DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 476, and 489

[CMS–4204–F]

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: Final rule.

SUMMARY: This final rule implements 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: These regulations are effective on October 11, 2024.

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:

I. Executive Summary

The purpose of this final 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 processes will 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 processes consist of the following:

- *Expedited appeals:* We are establishing 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 will be entitled to request an expedited appeal regarding that decision prior to release from the hospital. Appeals will be conducted by a Beneficiary & Family Centered Care—Quality Improvement Organization (BFCC–QIO).
- *Standard appeals:* Beneficiaries who do not file an expedited appeal will 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). 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 establishing 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, 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. Eligible beneficiaries will have 365 calendar days from the implementation date of this rule to file a request for a retrospective appeal. We will announce the implementation date on *CMS.gov* and/or *Medicare.gov.*

In general, as explained in this final rule, we are finalizing the procedures for these appeals as proposed. However, we are making some editorial/technical corrections to the regulations text, as well as several revisions and clarifications to the retrospective appeal procedures based on the public comments we received. These revisions include:

- Extending the timeframe for providers to submit a claim following a favorable decision from 180 calendar days to 365 calendar days.
- Extending the timeframe for providers to submit records as requested by a contractor from 60 calendar days to 120 calendar days.
- Clarifying the effect of a favorable appeal decision to explain that if a hospital chooses to submit a Part A inpatient claim, the hospital must refund any payments received for the Part B outpatient claim before submitting the Part A inpatient claim to Medicare. If a Part A claim is submitted, the previous Part B outpatient claim will be reopened and canceled, and any Medicare payments will be recouped to prevent duplicate payment.
- Clarifying the effect of a favorable decision for a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization to explain that the hospital must refund any payments collected for the outpatient services even if the hospital chooses not to submit a Part A claim for payment to the program.
- Clarifying the effect of favorable appeals involving beneficiaries who were enrolled in Medicare Part B at the time of hospitalization to explain that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services.
- Clarifying that out-of-pocket payments made by a family member on behalf of a beneficiary for SNF services (for the purpose of determining whether those SNF services are eligible for inclusion in an appeal under these procedures), may include out-of-pocket payments made by individuals who are not biologically related to the beneficiary (for example, a close family friend, roommate, or a former spouse).

II. Background

This rule finalizes a proposal issued in December 2023 [1] and 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 or otherwise qualified practitioner [2] but whose status during

[1] 88 FR 89506.

[2] As discussed in section III.A.1. of this final rule in response to a public comment, we acknowledge that under existing policies, for purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital if formally admitted as an inpatient pursuant to an order for hospital inpatient admission by a physician or certain qualified practitioners as defined in 42 CFR 412.3. We inadvertently omitted other qualified practitioners when describing the inpatient admission process and have revised our language in this final rule accordingly, when referencing persons ordering hospital inpatient admissions.

their stay is changed to outpatient by the hospital, thereby effectively denying Part A coverage for their hospital stay.[3] 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 final rule.

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''; [4]
- Have received or will have received an initial determination or Medicare Outpatient Observation Notice (MOON) [5] 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 SNF. 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.
- 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 or otherwise qualified practitioner'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 court stated that it intended to provide a meaningful opportunity for class members whose due process rights were violated to appeal the denial of Part A coverage, but it also stressed the need to provide a remedy for class members who endured undercompensated stays at skilled nursing facilities. It further stated that, since class members with Part B coverage had much of their past hospital stays paid for by such coverage, it 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 final rule, we describe the procedures that will 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 final rule, we describe the expedited and standard appeals procedures that will 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 (the ''prospective appeals process'').

Eligible beneficiaries who are hospitalized and entitled to an appeal under these procedures prior to the implementation date of the prospective appeals process will be able to utilize the retrospective appeals process, subject to the filing limitation proposed in § 405.932(a)(2)(i)(B).

The flowcharts below depict the overall appeals processes being finalized in this regulation. With the exception of some editorial revisions and updating the amount in controversy requirements for calendar year 2025 ($190 for an Administrative Law Judge hearing and $1,900 for judicial review), the flowcharts are the same as what was outlined in the proposed rule (88 FR 59509).

