including that QIOs review the services furnished to Medicare beneficiaries by physicians, other healthcare practitioners, and institutional and non-institutional providers of services (as defined in section 1861(u) of the Act and including hospitals). In addition, under section 1154(a)(18) of the Act, QIOs must also provide, subject to the terms of their contract with CMS, such other activities as the Secretary determines may be necessary for the purposes of improving the quality of care furnished to individuals with respect to items and services for which payment may be made under Medicare. This flexibility allows CMS to establish and further define the types of reviews performed by the QIOs in order to meet evolving needs and issues pertaining to healthcare delivered under the Medicare program.

As discussed in sections II. and III.A. of this rule, a recent court decision requires the Secretary to implement an appeal process for certain Medicare beneficiaries that is substantially similar to the existing hospital discharge appeals conducted by QIOs under §§ 405.1205 through 405.1208. See *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020)), *aff'd sub nom.*, *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022). These new review and appeals activities are within the scope of the Secretary's authority under section 1154(a)(18) of the Act to contract with QIOs to perform additional activities that are not already specified in section 1154 of the Act or other provisions. Section 1155 of the Act governs appeals of QIO determinations that are made under Title XI, subpart B, which includes section 1154 of the Act. Therefore, the proposed new QIO determinations, performed under section 1154(a)(18) of the Act, are subject to the appeal process specified in section 1155 of the Act.[14] Based on the QIOs' expertise and

[14] Under section 1155 of the Act, a beneficiary who is entitled to benefits under title XVIII (that is, a Medicare

longstanding performance of similar functions, CMS has determined that the QIOs are the most appropriate entity to perform beneficiary-initiated appeals of hospital reclassifications of inpatients to outpatients receiving observation services proposed in §§ 405.1211 through 405.1212.

This proposed expedited appeals process would be available to beneficiaries[15] who, after formally being admitted as an inpatient, have subsequently been reclassified by the hospital as an outpatient while the beneficiary is still in the hospital, receive observation services following the reclassification, and met one of the following two criteria:

- Their stay in the hospital was at least 3 days.
- Did not have Medicare Part B coverage (these eligible beneficiaries would not need to remain in the hospital for at least 3 days to be eligible for an appeal).

We are proposing in new § 405.1210(a)(3) the criteria that must be met for a beneficiary to be eligible for the new prospective appeal rights. We are proposing to require hospitals to deliver, as soon as possible after certain conditions are met and prior to release from the hospital, a new standardized beneficiary notice, informing eligible beneficiaries of the change in their status, the resulting effect on Medicare coverage of their stay, and their appeal rights if they wish to challenge that change. This new notice will be called the Medicare Change of Status Notice (MCSN). This new notice follows the format and structure of the Important Message from Medicare (IM), which is the notice hospitals are required, by § 405.1205, to provide to beneficiaries to inform them of their right to appeal an inpatient hospital discharge. See section IV.D. of this proposed rule for details on how to obtain a copy of the proposed MCSN form.

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beneficiary) and who is dissatisfied with a determination made by a QIO in conducting its review responsibilities shall be entitled to a reconsideration of such determination by the reviewing organization (that is, the QIO). For the purposes of these proposed appeals, section 1155 of the Act authorizes the QIO to conduct a reconsideration of its expedited determination regarding the hospital reclassification under proposed § 405.1211 to determine if an eligible beneficiary is entitled to coverage under Part A of the program.

[15] Since the court order specifically requires the provision of appeal rights to a defined set of class members, and that definition does not include the provider of services (that is, hospitals and SNFs), we are limiting party status for these new appeals to the defined class members. We note that this limitation currently exists for hospital discharge appeals procedures in §§405.1205 and 405.1206, where a provider of services does not have party status.

We considered alternatives to creating a new notice for this process. One consideration was standardizing and adding appeals information to the required written Condition Code 44 notification used by hospitals to inform beneficiaries when their status is changed from inpatient to outpatient after review by a hospital utilization review committee and the entire episode will be billed as outpatient. However, those eligible for this new process would be a small subset of the population receiving the existing Condition Code 44 notification. Specifically, individuals would not only require a change of status from inpatient to outpatient, they must also meet the criteria set forth in proposed § 405.1210 (a)(2) and (3) to pursue an appeal regarding a change in status. The vast majority of beneficiaries receiving the existing notification of inpatient to outpatient change will not be eligible for this new appeals process and would likely find the inclusion of information about an appeals process for which they are not eligible confusing. We also considered adding appeals information to the Medicare Outpatient Observation Notice (MOON). The MOON (42 CFR 489.20(y)) is used to inform beneficiaries who receive observation services for a certain amount of time that they are not hospital inpatients, but rather outpatients receiving observation services. However, like the change in status notice mentioned earlier, the MOON would be overbroad and the vast majority of beneficiaries receiving it would not be eligible for an appeal in this new process. Further, per section 1866(a)(1)(Y) of the Act, the MOON is only required for beneficiaries who have been outpatients receiving observation services for more than 24 hours, yet we are proposing that, for prospective appeals, beneficiaries reclassified from inpatients to outpatients receiving observation services be eligible for an appeal if any amount of time is spent in observation following the status change (in this respect, we are expanding the population of beneficiaries eligible for an appeal beyond the class as defined by the court, and not limiting eligibility to those beneficiaries who have received a MOON). Because the MOON is not required for observation stays shorter than 24 hours, using the MOON would likely result in not all eligible beneficiaries receiving notification of their appeal rights under the proposed new process. We concluded that a targeted appeals notice, delivered only to

those beneficiaries eligible for this specific appeal, would be the most effective and efficient means of informing eligible beneficiaries of their appeal rights.

The proposed MCSN contains a similar layout and language to the IM and includes information on the change in coverage, a description of appeal rights and how to appeal, and the implications for skilled nursing facility coverage following the hospital stay. We believe that by proposing the delivery of this largely generic notice, the notice delivery burden on hospitals would be as minimal as possible, without any adverse effect on patient rights. Much of the verbiage in the MCSN has been used in similar, consumer-tested CMS beneficiary notices which were subject to multiple comment periods during the PRA renewal process as language included in the IM and another similar Medicare appeals notice, the Notice of Medicare Non-Coverage.

We have reviewed the notice delivery procedures for the IM notice related to inpatient hospital discharges and have mirrored that process in this new process, wherever possible. In proposing this approach, our goal is to design notice procedures that balance a beneficiary's need to be informed about his or her appeal rights in an appropriate and timely manner, without imposing unnecessary burdens on hospitals.

We are proposing to require hospitals to deliver the notice to eligible beneficiaries as soon as possible after a beneficiary is eligible for this process per § 405.1210(a)(2) and (3), but no later than 4 hours prior to discharge. For beneficiaries with Part B, we propose that the notice must be delivered as soon as possible after the hospital reclassifies the beneficiary from inpatient to outpatient receiving observation services and the third day in the hospital is reached. Beneficiaries will likely not reach this required third day in the hospital until very close to release from the hospital. This is because these will be beneficiaries that hospitals have determined do not need an inpatient level of care and thus, the overall length of the hospital stay is not expected to exceed a few days. For beneficiaries without Medicare Part B coverage, we are proposing that hospitals must deliver the notice as soon as possible after the change in status from inpatient to outpatient receiving observation services because a 3-day hospital stay is not

required for these beneficiaries to be part of the class specified in the court order.

We believe the approach we are proposing would not be overly burdensome for hospitals as the proposed notice is standardized and requires very little customization by the hospital before delivery. The proposed notice is modeled after the existing hospital discharge appeals notice (Important Message from Medicare-IM), and like that notice, does not require extensive time for hospitals to prepare and deliver to beneficiaries. We believe that the number of beneficiaries that are eligible for this proposed appeal process would be significantly lower than the volume that receive the hospital discharge appeals notification. (Please see section IV.B. for more information on assumptions and estimates related to this proposed appeals process.) Additionally, the delivery of the MCSN notice to the beneficiary would mimic the process already in place for hospitals delivering the IM, so implementing this process should not be overly difficult or burdensome.

One notable difference, as compared to that for inpatient hospital discharge appeals, is that beneficiaries would not have financial liability protection during this new appeals process. Section 1869(c)(3)(C)(iii)(III) of the Act, which provides beneficiaries with coverage during the inpatient hospital discharge appeal, only applies to beneficiaries being discharged from a Medicare covered inpatient hospital stay, and thus would not be applicable to beneficiaries pursuing an appeal regarding the change in status from inpatient to outpatient receiving observation services.

We are proposing that the Quality Improvement Organizations (QIOs) perform these reviews. The nature of these reviews is consistent with the mission and functions of the QIO Program. QIOs have contracts with CMS under section 1862(g) of the Act and Part B of Title XI of the Act to perform certain statutorily required reviews of the services furnished to Medicare beneficiaries and to implement quality improvement initiatives involving Medicare beneficiaries, providers, and their communities. (See 42 CFR parts 475 through 480.) Historically, QIOs have performed expedited discharge reviews for beneficiaries appealing

inpatient discharges (42 CFR 405.1205 through 405.1208, 422.620 and 422.622) as well as similar expedited reviews for termination of provider services in non-hospital settings (42 CFR 405.1202 through 405.1204, 422.624, and 422.626). Currently, these reviews, as well as other case reviews related to the quality of care received by Medicare beneficiaries, compliance with certain conditions of coverage for inpatient services, and reviews of the validity of certain diagnostic and procedural information supplied by hospitals among other types of care reviews, are performed by the Beneficiary and Family Centered Care QIOs (BFCC-QIOs), while quality improvement initiatives are performed by a different type of QIO. If our proposal is finalized, we intend to require the BFCC-QIOs to perform this new type of appeal because their scope of knowledge, expertise and experience with beneficiary appeals and Medicare coverage ensures an adequate and reliable review.

Finally, the court order only requires that an *expedited* appeals process be made available to class members "who have stayed, or will have stayed, at the hospital for 3 or more consecutive days." For class members who lacked Part B and did not stay in the hospital for 3 or more consecutive days, it would appear that a non-expedited appeals process might be sufficient. Nonetheless, we are proposing to use the expedited process for all prospective appeals, with minor differences depending on whether the expedited appeal request is made timely. In other words, an eligible beneficiary may request the QIO review at or around the time of receiving the notice in a hospital, or after a claim is filed, and in both instances, beneficiaries will be afforded a review and determination by the QIO. An appeal filed outside of the expedited timeframes may also be referred to herein as a standard appeal.

2. Notifying Eligible Beneficiaries of Appeal Rights when a Beneficiary is Reclassified from an Inpatient to an Outpatient Receiving Observation Services (§ 405.1210)

To implement the changes we are proposing, we would revise Subpart J of 42 CFR 405 to add new §§ 405.1210 through 405.1212. These new proposed regulations are largely modeled after the existing regulations at §§ 405.1205 through 405.1206 controlling notices to

beneficiaries and the QIO review of hospital discharges.

Proposed new § 405.1210(a) sets forth the applicability and scope of this new appeals process along with definitions of specific terms used in the proposed new regulations. Specifically, in § 405.1210(a)(1) we propose to define a hospital as, for purposes of the new notice requirements and appeals process, any facility providing care at the inpatient hospital level, to include short term or long term, acute or non-acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services and including critical access hospitals (CAHs). This broad definition tracks § 405.1205(a).

Paragraphs (a)(2) and (a)(3) of proposed § 405.1210 address the circumstance and eligibility of beneficiaries for appeals in this new process. A change in status occurs when a hospital reclassifies a beneficiary from an inpatient to an outpatient receiving observation services. The phrase "outpatient receiving observation services" used in §§ 405.1210 through 405.1212 is used as defined in proposed § 405.931(h) to mean when the hospital changes beneficiary's status from inpatient to outpatient while the beneficiary is in the hospital and the beneficiary subsequently receives observation services following a valid order for such services. An eligible beneficiary, consistent with the court order, would be one who: (1) was formally admitted as a hospital inpatient; (2) while in the hospital was subsequently reclassified as an outpatient receiving observation services; and (3) either (A) was not enrolled in Part B coverage at the time of the beneficiary's hospitalization, or (B) stayed at the hospital for 3 or more consecutive days but was classified as an inpatient for fewer than 3 days. We are also proposing to be explicit in new § 405.1210(a)(iv)) that the period "3 or more consecutive days" is counted using the existing rules for determining coverage of SNF services under section 1861 of the Act and § 409.30 of this chapter. This means that the admission day is counted as a day, but the discharge day is not. For example, if a beneficiary is admitted to a Medicare covered inpatient hospital stay on a Monday and discharges on the following Wednesday, Monday and Tuesday

are counted towards the "3 or more consecutive days", but Wednesday is not.

The provisions of proposed § 405.1210(b) are designed to track closely with the provisions of § 405.1205 that require delivery of a notice to beneficiary about inpatient hospital discharges. We are proposing in § 405.1210(b)(1) that hospitals would be required to deliver a standardized, largely generic, notice informing eligible beneficiaries about the availability of the new appeals process.

We are proposing to require hospitals to deliver the notice to eligible beneficiaries as soon as possible after a beneficiary is eligible for this process per § 405.1210(a)(2) and (3) and no later than 4 hours prior to discharge. For beneficiaries with Part B, we propose that the notice must be delivered as soon as possible after the hospital reclassifies the beneficiary from inpatient to outpatient receiving observation services and the third day in the hospital is reached. For beneficiaries without Medicare Part B coverage, we propose that hospitals must deliver the notice as soon as possible after the change in status from inpatient to outpatient receiving observation services because a 3-day hospital stay is not required for these beneficiaries to be eligible for an appeal.

Per proposed § 405.1210(b)(2), the new notice would include (1) the beneficiary's right to request an expedited determination regarding the decision to change the beneficiary's status from an inpatient to an outpatient receiving observation services, including a description of the process as specified in § 405.1211, and the availability of possible appeals procedures if the beneficiary's request is untimely; (2) an explanation of the implications of the decision to change the status of the eligible beneficiary from an inpatient to an outpatient receiving observation services, the potential change in beneficiary hospital charges resulting from a favorable decision, and subsequent eligibility for Medicare coverage for SNF services; and (3) any other information required by CMS. As to category (2) (see § 405.1210(b)(2)(ii) of this proposed rule) regarding the implications of the decision, this notice would describe for eligible beneficiaries the possible changes in the charges for their hospital stay as well as the potential for non-coverage if they

enter a skilled nursing facility after the hospital stay.

Proposed new § 405.1210(b)(3) and (4) provide that notice delivery would be valid when the notice is delivered as required in § 405.1210(a)(3) and the beneficiary signs and dates the notice to indicate receipt and that the beneficiary understands the notice. Further, if a beneficiary refuses to sign the notice to acknowledge receipt, the hospital may annotate its copy of the beneficiary's notice to indicate the refusal. The date of refusal would be considered the date of receipt of the notice. The hospital would be required to maintain a copy of the signed or annotated notice as part of its records regarding the stay, per federal or state law.

As with existing beneficiary notice requirements, hospitals generally would need to determine whether a patient is capable of comprehending and signing the notice. Hospitals would be required to comply with applicable State laws and CMS guidance regarding the use of representatives and have procedures in place to determine an appropriate representative.

3. Expedited Determination Procedures when a Beneficiary is Reclassified from an Inpatient to an Outpatient Receiving Observation Services (§ 405.1211)

Proposed new § 405.1211 sets forth the procedures for the proposed new expedited QIO review leading up to issuance and effect of the QIO's determination. Proposed § 405.1211 would establish the responsibilities of the hospitals, QIOs, and beneficiaries relative to the process.

Proposed § 405.1211(a) describes a beneficiary's right to request an expedited determination by a QIO when they are reclassified by their hospital from an inpatient to an outpatient receiving observation services, and the beneficiary meets the criteria to be eligible for an appeal as established in § 405.1210(a)(3). As previously discussed, QIOs are experienced in performing expedited appeals for beneficiaries in a hospital setting and thus, are well prepared to implement and execute this new appeals process in an effective and expeditious manner. Currently, Beneficiary and Family Centered QIOs (BFCC-QIOs) perform the case review functions that are similar to the reviews that would be required by §§ 405.1211 and 405.1212, so

we intend to assign these new reviews to BFCC-QIOs under our contracts with them; in the event that CMS reconsiders in the future how QIO functions are assigned and the categorization of QIOs, we intend that the type of QIOs that perform case review functions (see 42 CFR 405.1200 through 405.1208, 475.102, 476.1 *et. seq*.) would also perform these new reviews of changes in status.

In new § 405.1211(b), we are proposing the process for eligible beneficiaries to request an expedited determination by the QIO. First, the eligible beneficiary's request must be by telephone to the QIO, or in writing. We are not proposing any parameters of what a request in writing would constitute, but it could be an email or fax transmitted to the QIO. We are also proposing at § 405.1211(b)(1) the timeframe for requesting such an appeal: eligible beneficiaries would be required to request an appeal to the QIO prior to release from the hospital. The notice required under proposed § 405.1210 would identify the BFCC-QIO that serves the geographic area that includes the hospital so that this information is available to the eligible beneficiary.

Proposed sections 405.1211(b)(2) and (b)(3) would explain the responsibilities of beneficiaries to discuss the case, if requested by the QIO, and their right to submit written evidence to be considered by the QIO. Per proposed § 405.1211(b)(4), if an eligible beneficiary requests an appeal timely, they would not be billed during the QIO appeals process. However, if the appeal is untimely, the hospital may bill a beneficiary before this QIO process is complete; proposed paragraphs (b)(4) and (e) make this clear. Finally, we are also proposing, in § 405.1211(b)(5), that an eligible beneficiary may file a request for review by the QIO regarding the change in status after the deadline established in proposed § 405.1211(b)(1) (that is, the beneficiary may file the request after release from the hospital) but that the QIO's determination will be provided on a different timeframe and the eligible beneficiary will not be entitled to the billing protection proposed in paragraph (e). Keeping untimely appeals with the QIO will provide beneficiaries with a decision far sooner though (two calendar days), than if those beneficiaries were provided with the timeframes set forth in the standard claims appeals (60 days

at the first level of the claims appeals process). We are proposing that these untimely requests may be made at any time in order to afford maximum opportunity for beneficiaries to exercise their appeal rights. Of most concern is those beneficiaries who may have had a SNF stay following their change in status from an inpatient to an outpatient receiving observation services. These beneficiaries should have the maximum opportunity to appeal and potentially obtain coverage for what might have been a costly out-of-pocket outlay.

Proposed § 405.1211(c)(1) through (c)(5) describe the procedures that the QIO would be required to follow in performing the expedited determination. We propose at § 405.1211(c)(1) that the QIO must immediately notify the hospital that a request for an expedited appeal has been made. In addition, as proposed in § 405.1211(c)(2) and (3), the QIO would be required to determine whether valid notice was delivered and examine medical and other relevant records that pertain to change in status. As proposed at § 405.1211(c)(4) and (5), the QIO would be required to solicit the views of the beneficiary and provide the hospital an opportunity to explain why the reclassification of the beneficiary from an inpatient to an outpatient receiving observations services is appropriate. T***he QIO will review the information submitted with the appeal request and any additional information it obtains to determine if the inpatient admission satisfied the relevant criteria for Part A coverage at the time the services were furnished.***

Proposed section 405.1211(c)(6) addresses the timing of the QIO's determination. Per proposed paragraph (c)(6)(i), the QIO must render a decision and notify all relevant persons and entities within one calendar day of receiving all requested pertinent information if the eligible beneficiary requested the expedited determination as specified in proposed § 405.1211(b)(1) (that is, no later than the day of release from the hospital). Based on current experience regarding documentation submitted by hospitals under other expedited beneficiary appeal timeframes, we do not anticipate that the QIO will encounter delays in receiving any information necessary from the hospital once the hospital is notified of the appeal (see proposed § 405.1211(d)(1)). This timeframe is as rapid as possible to minimize potential liability for

beneficiaries as well as to maximize their potential for coverage in a skilled nursing facility should they obtain a favorable decision by the QIO. A Medicare covered skilled nursing facility stay must begin within 30 days of a beneficiary's discharge from a hospital. To that end, QIOs would make their decisions as quickly as possible so beneficiaries receiving favorable decisions will have time to plan for and begin a SNF stay within the 30-day parameter.

Proposed § 405.1211(c)(6)(ii) provides that the 1 calendar day QIO decision deadline does not apply if a beneficiary makes an untimely request for an expedited appeal, but that the QIO would still accept the request and render a decision within two calendar days after the QIO receives all requested information that the hospital must provide per proposed § 405.1211(d)(1). This provides a beneficiary with the maximum ability to exercise their right to an expedited appeal, and the opportunity to obtain SNF coverage within the Medicare coverage limitation of 30 days after leaving a hospital, should their appeal to the QIO be favorable. Both proposed paragraphs (c)(6)(i) and (ii) require the QIO to provide notice of its expedited determination

In § 405.1211(c)(7) we propose that if the QIO does not receive the information needed to make its decision, the QIO may move forward and make a decision based on the information it has at the time. This is to protect the interests of the beneficiary by ensuring they receive their decision within the QIO's required timeframes of 1 calendar day for a timely request and two calendar days for an untimely request.

The QIO decision, as required by proposed § 405.1211(c)(8), must be conveyed to the eligible beneficiary, the hospital, and SNF (if applicable) by telephone followed by a written notice. We are proposing that the QIO's written notice of its determination must include the basis for the determination, a detailed rationale for the QIO decision, an explanation of the Medicare payment consequences of the determination, and information about the beneficiary's right to an expedited reconsideration as set forth in § 405.1212, including how and in what time period a beneficiary may make that reconsideration request. The basis of a decision is a description of, and citations to, the Medicare coverage rule, instruction, or other policies

applicable to the review. A detailed rationale is an explanation of why services do or do not meet the relevant criteria for Part A coverage based on the facts specific to the beneficiary's situation and the QIO's review of the pertinent information provided by the hospital (as with other expedited beneficiary appeals of hospital discharges and service terminations).

Proposed § 405.1211(d) sets forth the responsibilities of hospitals in the expedited appeals process. Section 405.1211(d)(1) provides that the hospital must supply all information that the QIO needs, no later than noon of the calendar day after the QIO notifies the hospital of the appeals request. We are also proposing that at the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing). Section 405.1211(d)(2) requires that hospitals, upon request, must provide the beneficiary any documentation, including written records of any information provided by telephone, it provides to the QIO. We are proposing that this obligation work the same way that it does under § 405.1206(d)(3), specifically that the hospital may charge a reasonable amount to cover the costs of duplicating and delivering the requested materials and must accommodate such a request by no later than close of business of the first day after the material is requested by the beneficiary or the beneficiary's representative.

In § 405.1211(e), we propose that a hospital may not bill a beneficiary who has appealed timely for any services at issue in the appeal until the expedited determination process (and reconsideration process) is complete. Although there is liability protection in the inpatient discharge expedited appeals process under section 1869(c)(3)(C)(iii) of the Act (incorporating the financial liability protection in section 1154(e)(4) of the Act in effect prior to the enactment of section 1869(c)(3)(C)) of the Act, there is no statutory provision protecting the beneficiary from financial liability for the hospital stay and services furnished during the pendency of the QIO's review proposed here. Therefore, we are proposing only that the hospital may not bill the beneficiary until after the QIO has issued its determination. This proposal mirrors existing procedures for the similar expedited appeals procedures the termination of non-hospital services

found at § 405.1202(g). This process would not extend coverage available to beneficiaries during an appeal, which is consistent with § 405.1202(g).

Proposed § 405.1211(f) sets forth that a QIO determination is binding for payment purposes on the beneficiary, hospital, and MAC, unless the beneficiary pursues an expedited reconsideration per § 405.1212. The decision is binding for purposes of payment only, such that if the hospital submits a claim under Part A, CMS will make payment.

4. Expedited Reconsideration Procedures when a Beneficiary is Reclassified from an Inpatient to an Outpatient Receiving Observation Services (§ 405.1212)

In new § 405.1212 we propose to set forth the procedures for the new expedited reconsideration process. Proposed § 405.1212 contains the responsibilities of the hospitals, QIOs, and beneficiaries relative to the reconsideration process.

Proposed § 405.1212(a) describes an eligible beneficiary's right to request an expedited reconsideration by a QIO when they are dissatisfied with the expedited determination decision by the QIO.

In § 405.1212(b) we are proposing a process for beneficiaries to request an expedited reconsideration by a QIO. Proposed paragraph (b)(1) provides that beneficiaries must request an appeal to the QIO no later than noon of the calendar day following the initial notification of the expedited determination by the QIO. Under this proposal, the earlier of the calendar day of the QIO's notification of the beneficiary by telephone or in writing of its determination (under § 405.1211(c)(8)) would start the timeframe for the beneficiary to request an expedited reconsideration. The beneficiary's request for a reconsideration may be in writing or by telephone.

Proposed §§ 405.1212(b)(2) and (b)(3) also explain the responsibilities of beneficiaries to discuss the case, if requested by the QIO, as well as beneficiaries' right to submit written evidence to be considered by the QIO. Finally, proposed (b)(4) and (b)(5) state that if a beneficiary requests an appeal timely, they would not be billed until the QIO makes its

reconsideration decision; however, if the beneficiary's request for an expedited reconsideration is untimely, the hospital may bill a beneficiary before the reconsideration determination has been made.

Proposed §§ 405.1212(c)(1) through 405.1212(c)(4) describe the procedures that the QIO must follow in performing the expedited reconsideration. Specifically, we propose in § 405.1212(c)(1) that the QIO must immediately notify a hospital that a request for an expedited reconsideration has been made; this means that the notice to the hospital must be the day the QIO receives the request for expedited reconsideration. Per proposed § 405.1212(c)(2), the QIO would be required to offer both the beneficiary and the hospital an opportunity to provide further information. An example of further information from the hospital could include an explanation of why the beneficiary was reclassified from an inpatient to an outpatient receiving observation services. Similarly, an example of further information from the eligible beneficiary could include an explanation of why inpatient status should have been maintained.

Proposed § 405.1212(c)(3)(i) provides that the QIO must render a decision and notify all relevant persons and entities within two calendar days of receiving all information necessary to complete the appeal if the beneficiary requested the reconsideration by noon of the day after receiving notice of the QIO's determination under § 405.1211. This timeframe is as rapid as possible to minimize potential liability for beneficiaries as well as to maximize their potential for coverage in a SNF should they obtain a favorable reconsideration decision by the QIO. A Medicare covered skilled nursing facility stay must begin within 30 days of a beneficiary's discharge from a hospital. To that end, we are proposing a review process for QIOs to make their decisions as quickly as possible so beneficiaries receiving favorable decisions will have time to plan for and begin a SNF stay within the 30-day limit for coverage.

Proposed § 405.1212(c)(3)(ii) provides that if a beneficiary makes an untimely request for an expedited reconsideration, the QIO must still accept the request and render a decision within 3 calendar days. Under this proposal, the two-calendar day QIO decision deadline does

not apply in the case of an untimely request for an expedited reconsideration. However, the expeditious 3-day untimely timeframe affords a beneficiary the ability to exercise their right to an expedited appeal and potentially be entitled to SNF coverage within the 30-calendar day time limit for SNF coverage following hospital release, should they receive a favorable expedited reconsideration determination from a QIO.

The QIO decision, as required by proposed § 405.1212(c)(4)(i-iv), must include the basis and detailed rationale for the QIO decision. The basis of a decision is a description of, and citations to, the Medicare coverage rule, instruction, or other policies applicable to the review. A detailed rationale includes the facts specific to the beneficiary's situation and a detailed explanation of why the inpatient admission did or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished. The decision must also include the potential financial ramifications, such as deductibles or coinsurance for the beneficiary, the beneficiary's right to a hearing by an ALJ, and how a beneficiary may make a request for an expedited reconsideration.

Proposed § 405.1212(d) sets forth the responsibilities of hospitals in the expedited appeals process. As proposed, a hospital may, but is not required to, submit evidence to be considered by a QIO in making its reconsideration decision. If a hospital does not furnish a QIO with requested additional information, the QIO may proceed to make a decision based on the information used in the expedited determination. This is to protect the interests of the beneficiary by ensuring they receive their decision within the BFCC-QIO's required timeframes of two calendar days for a timely request and 3 calendar days for an untimely request. This proposed policy is consistent with obligations on hospitals in the second level expedited review of a hospital discharge and on providers of services in the second level expedited review of a termination of provider services (§ 422.1204(e)).

In § 405.1212(e) we propose that a hospital may not bill a beneficiary who has appealed timely for any services at issue in the appeal until the expedited reconsideration process is

complete.

Proposed § 405.1212(f) sets forth that a QIO reconsideration is binding on the beneficiary, hospital, and MAC unless the beneficiary pursues an appeal with an ALJ in accordance with 42 CFR part 478 subpart B. This concept is consistent with the existing claims appeals process currently established under §§ 405.1000 through 405.1140. The decision is binding for purposes of payment only, such that if the hospital submits a claim under Part A, CMS will make payment.

Per section 1155 of the Act, a beneficiary who is dissatisfied by a QIO's reconsideration of its initial decision may seek additional administrative review and, ultimately, judicial review, if the amount in controversy limits are met.[16] Our proposal follows that process.

5. Conforming Changes Beneficiary Notice of Discharge or Change in Status Rights (§ 489.27)

In conjunction with the proposed notice provisions §§ 405.1210 through 405.1212, we are proposing to make conforming changes to a related existing regulatory provision. We propose to amend the provider agreement requirements in § 489.27(b) to cross-reference the proposed notice requirements. Thus, proposed § 489.27(b) would specify that delivery of the proposed appeals notice is required as part of the Medicare provider agreement. Lastly, to account for this conforming change, we are proposing to change the title of § 489.27 to include "change in status" to more accurately reflect the actions that would require the issuance of a notice.

6. Conforming Changes to Quality Improvement Organization (QIO) Review Regulations

We are also proposing to amend the QIO regulations at § 476.71(a) to conform with the proposed changes in review responsibilities at §§ 405.1210 through 405.1212. The proposed amendment to the QIO regulations would add a new review type to the currently enumerated list of reviews performed by QIOs, specifically for beneficiary appeals of hospital reclassifications

[16] Under section 1155 of the Act, for an appeal with an ALJ, the amount in controversy must be $200 or more, and for judicial review, the amount in controversy must be $2,000 or more.

of a fee-for-service beneficiary's inpatient status to that of outpatient receiving observation services. The beneficiary eligibility requirements for filing expedited appeals and the required processes for those appeals are proposed in sections III.B.1 through III.B.5 of this proposed rule. This proposed amendment to the QIO regulation would specify that QIO perform review functions for these beneficiary appeals in a manner that is consistent with other QIO review functions while ensuring alignment with the proposed beneficiary eligibility and process requirements for such appeals.

The QIO regulations at 42 CFR 476.1(a) define "QIO review" as a review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors. Under regulations at § 476.71, the QIO's review responsibilities currently include: (1) whether services are or were reasonable and medically necessary for diagnosis or treatment; (2) whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints; (3) whether care and services furnished or proposed on an inpatient basis could be effectively furnished more economically on an outpatient basis or in another inpatient setting; (4) diagnostic related group (DRG) validation of diagnosis and procedure information provided by hospitals; (5) the completeness, adequacy and quality of hospital care provided; (6) medical necessity, reasonableness and appropriateness of hospital admissions and discharges; (7) medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional outlier payment is sought; and (8) whether a hospital has misrepresented admission or discharge information resulting in unnecessary or multiple admissions, or inappropriate billing.

Our proposed amendment to § 476.71(a) would add paragraph (9) to this list of QIO review responsibilities to include the new beneficiary-initiated appeals proposed here for when a hospital reclassifies certain fee-for-service beneficiaries' admission status from inpatient to that of outpatient.

In considering the existing hospital discharge appeals process, CMS determined that the

circumstances for these new appeals, and the potential impact of such appeal decisions on Part A coverage for subsequent care in other settings, necessitated a new notification process and review timelines which differ from the processes that govern the existing hospital discharge appeals process. These new appeals are proposed in section III.B of this proposed rule and would be in new appeals regulations at §§ 405.1210 through 405.1212.

The proposed amendment to the QIO regulations, as previously discussed, applies to the processes and timeframes for the new appeals discussed in section III.B of this proposed rule, which have been designed to meet the needs of beneficiaries who have had their inpatient status reclassified to outpatient receiving observation services.

We welcome public comment on the addition of these appeals.

C. *Severability*

Finally, we note that while the various provisions of this proposed rule are intended to implement the District Court order in *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020), *aff'd sub nom.*, *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022), the proposals described previously for retrospective appeals and prospective appeals would be, if finalized, distinct provisions. We believe these distinct processes may function independent of each other. To the extent a court may enjoin any part of a final rule, the Department intends that other provisions or parts of provisions should remain in effect. Should they be finalized, we intend that any provision of the proposals described in this section or in another section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, would be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding is one of utter invalidity or unenforceability, in which event we intend that the provision would be severable from the other finalized provisions described in this section and in other sections and would not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.) we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a "collection of information" requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the proposed rule, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment (see section IV.D of this proposed rule) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. *Wage Estimates*

Private Sector: To derive average costs, we used wage data from the U.S. Bureau of Labor Statistics' (BLS) May 2022 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/2022/may/oes_nat.htm). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs, and our adjusted hourly wage.

TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse	29-1141	39.78	39.78	79.56

As indicated, we are adjusting our hourly wage estimate by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $21.98/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices[17] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,059[18] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $26.48/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.50/hr ($26.48/hr x 0.17), resulting in the post-tax hourly wage rate of $21.98/hr ($26.48/hr - $4.50/hr). Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. *Proposed Information Collection Requirements (ICRs)*

This proposed rule sets forth new appeals procedures as required by the court order in the case *Alexander v. Azar*, 613 F. Supp. 3d 559 (D. Conn. 2020)), *aff'd sub nom.*, *Barrows v.*

[17] https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf
[18] https://fred.stlouisfed.org/series/LEU0252881500A

Becerra, 24 F.4th 116 (2d Cir. 2022). Certain beneficiaries in Original Medicare, who are initially admitted to a hospital as an inpatient by a physician but whose status during their stay was changed to outpatient receiving observation services by the hospital, thereby effectively denying Part A coverage for their hospital stay, may pursue an appeal under this proposed rule. In some cases, the status change also affects coverage of a beneficiary's post-hospital extended care services furnished in a skilled nursing facility (SNF). The appeal is filed with Medicare to decide if the inpatient admission meets the relevant criteria for Part A coverage.

1. ICRs Regarding Retrospective Appeals Requests (§ 405.932)

The proposals in new § 405.932 will be submitted to OMB for review under control number 0938-TBD (CMS-10885). At this time, the control number has yet to be determined, but will be assigned by OMB upon their clearance of this proposed collection of information request. CMS will include that number in the subsequent CMS-4204-F final rule. OMB will issue the control number's expiration date upon their approval of the final rule's collection of information request. The issuance of that date can be monitored at www.Reginfo.gov.

As discussed in section III.A.3, § 405.932 proposes that eligible parties may file in writing an appeal related to a change in patient status which resulted in the denial of Part A coverage. A written appeal request must be received by the eligibility contractor no later than 365 days after the implementation date of the final rule. Details regarding the deadline to file an appeal and where such appeals should be filed would be posted to Medicare.gov once the retrospective appeals process is operational. The written request must include the following information:

- Beneficiary name.
- Beneficiary Medicare number (the number on the beneficiary's Medicare card).
- Name of the hospital and dates of hospitalization.
- Name of the SNF and the dates of stay (as applicable).

If the appeal includes SNF services not covered by Medicare, the written request must also

include an attestation to the out-of-pocket payment(s) made by the beneficiary for such SNF services and must include documentation of payments made to the SNF for such services.

We estimate that it would take an individual approximately 30 minutes (0.5 hr) to complete the appeal request including the attestation and documentation of out-of-pocket payments for SNF services and submit the completed information to the eligibility contractor.

Because this is a new appeal right and associated process, CMS does not have precise data and cannot meaningfully estimate how many individuals may request an appeal under the new appeals process. However, we believe that the closest equivalent is using the rate of individuals who appeal denials of initial claim determinations under the claim appeals process at the first level of appeal to a MAC (which is 3 percent), and aligning it with the appeal rates of higher levels of appeal (ranging from 21 percent to 27 percent) to arrive at an estimate of 20 percent. This estimate reflects our expectation that eligible parties in this process will be more motivated than in the claim appeals process to avail themselves of this unique opportunity for a retrospective appeal on potentially high dollar claims.

Based on these data, we estimate that the total number of eligible beneficiaries is 32,894.[19] Assuming that 20 percent of individuals (6,579 = 32,894 x 0.20) who are eligible to appeal will file a request, we estimate a one-time burden of 3,290 hours (6,579 requests × 0.5 hr/request) at a cost of $72,314 (3,290 hr × $21.98/hr).

2. ICRs Regarding Notifying Beneficiaries of Appeal Rights when Hospital Inpatient Coverage is Reclassified to Coverage as an Outpatient Receiving Observation Services (§ 405.1210)

The proposals in new § 405.1210 will be submitted to OMB for review under control number 0938-TBD (CMS-10868). At this time, the control number has yet to be determined, but will be assigned by OMB upon their clearance of this proposed collection of information request.

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19. The data used in this report came from the 2022 CMS Part B institutional administrative claims data for 100 percent of Medicare beneficiaries enrolled in the fee-for-service (FFS) program, which are available from the Integrated Data Repository (IDR). The IDR contains a subset of data transmitted by the Common Working File (CWF), a computerized database maintained by CMS in connection with its processing and payment of Medicare claims.

CMS will include that number in the subsequent CMS-4204-F final rule. OMB will issue the control number's expiration date upon their approval of the final rule's collection of information request. The issuance of that date can be monitored at reginfo.gov.

Section 405.1210 proposes to require hospitals to deliver, prior to discharge, a standardized notice informing eligible beneficiaries of the change in status from an inpatient to an outpatient receiving observation services, and their appeal rights if they wish to challenge that change.

The proposed Medicare Change of Status Notice (MCSN) is new and is intended to be furnished only to those beneficiaries eligible for this specific proposed new appeal. The proposed MCSN notice contains only two fields that hospitals must complete: (1) the beneficiary's name, and (2) the beneficiary's identifier number. The remaining information (information on the change in coverage, a description of appeal rights and how to appeal, and the implications for skilled nursing facility coverage following the hospital stay) is standardized.

For beneficiaries with Medicare Part B coverage, hospitals would be required to deliver the notice to eligible beneficiaries as soon as possible after hospital reclassifies the beneficiary from an inpatient to an outpatient and the beneficiary has stayed in the hospital for 3 or more consecutive days but was an inpatient for fewer than 3 days. The notice must be delivered no later than 4 hours before the beneficiary is released from the hospital.

For beneficiaries without Medicare Part B coverage, hospitals would be required to deliver the notice to eligible beneficiaries as soon as possible after the change from inpatient to outpatient with observation services is made as a 3-day hospital stay is not required for these beneficiaries. The notice must be delivered no later than 4 hours before the beneficiary is released from the hospital.

We estimate it would take 10 minutes (0.1667 hr) at $79.56/hr for a Registered Nurse to complete the two data fields and deliver each notice to the applicable beneficiary.

The 10-minute estimate is same as that for our Important Message from Medicare (CMS-

10065/10066; OMB 0938-1019), which the proposed MCSN notice is modeled after.

In 2022 there were approximately 15,655 instances where hospital stays met the criteria for an appeal.[20,21] With regard to this proposed rule we estimate that hospitals would be required to give an estimated 15,655 MCSN notices to beneficiaries each year. In aggregate, we estimate an annual hospital burden of 2,610 hours (15,655 notices x 0.1667 hr/notice) at a cost of $207,652 (2,610 hr x $79.56/hr).

Please note, our data does not permit us to determine whether the observation services occurred prior to the initial inpatient stay or followed the change in status from inpatient to outpatient, as required to qualify for an appeal. As a result, 15,655 MCSN notices likely overstates the number of beneficiaries eligible for an appeal.

Please see section IV.D. of this proposed rule if you wish to view the draft standardized notice and supporting documentation.

3. ICRs Regarding Applicable QIO Review Regulations (§ 476.71 and § 476.78)

In section III.B. of this proposed rule, we are proposing that the QIOs would review the prospective expedited appeals under their contracts with the Secretary. CMS expects to revise the BFCC-QIO's contracts under the 13th Statement of Work to include the new prospective expedited appeals requirements after publication of the subsequent final rule. The additional costs to the government for the BFCC-QIOs to review the new appeals would include payment for the additional level of effort associated with communicating with beneficiaries and hospitals for the duration of the appeal, collecting and reviewing patient records, performing reconsiderations if requested, and providing case files requested for further levels of review if needed. It also would include the cost of reimbursing hospitals for the submission of patient records for prospective expedited appeals. Hospitals would submit patient records and request

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20. The data used in this report come from the 2022 CMS Part B institutional administrative claims data for 100 percent of Medicare beneficiaries enrolled in the fee-for-service (FFS) program, which are available from the CMS Chronic Condition Data Warehouse (www2.ccwdata.org/web/guest/home), accessed August 2023.

21. The data used in this report come from the 2022 CMS Part B institutional administrative claims data for 100 percent of Medicare beneficiaries enrolled in the fee-for-service (FFS) program, which are available from the CMS Chronic Condition Data Warehouse (www2.ccwdata.org/web/guest/home), accessed August 2023.

reimbursement from the QIO using the process established in the existing memorandums of agreement (MOAs) under §476.78(a) between hospitals and the QIO having jurisdiction over the particular State in which the hospital stay occurred.

As discussed in section III.B. of this proposed rule, hospitals would be required to submit patient records to the QIOs for prospective expedited appeals under proposed § 405.1211(d). Existing QIO regulations at § 476.78(b)(2) and (c) require providers and practitioners to electronically submit patient records to the QIOs for purposes of one or more QIO functions and allow for the reimbursement of providers and practitioners by the QIO for the electronic submission of patient records for one or more QIO functions at a rate of $3.00 per submission under § 476.78(e)(2). Hospitals that have waivers for the required electronic submission of records under §476.78(d) may be reimbursed by the QIO at a rate of $0.15 per page for submission of the patient records under § 476.78(e)(3).

The estimation methodology used to determine the reimbursement rates for electronic and non-electronic submission of patient records for one or more QIO functions is discussed further in section IX.A. of the Fiscal Year (FY) 2021 Hospital Inpatient Prospective Payment System (IPPS)/Long-Term Care Prospective Payment System (LTCH PPS) final rule (85 FR 58977 through 58985). This estimation methodology is appropriate when applied to the proposed prospective expedited appeals due to the substantial similarity of its requirements and processes to those of other QIO functions upon which these rates were determined.

In section III.B.6 of this proposed rule, we are proposing the addition of a QIO review type at § 476.71(a)(9) making the QIO's review of the prospective expedited appeals under proposed § 405.1211(d) a QIO function using our authority in section 1154(a)(18) of the Act. As established earlier in the ICR section, the proposed prospective appeals process would constitute a CMS administrative action toward a specific individual or entity. Thus, the preparation and submission of the appeal, supporting documentation needed for the appeal, and communications between the QIO and parties to the appeal are not subject to the PRA as stipulated under 5 CFR

1320.4(a)(2).

C. *Summary of Annual Burden Estimates for Proposed Changes*

TABLE 2: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID Number)	Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 405.932	0938-TBD (CMS-10885)	32,894 beneficiaries	6,579	0.5 (30 min)	3,290	21.98	72,314
§ 405.1210	0938-TBD (CMS-10868)	6,162 hospitals	15,655	0.1667 (10 min)	2,610	79.56	207,652
TOTAL		39,056	22,234	varies	5,900	varies	279,966

D. *Submission of Comments*

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the DATES and ADDRESSES section of this proposed rule and identify the rule (CMS-4204-P), the ICR's CFR citation, and OMB control number.

V. 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), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), 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).

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). The Executive Order 14094 entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O.) amended section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f)(1) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year. A regulatory impact analysis (RIA) must be prepared for the rules with significant regulatory action/s as per section 3(f)(1) ($200 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a significant rule under section 3(f)(1).

We are making the determination that the proposed new appeals process will not have a significant financial impact on the Medicare program or interested parties based on our assumption about the overall number of projected appeals. While it is difficult to project how many beneficiaries will pursue appeals under this new process, overall, we anticipate a relatively low volume of retrospective appeals. We estimate that the total number of eligible beneficiaries is 32,894.[22] We are projecting approximately 6,600 appeals at the first level of appeal (MAC level); 5,000 appeals at the second level of appeal (QIC Level); 2,800 appeals at the third level of appeal (ALJ level); and 150 at the Medicare Appeals Council. There will be administrative costs associated with tasking a contractor to serve as a point of contact and clearinghouse for incoming retrospective appeals requests.

We also anticipate a very low volume of prospective and standard appeals on an ongoing

22 The data used in this report came from the 2022 CMS Part B institutional administrative claims data for 100 percent of Medicare beneficiaries enrolled in the fee-for-service (FFS) program, which are available from the Integrated Data Repository (IDR). The IDR contains a subset of data transmitted by the Common Working File (CWF), a computerized database maintained by CMS in connection with its processing and payment of Medicare claims.

basis. We estimate that around 15,000 notices informing beneficiaries of their change in status and informing them of their right to appeal will be delivered annually.[23] We are estimating an appeal rate of 50 percent, which would result in about 7,500 appeals per year.

While our estimates reflect a relatively low number of appeals, we acknowledge that there will be administrative costs for hospitals to accommodate the new appeals process, as well as costs associated with modifying contracts for MACs, QICs, and the BFCC-QIOs to perform the retrospective, prospective and standard appeals. We welcome comment on these proposed estimates.

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 $9.0 million to $47.0 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 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital at 42 CFR 412.108 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 proposed regulation 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

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23 The data used in this report come from the 2022 CMS Part B institutional administrative claims data for 100 percent of Medicare beneficiaries enrolled in the fee-for-service (FFS) program, which are available from the CMS Chronic Condition Data Warehouse (www2.ccwdata.org/web/guest/home), accessed August 2023.

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 2023, that threshold is approximately $177 million. This rule will 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.

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

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 18, 2023.

List of Subjects

42 CFR Part 405

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

42 CFR Part 476

Grant programs-health, Health care, Health facilities, Health professions, Health records, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 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 continues 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).

2. Subpart I is amended by adding an undesignated center heading after § 405.930 and §§ 405.931, 405.932, 405.934, 405.936, and 405.938 to read as follows to read as follows:

Retrospective Appeals for Changes in Patient Status that Resulted in Denial of Part A Coverage for Hospital Services

Sec.

§ 405.931 Scope, basis, and definitions.

(a) *Scope and basis*. The provisions in §§ 405.931 through 405.938--

(1) Implement a federal district court order requiring appeal rights for hospital stays on or after January 1, 2009, for a specified class of beneficiaries under certain conditions (defined in § 405.931(b)(1)) who were admitted to a hospital as inpatients, but were subsequently reclassified by the hospital as outpatients receiving observation services; and

(2) Apply to retrospective appeals, that is, appeals for hospital outpatient services, and as applicable, post-hospital extended care services in a skilled nursing facility (SNF services), furnished to eligible parties as defined in paragraph (b) of this section before the implementation of the prospective appeal process set forth in §§ 405.1210 through 405.1212.

(b) *Definitions*. For the purposes of the appeals conducted under §§ 405.931 through 405.938, the following definitions apply:

Eligible party means a beneficiary who, on or after January 1, 2009, meets the following criteria, and is, thus, eligible to request an appeal under §§ 405.931 through 405.938:

(i) Was formally admitted as a hospital inpatient.

(ii) While in the hospital was subsequently reclassified as an outpatient receiving observation services (as defined in § 405.931(h)).

(iii) Has received an initial determination (as defined in § 405.920) or a Medicare Outpatient Observation Notice (MOON) (as described in § 489.20(y)) indicating that the observation services are not covered under Medicare Part A.

(iv)(A) Was not enrolled in the Supplementary Medical Insurance program (that is, Medicare Part B coverage) at the time of beneficiary's hospitalization; or

(B) Stayed at the hospital for 3 or more consecutive days but was designated as an inpatient for fewer than 3 days, unless more than 30 calendar days has passed after the hospital stay without the beneficiary's having been admitted to a SNF.

(v) Medicare beneficiaries who meet the requirements of the paragraph (iv)(A) or (B) of this definition but who pursued an administrative appeal and received a final decision of the Secretary before September 4, 2011, are excluded from the definition of an eligible party.

Eligibility contractor means the contractor who meets all of the following:

(i) Is identified on the Medicare.gov website for accepting appeal requests.

(ii) Receives appeal requests and makes determinations regarding eligibility for the appeal under §§ 405.931 through 405.938.

(iii) Issues notices of eligibility.

(iv) Refers valid appeal requests to the processing contractor for a decision on the merits of the appeal.

Processing contractor means the contractor responsible for conducting the first-level appeal and issuing a decision on the merits of the appeal. Appeals under § 405.932 are conducted by the MAC who, at the time of the referral of the request for appeal under

§405.932(d)(2), has jurisdiction over claims submitted by the hospital where the eligible party received the services at issue.

(c) *Party to an appeal*. For the purposes of the appeals conducted under §§ 405.931 through 405.938, an eligible party is the only party to the appeal. The provisions of § 405.906 do not apply to appeals processed under these provisions, and the provider that furnished services to an eligible party may not file a request for an appeal and is not considered a party to any appeal decision or determination.

(d) *Authorized representatives, appointed representatives, or representatives of a deceased eligible party*. For the purposes of appeals conducted under §§ 405.931 through 405.938:

(1) The provisions of § 405.910 apply to an eligible party appointing a representative to assist in such appeal, as appropriate, except as follows:

(i) A provider of services who furnished items or services to a beneficiary whose claims are the subject of an appeal under the provisions of §§ 405.931 through 405.938 is prohibited from representing the beneficiary or eligible party in such appeal.

(ii) [Reserved.]

(2) An authorized representative (as defined in § 405.902) may act on behalf of an eligible party and has all of the same rights and responsibilities of an eligible party throughout the appeals process.

(3) The provisions of § 405.906(a)(1) apply to a deceased eligible party in the same manner in which such provisions apply to a deceased beneficiary.

(4) The provisions of § 405.906(c) do not apply.

(5) A beneficiary who is an eligible party is considered unrepresented if the beneficiary meets any of the following:

(i) Has not appointed a representative under § 405.910.

(ii) Has an authorized representative as defined in § 405.902.

(iii) Has appointed as its representative a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

(iv) Is deceased but met the conditions for an eligible party in paragraph (b)(1) of this section and the appeal is filed by an individual who meets the conditions set forth in § 405.906(a)(1).

(e) *Prohibition on assignment of appeal rights*. For the purposes of the appeals conducted under §§ 405.931 through 405.938, an eligible party may not assign appeal rights to a provider under the provisions of § 405.912.

(f) *Date of receipt of a notice or decision*. For the purposes of the appeals conducted under §§ 405.931 through 405.938, the date of receipt of a notice or decision sent by the eligibility contractor, processing contractor or other appeals adjudicator is presumed to be 5 calendar days following the date on the notice unless there is evidence to the contrary.

(g) *Three or more consecutive days*. For the purposes of the appeals conducted under §§ 405.931 through 405.938, when determining if a beneficiary is an eligible party and for the purposes of determining coverage of SNF services under section 1861 of the Act, inpatient hospital days are counted in accordance with § 409.30, that is, a patient must have a qualifying inpatient stay of at least 3 consecutive calendar days starting with the admission day but not counting the discharge day.

(h) *Outpatient receiving observation services*. For the purposes of appeals conducted under §§ 405.931 through 405.938 when determining if a beneficiary is an eligible party, a beneficiary is considered an outpatient receiving observation services when the hospital changes beneficiary’s status from inpatient to outpatient while the beneficiary is in the hospital and the beneficiary subsequently receives observation services following a valid order for such services.

§ 405.932 Right to appeal a denial of Part A coverage resulting from a change in patient status.

(a) *Filing an appeal request related to a change in patient status which resulted in the denial of Part A coverage.* (1) Only an eligible party, the party's appointed representative, or an authorized representative of an eligible party may request an appeal at any level of the appeals process under §§ 405.931 through 405.938.

(2) To initiate an appeal under §§ 405.931 through 405.938, an eligible party, the party's appointed representative, or an authorized representative of an eligible party must meet the following requirements:

(i) Submit a request for an appeal in writing to the eligibility contractor.

(ii) The request must be received by the eligibility contractor no later than 365 days after the implementation date of the final rule. The eligibility contractor denies the written request if it is not received by the applicable filing timeframe under § 405.932(d)(3), unless the eligible party established good cause for late submission as specified in § 405.942(b)(2) and (3).

(3) If an eligible party (or the party's representative) misfiles a request for appeal with a contractor or government entity other than the eligibility contractor, then for the purpose of determining timeliness of the request for appeal, the date the misfiled request was received by the contractor or government agency is considered the date of receipt. The misfiled request and all documentation must be forwarded to the eligibility contractor within 30 calendar days of receipt, or as soon as practicable.

(b) *Content of the appeal request.* (1) The written request filed by an eligible party, the party's appointed representative, or an authorized representative of an eligible party may be made on a model CMS form. If the model form is not used, to be valid, the written request must include all of the following identifying information:

(i) Beneficiary name.

(ii) Beneficiary Medicare number (the number on the beneficiary's Medicare card).

(iii) Name of the hospital and dates of hospitalization.

(iv) Name of the SNF and the dates of stay (as applicable).

(2) If the appeal includes SNF services not covered by Medicare, the written request must also include an attestation to the out-of-pocket payment(s) made by the beneficiary for such SNF services and must include documentation of payments made to the SNF for such services.

(i) Payments for an eligible party's SNF services made by a third-party payer do not constitute out-of-pocket expenses or payment for an eligible party. If a third-party payer made payment for the eligible party's SNF services, then the services are excluded from consideration in the appeal.

(ii) Payments made for cost sharing (including, but not limited to, coinsurance and deductible) for SNF services covered by a third-party payer are not considered an out-of-pocket payment for the purposes of this provision.

(iii) Payments made by a family member for an eligible party's SNF services are considered an out-of-pocket payment for the eligible party.

(3) In the written request for an appeal, an eligible party (or their representative) may include an explanation of why the hospital admission satisfied the relevant criteria for Part A coverage and should have been covered under the Part A hospital insurance benefit instead of under the Part B supplementary medical insurance benefit.

(c) *Evidence and other information to be submitted with the appeal request*. (1) Eligible parties (or their representatives) are encouraged to submit all available information and documentation, including medical records related to the hospital stay and SNF services, as applicable, at issue in the appeal with the written request for an appeal.

(2) If the eligibility contractor determines there is information missing from the request that is needed to establish the beneficiary's eligibility as a party under § 405.931(b)(1) or satisfy other conditions for eligibility for an appeal, the eligibility contractor works with the appropriate MAC and attempts to obtain the information from the provider or the eligible party (or the party's representative) or both, as applicable. The eligibility contractor allows up to 60 calendar days for submission of missing information.

(3) If the necessary information cannot be obtained from either the provider or the eligible party (or the party's representative), the eligibility contractor makes an eligibility determination based on the information available.

(d) *Determining eligibility for an appeal*. (1)(i) The eligibility contractor reviews the information submitted with the appeal request and any additional information it obtains to determine if the individual submitting the appeal request is an eligible party and that the services previously furnished are eligible for an appeal under § 405.931.

(ii) The eligibility contractor mails or otherwise transmits the notice of its determination to the eligible party (or the party's representative) within 60 calendar days of receipt of the appeal request.

(iii) The time between the eligibility contractor's request for missing information and receipt of such information (or in the case of information that is requested but is not received, the time allowed by the contractor to submit the information) does not count toward the timeframe for issuing a notice to the eligible party (or the party's representative).

(2) If the eligibility contractor determines that the individual is an eligible party and the services previously furnished are eligible for an appeal, the eligibility contractor—

(i) Issues a notice of acceptance to the eligible party (or the party's representative), explaining that the appeal has been accepted for processing; and

(ii) Refers the appeal to the processing contractor for adjudication under § 405.932(e).

(3)(i) If the eligibility contractor determines that the request for appeal is untimely or incomplete, the individual does not satisfy the requirements for an eligible party, or the services previously furnished are not eligible for an appeal, the eligibility contractor issues a denial notice to the individual (or the party's representative) in writing.

(ii) The denial notice explains that the request is not eligible for an appeal, the reason(s) for the denial of the appeal request, and the process for requesting a review of the eligibility denial under § 405.932(e).

(4) Notices regarding eligibility for an appeal issued by the eligibility contractor are written in a manner to be understood by the eligible party or the party's representative.

(e) *Review of an eligibility contractor's denial of a request for an appeal*. (1)(i) An individual (or their representative) may request a review of the eligibility contractor's denial of a request for an appeal by filing a request in writing with the eligibility contractor.

(ii) The request for review should explain the reason(s) the denial of the request for an appeal was incorrect, and should include additional information, as applicable, to support the validity of the original appeal request.

(2) The request for review, with any additional information, must be received by the eligibility contractor no later than 60 calendar days from the date of receipt of the denial notice. If the request for review is received after this deadline, the individual (or the individual's representative) must establish good cause for untimely filing. In determining whether good cause for untimely filing exists, the eligibility contractor applies the provisions in § 405.942(b)(2) and (3).

(3) The review by the eligibility contractor must be conducted by individuals not involved in the initial denial of the request for an appeal.

(4) The eligibility contractor may issue a decision that affirms or reverses the denial of the request for an appeal or may dismiss the request for review. The notice of the eligibility contractor's decision must meet both of the following requirements:

(i) Be written in a manner to be understood by the individual or the individual's representative.

(ii) Be mailed or otherwise transmitted in writing within 60 calendar days of the date of receipt of the request for review.

(5) If the decision is to affirm the denial, or dismiss the request, the eligibility contractor must explain the rationale for the decision.

(6) A denial notice under paragraph (d)(3) of this section issued due to receipt of an untimely appeal request must be reversed if the eligible party (or the party's representative) establishes good cause for late filing under § 405.942(b)(2) and (3).

(7) If the eligibility contractor reverses the initial denial of the request for appeal, the eligibility contractor forwards the request for appeal to the processing contractor under § 405.932(f).

(8) The eligibility contractor's decision that affirms the initial denial of a request for an appeal is binding and not subject to further review.

(9) If the eligibility contractor determines that the request for review of the eligibility denial under paragraph (e)(2) of this section was not submitted timely, and the eligibility contractor did not find good cause for the untimely submission, then the eligibility contractor dismisses the request for review, and such dismissal is binding and not subject to further review.

(f) *Processing eligible requests for appeal*. (1) If the processing contractor determines there is necessary information missing from the appeal case file, the processing contractor attempts to obtain the information from the provider or the eligible party (or the party's representative), as applicable.

(i) The processing contractor allows the provider or eligible party (or the party's representative), or both, up to 60 calendar days to submit missing information.

(ii) If the provider or eligible party (or the party's representative) does not submit the missing information within the allotted time, the processing contractor makes a decision on the request for appeal based on the information available.

(iii) The time between the processing contractor's request for information and receipt of such information (or in the case of information that is requested but is not received, the time allowed by the contractor to submit the information) does not count toward the timeframe for issuing the processing contractor's decision.

(2) The processing contractor reviews the information submitted with the appeal request and any additional information it obtains to determine if the inpatient admission satisfied the relevant criteria for Part A coverage at the time services were furnished. If the appeal request also includes a request to review denied SNF services that are eligible for an appeal, the processing contractor also determines if such eligible SNF services satisfied relevant criteria for Part A coverage at the time the services were furnished.

(3) Subject to the provisions in paragraph (e)(1) of this section, the processing contractor mails or otherwise transmits its written decision on the request for appeal within 60 calendar days of receipt of the request.

(g) *Notice and content of the decision*. (1) If the processing contractor determines that the inpatient admission, and as applicable, SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the processing contractor issues notice of the favorable decision to the eligible party (or the party's representative). The processing contractor also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the processing contractor determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, then the processing contractor issues notice of the unfavorable or partially favorable decision to the eligible party (or the party's representative).

(ii) The processing contractor issues a notice of a partially favorable decision to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The notice issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission, and as applicable, the SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) If a favorable decision, the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amounts of benefits due.

(vi) If an unfavorable or partially favorable decision, a statement of any specific missing documentation that should be submitted with a request for reconsideration, if applicable.

(vii) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(viii) If an unfavorable or partially favorable decision, information about the procedures for filing a request for reconsideration under § 405.934.

(ix) Any other requirements specified by CMS.

(4) As applicable, a notice of a favorable decision issued to the SNF (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of beneficiary's hospitalization), includes all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the SNF services satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(5) In the case of a favorable decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, notice is issued to the hospital that includes all of the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(6) In the case of a partially favorable decision issued to a SNF, the notice includes the following:

(i) A clear statement of the decision made by the processing contractor.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to a QIC under §405.934.

(vi) Any other requirements specified by CMS.

(h) *Effect of a favorable appeal decision*. (1)(i) If the processing contractor issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by the processing contractor, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable:

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 180 calendar days of receipt of the notice of a favorable decision.

(ii) In the case of an appeal for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services and may then submit a Part A inpatient claim for such services within 180 calendar days of receipt of the notice of a favorable decision.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 Subparts B through D of this chapter.

(i) A favorable appeal decision is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986.

(ii) The provisions regarding reopening of a redetermination in § 405.980(b) and (c) apply in the same manner to favorable decisions issued under this section.

(4) The notice of a favorable decision issued to a hospital and, as applicable, a SNF does not convey party status to such provider.

(i) *Effect of an unfavorable or partially favorable decision*. (1) An unfavorable or partially favorable appeal decision is considered binding unless—

(A) It is reopened and revised under the provisions of §§ 405.980 through 405.986; or

(B) An eligible party (or the party’s representative) files a request for reconsideration under § 405.934.

(2) The provisions regarding reopening of a redetermination in §§ 405.980(b) and (c) apply in the same manner to unfavorable or partially favorable decisions issued under this section.

§ 405.934 Reconsideration.

(a) *Filing a request for reconsideration*. An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the decision rendered by a processing contractor in § 405.932(g)(2) may request a reconsideration with a QIC within 180 calendar days of receipt of the processing contractor's notice. The request for reconsideration must include the elements specified in the processing contractor's notice.

(b) *Applicability of other provisions*. The provisions in §§ 405.960 through 405.978 that apply to reconsiderations of initial determinations apply to the extent they are appropriate/in the same manner to reconsiderations performed by a QIC under this section unless otherwise specified.

(c) *Notice and content of a reconsideration*. (1) If the QIC determines that the inpatient admission, and as applicable, eligible SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the QIC issues notice of the favorable reconsideration to the eligible party (or the party's representative). The QIC also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the QIC determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, then the QIC issues notice of the unfavorable or partially favorable reconsideration to the eligible party (or the party's representative).

(ii) The QIC issues a notice of a partially favorable reconsideration to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The notice of reconsideration must be mailed or otherwise transmitted within 60 calendar days of the QIC's receipt of the request for reconsideration, subject to the exceptions specified in § 405.970.

(4) The notice of reconsideration issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission, and as applicable, the SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) If a favorable decision, the effect of such decision, including a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amounts of benefits due.

(vi) If the decision in § 405.932(f) indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration.

(vii) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(viii) If an unfavorable or partially favorable decision, information concerning an eligible parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions and other procedures for filing a request for an ALJ hearing under § 405.936.

(ix) Any other requirements specified by CMS.

(5) As applicable, a notice of a favorable reconsideration issued to the SNF (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization), includes all of the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(vi) Any other requirements specified by CMS.

(6) In the case of a favorable reconsideration for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, notice is issued to the hospital that includes all the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then

submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(vi) Any other requirements specified by CMS.

(7) In the case of a partially favorable reconsideration issued to a SNF the notice includes the following:

(i) A clear statement of the decision made by the QIC.

(ii) The reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage.

(iii) A summary of the facts, including as appropriate, a summary of any clinical or scientific evidence used in making the determination.

(iv) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to an ALJ under §405.936.

(vi) Any other requirements specified by CMS.

(d) *Effect of a favorable reconsideration*. (1)(i) If the QIC issues a reconsideration decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable reconsideration, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and

payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable:

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 180 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of an appeal for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services and may then submit a Part A inpatient claim for such services within 180 calendar days of receipt of the notice of a favorable decision.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 Subparts B through D of this chapter.

(4) A favorable reconsideration is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of a reconsideration in § 405.980(d) and (e) apply in the same manner to favorable reconsiderations issued under this section.

(5) The notice of a favorable reconsideration sent to a hospital and, as applicable, a favorable or partially favorable reconsideration sent to a SNF does not convey party status.

(e) *Effect of an unfavorable or partially favorable reconsideration*. (1) An unfavorable or partially favorable reconsideration is considered binding unless—

(i) It is reopened and revised under the provisions of § 405.980(d) or (e); or

(ii) An eligible party (or the party's representative) files a request for a hearing by an ALJ under § 405.936.

(2) The provisions regarding reopening of a reconsideration in §405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

§ 405.936 Hearings before an ALJ and decisions by an ALJ or Attorney Adjudicator.

(a) *Filing a request for hearing*. An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the reconsideration rendered by a QIC in § 405.934(c)(2), or a dismissal of a request for reconsideration, may request a hearing before an ALJ within 60 calendar days of receipt of the reconsideration. The request for hearing must include the elements specified in the QIC's reconsideration.

(b) *Applicability of other provisions*. The provisions in §§ 405.1000 through 405.1064 that apply to ALJ hearings and decisions by an ALJ or an attorney adjudicator apply to the extent they are appropriate/in the same manner to ALJ hearings and decisions by an ALJ or an attorney adjudicator under this section unless otherwise specified.

(c) *Calculating the amount remaining in controversy for an ALJ hearing or judicial review*. (1)(i) A request for ALJ hearing for an appeal under the provisions of §§ 405.931 through 405.938 must meet the amount in controversy requirement in § 405.1006(b).

(ii) A request for judicial review in federal district court for an appeal under the provisions of §§ 405.931 through 405.938 must meet the amount in controversy requirement in § 405.1006(c), subject to the calculation methodology set forth in this paragraph.

(2) For appeals under the provisions of §§ 405.931 through 405.938, the amount remaining in controversy for an ALJ hearing or for judicial review in federal district court under § 405.1136 is determined by the sum of the billed charges on the Part B outpatient hospital claim and, as applicable, any billed charges for the SNF claim at issue, if such claims were submitted to Medicare. If no SNF claim was submitted for services furnished to the beneficiary, then the billed charges to the beneficiary as indicated on an itemized statement or evidence of payment made by the beneficiary for such services are used in calculating the amount remaining in controversy.

(3) In the case of an appeal under the provisions of §§ 405.931 through 405.938 filed by an eligible party who was not enrolled in Part B at the time of hospitalization, and no Part B outpatient hospital claim was billed to Medicare, the amount remaining in controversy is determined by the charges billed to the beneficiary by the hospital for the outpatient hospital stay and billed charges for SNF services, if applicable. An itemized statement from the provider such services, or evidence of the payment made by the beneficiary to the provider is acceptable for the purpose of calculating the amount remaining in controversy.

(4) Any payments made, including coinsurance and deductible, for the Part B outpatient hospital claim, and as applicable, the SNF claim must not reduce the calculation of the amount in controversy for the purposes of a hearing or judicial review under this paragraph.

(d) *Notice and content of an ALJ or attorney adjudicator decision*. (1) If the ALJ or attorney adjudicator determines that the inpatient admission, and as applicable, eligible SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, then the ALJ or attorney adjudicator issues notice of the favorable decision to the eligible party (or the party's representative).

(ii) The ALJ or attorney adjudicator also notifies the hospital and SNF, as applicable, in the case of a favorable determination for Part A coverage.

(2)(i) If the ALJ or attorney adjudicator determines that the inpatient admission, or as applicable, SNF services, did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, then the ALJ or attorney adjudicator issues notice of the unfavorable or partially favorable decision to the eligible party (or the party's representative).

(ii) The ALJ or attorney adjudicator issues a notice of a partially favorable decision to the SNF if the inpatient admission satisfied the relevant criteria for Part A coverage, but the SNF services did not satisfy the relevant criteria for Part A coverage.

(3) The ALJ or attorney adjudicator decision issued to the eligible party (or the party's representative) must be written in a manner calculated to be understood by the eligible party (or the party's representative) and include all of the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission, and as applicable SNF services, satisfied or did not satisfy the relevant criteria for Part A coverage at the time the services were furnished, and, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The procedures for obtaining additional information concerning the decision, such as specific provisions of the policy, manual, regulations, or other rules used in making the decision.

(vi) If a favorable decision, the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amount of benefits due.

(vii) If an unfavorable decision or a partially favorable decision, information about the procedures for filing a request for review by the Appeals Council under § 405.938.

(4) As applicable, a notice of a favorable ALJ or attorney adjudicator decision (including a decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary’s hospitalization) issued to the SNF, includes the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the SNF services, satisfied the relevant criteria for Part A coverage at the time the services were furnished, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(5) In the case of a favorable ALJ or attorney adjudicator decision for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of beneficiary's hospitalization, notice is issued to the hospital that includes all of the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(6) In the case of a partially favorable decision issued to a SNF, the notice includes the following:

(i) A clear statement of the decision made by the ALJ or attorney adjudicator.

(ii) The findings of fact.

(iii) The conclusions of law.

(iv) The reason for the determination that the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, and the reason the SNF services did not satisfy the relevant criteria for Part A coverage, and to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(v) The effect of such decision, including a statement explaining that the decision is being sent for informational purposes only, and that only the eligible party may appeal the decision to the Medicare Appeals Council under §405.938.

(7) The timeframe within which notices must be issued under this paragraph are determined under the provisions in § 405.1016.

(e) *Effect of a favorable ALJ or attorney adjudicator decision*. (1)(i) If the ALJ or attorney adjudicator issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by an ALJ or attorney adjudicator any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable:

(i) The SNF that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 180 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of an appeal for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital that furnished services must refund any payments collected for the outpatient hospital services and may then submit a Part A inpatient claim for such services within 180 calendar days of receipt of the notice of a favorable decision.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 Subparts B through D of this chapter.

(4) A favorable ALJ or attorney adjudicator decision is considered binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of an ALJ or attorney adjudicator decision in § 405.980(d) and (e) apply in the same manner to favorable ALJ or attorney adjudicator decisions issued under this section.

(5) The notice of a favorable decision issued to a hospital and, as applicable, notice of a favorable or partially favorable decision sent to a SNF does not convey party status to such provider.

(f) *Effect of an unfavorable or partially favorable ALJ or attorney adjudicator decision*. (1) An unfavorable or partially favorable ALJ or attorney adjudicator decision is considered binding unless—

(i) It is reopened and revised under the provisions of § 405.980(d) or (e); or

(ii) An eligible party (or the party's representative) files a request for Medicare Appeals Council review under § 405.938.

(2) The provisions regarding reopening of an ALJ or attorney adjudicator decision in § 405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

§ 405.938 Review by the Medicare Appeals Council and judicial review.

(a) *Filing a request for Council review*. An eligible party, the party's appointed representative, or an authorized representative who is dissatisfied with the unfavorable decision of an ALJ or an attorney adjudicator in § 405.936(d)(2) may request the Council review the decision within 60 calendar days of receipt of the decision. The request for review must contain the elements specified in the ALJ or attorney adjudicator's decision notice.

(b) *Applicability of other provisions*. The provisions in §§ 405.1100 through 405.1130 that apply to Council review apply to the extent they are appropriate/in the same manner to Council review under this section unless otherwise specified.

(c) *Notice of the Council's action*. (1) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on consideration of additional evidence in § 405.1122, the Council makes a decision or remands the case to an ALJ or attorney adjudicator.

(2) The Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or recommended decision.

(3) Notice of the Council's decision or remand order is issued to the eligible party (or the party's representative).

(i) In the case of a modification or reversal of the ALJ's or attorney adjudicator's decision that is favorable to the eligible party, the Council's decision includes information regarding the effect of such decision, including, as applicable, a statement about the obligation of the SNF to refund any amounts collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) for services covered under Part A in order to determine the amount of benefits due.

(ii) If the appeal involves a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, a modification or reversal of the ALJ's or attorney adjudicator's decision that is favorable to the eligible party with respect to hospital services also includes a statement about the obligation of

the hospital to refund any amounts collected for the outpatient hospital services, and that the hospital may then submit a new claim for covered inpatient hospital services in order to determine the amount of benefits due.

(iii)(A) If the Council adopts or modifies an ALJ or attorney adjudicator decision that is unfavorable or partially favorable to the eligible party, the decision includes information about the procedures for filing a request for judicial review under § 405.1136, including information regarding the amount in controversy requirement in § 405.936(c).

(B) A partially favorable decision issued by the Council refers to a determination that the inpatient admission satisfied the relevant criteria for Part A coverage but the SNF services did not satisfy the relevant criteria for Part A coverage.

(4) Notice of a Council decision, favorable or partially favorable to the eligible party, that modifies or reverses the decision or recommended decision by an ALJ or attorney adjudicator, or a remand order that is favorable to the eligible party, is issued to the SNF, as applicable, and to the hospital in the case of an appeal filed by, or on behalf of, a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of hospitalization.

(i)(A) Notice issued to the SNF includes information regarding the effect of such decision, including, as applicable, a statement explaining that the SNF must refund any payments collected from the beneficiary for the covered SNF services, and that the SNF may then submit a new claim(s) to determine the amount of benefits due for the covered services.

(B) A decision that is partially favorable to the eligible party is sent to the SNF and explains the reason the hospital admission satisfied the relevant criteria for Part A coverage at the time the services were furnished, the reason the SNF services did not satisfy the relevant criteria for Part A coverage and explains that the decision is being sent for informational purposes only.

(ii) Notice issued to a hospital (in the case of an appeal filed by, or on behalf of, a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of hospitalization) includes information regarding the effect of such decision, including a statement explaining that the hospital must refund any payments collected for the outpatient hospital services, and that the hospital may then submit a new Part A inpatient claim in order to determine the amount of benefits due for covered services.

(5) The timeframe within which notices must be sent under this paragraph are determined under the provisions in § 405.1100.

(d) *Effect of a favorable Council decision*. (1)(i) If the Council issues a decision that the beneficiary's inpatient admission satisfied the relevant criteria for Part A coverage and the hospital's decision to change the inpatient admission to outpatient receiving observation services was therefore erroneous, the beneficiary's reclassification as an outpatient is disregarded for the purposes of determining Part A benefits, including both Part A hospital coverage and Part A SNF coverage, if applicable.

(ii) For the purposes of effectuating a favorable decision by the Council, any claims previously submitted for outpatient hospital services and payments made for such services (including any applicable deductible and coinsurance amounts) are not reopened or revised by the MAC, and payment, as applicable, for covered SNF services may be made by the MAC to the SNF without regard to the hospital claim.

(2) In order to determine Part A benefits to be paid and to make payment for covered services as a result of a favorable decision, as applicable--

(i) The SNF, that furnished services to the beneficiary must refund payments previously collected from the beneficiary for the covered services and may then submit a Part A claim(s) for such services within 180 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of an appeal for a beneficiary not enrolled in the Supplementary Medical Insurance program (Medicare Part B) at the time of the beneficiary's hospitalization, the hospital

that furnished services must refund any payments collected for the outpatient hospital services and may then submit a Part A inpatient claim for such services within 180 calendar days of receipt of the notice of a favorable decision.

(3) The hospital, and as applicable, the SNF, must comply with all applicable provisions regarding charges to the beneficiary for covered services, including but not limited to relevant provisions in part 489 Subparts B through D of this chapter.

(4) A favorable Council decision is considered final and binding unless it is reopened and revised under the provisions of §§ 405.980 through 405.986. The provisions regarding reopening of a Council decision in § 405.980(d) and (e) apply in the same manner to favorable Council decisions issued under this section.

(5) The notice of a favorable decision issued to a hospital and, as applicable, notice of a favorable or partially favorable decision issued to SNF does not convey party status to such provider.

(e) *Effect of an unfavorable or partially favorable Appeals Council decision*. (1) An unfavorable or partially favorable Appeals Council decision is considered final and binding unless it is reopened and revised under the provisions of § 405.980(d) or (e), or a Federal district court issues a decision modifying the Council's decision.

(2) The provisions regarding reopening of an Appeals Council decision in § 405.980(d) and (e) apply in the same manner to unfavorable and partially favorable decisions issued under this section.

(f) *Judicial review.* (1) An eligible party (or the party's representative) dissatisfied with a final and binding decision under paragraph (e) of this section who satisfies the amount in controversy requirement in § 405.936(c) may request judicial review in Federal district court under the procedures set forth in § 405.1136.

(2) An eligible party (or the party's representative) who satisfies the amount in controversy requirement in § 405.936(c) and the requirements to escalate a case from the

Council in § 405.1132 may request judicial review in Federal district court under the procedures set forth in § 405.1136.

3. The heading of subpart J is revised to read as follows:

Subpart J-- Procedures and Beneficiary Rights for Expedited Determinations and Reconsiderations when Coverage is Changed or Terminated

4. Add §§ 405.1210, 404.1211, and 405.1212 to read as follows:

§ 405.1210 Notifying eligible beneficiaries of appeal rights when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1210 through 405.1212, the term "hospital" is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non-acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition includes critical access hospitals (CAHs).

(2) For purposes of §§ 405.1210 through 405.1212, the change in status occurs when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services (as defined in § 405.931(h)).

(3) For purposes of §§ 405.1210 through 405.1212, a beneficiary is eligible to pursue an appeal regarding a change in status when the beneficiary meets all the following:

(i) Was formally admitted as a hospital inpatient in accordance with an order for inpatient admission by a physician or other qualified practitioner.

(ii) Was subsequently reclassified by the hospital as an outpatient receiving observation services after the admission.

(iii)(A) Was not enrolled in Part B coverage at the time of the beneficiary's hospitalization; or

(B) Stayed at the hospital for 3 or more consecutive days but was classified as an inpatient for fewer than 3 days.

(iv) The period "3 or more consecutive days" is counted using the rules for determining coverage of SNF services under section 1861 of the Act and § 409.30 of this chapter (that is, a beneficiary must have a qualifying inpatient stay of at least 3 consecutive calendar days starting with the admission day but not counting the discharge day).

(b) *Advance written notice of appeal rights.* For all eligible beneficiaries, hospitals must deliver valid, written notice of an eligible beneficiary's' right to pursue an appeal regarding the decision to reclassify the beneficiary from an inpatient to an outpatient receiving observation services. The hospital must use a standardized notice specified by CMS in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice not later than 4 hours before release from the hospital and as soon as possible after the earliest of either of the following:

(i) The hospital reclassifies the beneficiary from an inpatient to an outpatient receiving observation services and the beneficiary is not enrolled in Part B.

(ii) The hospital reclassifies the beneficiary from an inpatient to an outpatient receiving observation services and the beneficiary has stayed in the hospital for 3 or more consecutive days but was an inpatient for fewer than 3 days.

(2) *Content of the notice.* The notice must include the following information:

(i) The eligible beneficiary's' change in status and the appeal rights under §405.1211 if the beneficiary wishes to pursue an appeal regarding that change.

(ii) An explanation of the implications of the change in status, including the potential change in beneficiary hospital charges resulting from a favorable decision, and subsequent eligibility for Medicare coverage for SNF services.

(iii) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of appeal rights described in this section is valid if --

(A) The eligible beneficiary (or the eligible beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents and except as provided in paragraph (b)(4) of this section; and

(B) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

(4) *If an eligible beneficiary refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

§ 405.1211 Expedited determination procedures when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Beneficiary's right to an expedited determination by the QIO.* An eligible beneficiary has a right to request an expedited determination by the QIO when--

(1) A hospital changes a beneficiary's status from an inpatient to an outpatient receiving observation services; and

(2) The beneficiary meets other eligibility criteria as specified in §405.1210(a)(3).

(b) *Requesting an expedited determination.* (1) A eligible beneficiary who wishes to exercise the right to an expedited determination must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made in writing or by telephone before release from the hospital.

(2) The eligible beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The eligible beneficiary may, but is not required to, submit written evidence to be considered by the QIO in making its decision.

(4) An eligible beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the billing protection under paragraph (e) of this section, as applicable.

(5) An eligible beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, may still request an expedited QIO determination at any time. The QIO issues a decision in accordance with paragraph (c)(ii) of this section, but the coverage protection under paragraph (e) of this section does not apply.

(c) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 405.1210(b)(3).

(3) The QIO examines the medical and other records that pertain to the change in status.

(4) The QIO must solicit the views of the eligible beneficiary (or the eligible beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the reclassification of the beneficiary from an inpatient to an outpatient receiving observation services is appropriate.

(6) The following timeframes apply for the QIO's decision when an eligible beneficiary requests --

(i) A timely expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination within 1 calendar day of receiving all requested pertinent information specified in paragraph (d)(1)(i) of this section; or

(ii) An untimely request for a QIO expedited determination, the QIO must make a determination within 1 calendar day after the QIO receives all requested information specified in paragraph (d)(1)(i) of this section.

(7) If the QIO does not receive the information needed to make its decision, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information.

(8) When the QIO issues an expedited determination, the QIO must notify the eligible beneficiary, the hospital, and SNF (if applicable) of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination.

(iv) Information about the eligible beneficiary's right to an expedited reconsideration of the QIO's determination as set forth in § 405.1212, including how to request a reconsideration and the time period for doing so.

(d) *Responsibilities of hospitals.* (1)(i) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notice as required in § 405.1210(b) of this section.

(ii) The hospital must furnish this information as soon as possible, but no later than by noon of the calendar day after the QIO notifies the hospital of the request for an expedited determination.

(iii) At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(2)(i) At an eligible beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone.

(ii) The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation or delivering or both it to the beneficiary.

(iii) The hospital must accommodate such a request by no later than close of business of the first calendar day after the material is requested.

(e) *Billing during QIO expedited review*. When an eligible beneficiary requests an expedited determination in accordance with paragraphs (b)(1) through (b)(4) of this section, the hospital may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

(f) *Effect of an expedited QIO determination.* The QIO determination is binding for payment purposes upon the eligible beneficiary, hospital, and MAC, except if the eligible beneficiary is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 405.1212.

§ 405.1212 Expedited reconsideration procedures regarding Part A coverage when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

(a) *Beneficiary's right to an expedited reconsideration.* An eligible beneficiary who is dissatisfied with a QIO's expedited determination per § 405.1211(c)(6) may request an expedited reconsideration by the QIO identified in the written notice specified in §405.1211(c)(8)(iv).

(b) *Requesting an expedited reconsideration.* (1) An eligible beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIO, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone or in writing) after receipt of the QIO's determination.

(2) The eligible beneficiary, or his or her representative, must be available to answer questions or supply information that the QIO may request to conduct its reconsideration.

(3) The eligible beneficiary may, but is not required to, submit evidence to be considered by the QIO in making the reconsideration.

(4) An eligible beneficiary who makes a timely request for an expedited reconsideration in accordance with paragraph (b)(1) of this section is subject to the billing protection under paragraph (e) of this section, as applicable.

(5) An eligible beneficiary who fails to make a timely request for an expedited reconsideration by a QIO, as described in paragraph (b)(1) of this section, may still request an expedited QIO reconsideration at any time. The QIO issues a reconsideration in accordance with paragraph (c)(3)(ii) of this section, but the billing protection under paragraph (e) of this section does not apply.

(c) *Procedures and responsibilities of the QIO.* (1) On the day the QIO receives the request for an expedited reconsideration under paragraph (b) of this section, the QIO must immediately notify the hospital of the request for an expedited reconsideration.

(2) The QIO must offer the eligible beneficiary and the hospital an opportunity to provide further information.

(3) When the eligible beneficiary makes --

(i) A timely request from in accordance with paragraph (b)(1) of this section, the QIO must make a reconsideration determination within 2 calendar days of receiving all requested pertinent information; or

(ii) An untimely request, the QIO must make a reconsideration determination within 3 calendar days of receiving all requested pertinent information.

(4) When the QIO issues an reconsideration determination, the QIO must notify the eligible beneficiary, the hospital, and SNF, if applicable, of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination.

(iv) Information about the eligible beneficiary's right to appeal the QIO's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(d) *Responsibilities of the hospital.* A hospital may, but is not required to, submit evidence to be considered by a QIO in making its reconsideration decision. If a hospital fails to comply with a QIO's request for additional information beyond that furnished to the BFCC-QIO for purposes of the expedited determination, the QIO makes its reconsideration decision based on the information available.

(e) *Billing during QIO reconsideration.* When an eligible beneficiary requests an expedited reconsideration in accordance with the deadline specified in paragraph (b)(1) of this section, the hospital may not bill the beneficiary for any disputed services until the QIO makes its reconsideration decision.

(f) *Effect of an expedited QIO reconsideration.* The QIO expedited reconsideration is binding for payment purposes only, upon the eligible beneficiary, hospital, and MAC, except if a beneficiary elects to request a hearing by an ALJ in accordance with 42 CFR part 478 subpart B if he or she is dissatisfied with the expedited reconsideration decision.

PART 476 – QUALITY IMPROVEMENT ORGANIZATION REVIEW

5. The authority citation for part 476 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

6. Section 476.71 is amended by adding paragraph (a)(9) to read as follows:

§ 476.71 QIO review requirements.

(a) * * *

(9) Hospital reclassification of a beneficiary's inpatient admission status to that of an outpatient receiving observation services when a beneficiary meets the eligibility criteria at §§ 405.1210 through 405.1212 of this chapter. Appeals of determinations are available as specified in § 405.1212(f) of this chapter.

* * * * *

PART 489 -- PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

7. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

8. Section 489.27 is amended by revising the section heading and paragraph (b) to read as follows:

§ 489.27 Beneficiary notice of discharge or change in status rights.

* * * * *

(b) *Notification by hospitals and other providers*. Hospitals and other providers (as identified at §489.2(b)) that participate in the Medicare program must furnish each Medicare beneficiary, or representative, applicable CMS notices in advance of discharge, termination of Medicare services, or of changes from inpatient to outpatient status, including the notices required under §§ 405.1200, 405.1202, 405.1206, 405.1210, and 422.624 of this chapter.

Dated: December 18, 2023.

Xavier Becerra,
Secretary,
Department of Health and Human Services.

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