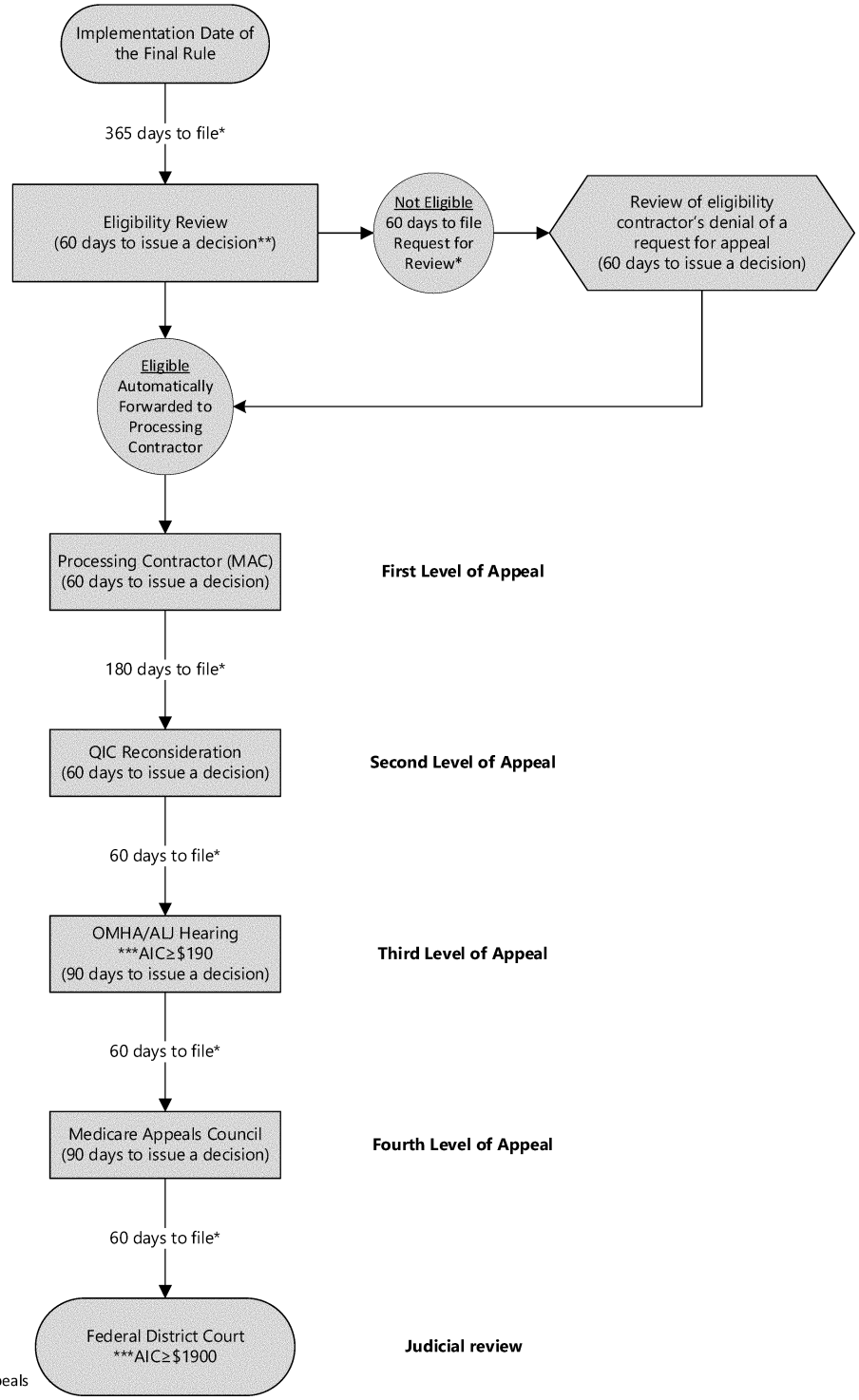
BILLING CODE 4120–01–P

[3] The terms of the court order refer to denials of Part A coverage. Consistent with the court order, the appeals processes in this rule do not extend to enrollees in MA plans. MA 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 has refused to authorize an inpatient admission, the enrollee may request a standard or expedited plan reconsideration of that organization determination (42 CFR 422.566(b), 422.580 through 422.596, and 422.633).

[4] For the purposes of 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 (see 42 CFR 405.931(h)).

[5] 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.cms.gov//medicare/forms-notices/beneficiary-notices-initiative/ffs-ma-moon.*

Retrospective Review Process

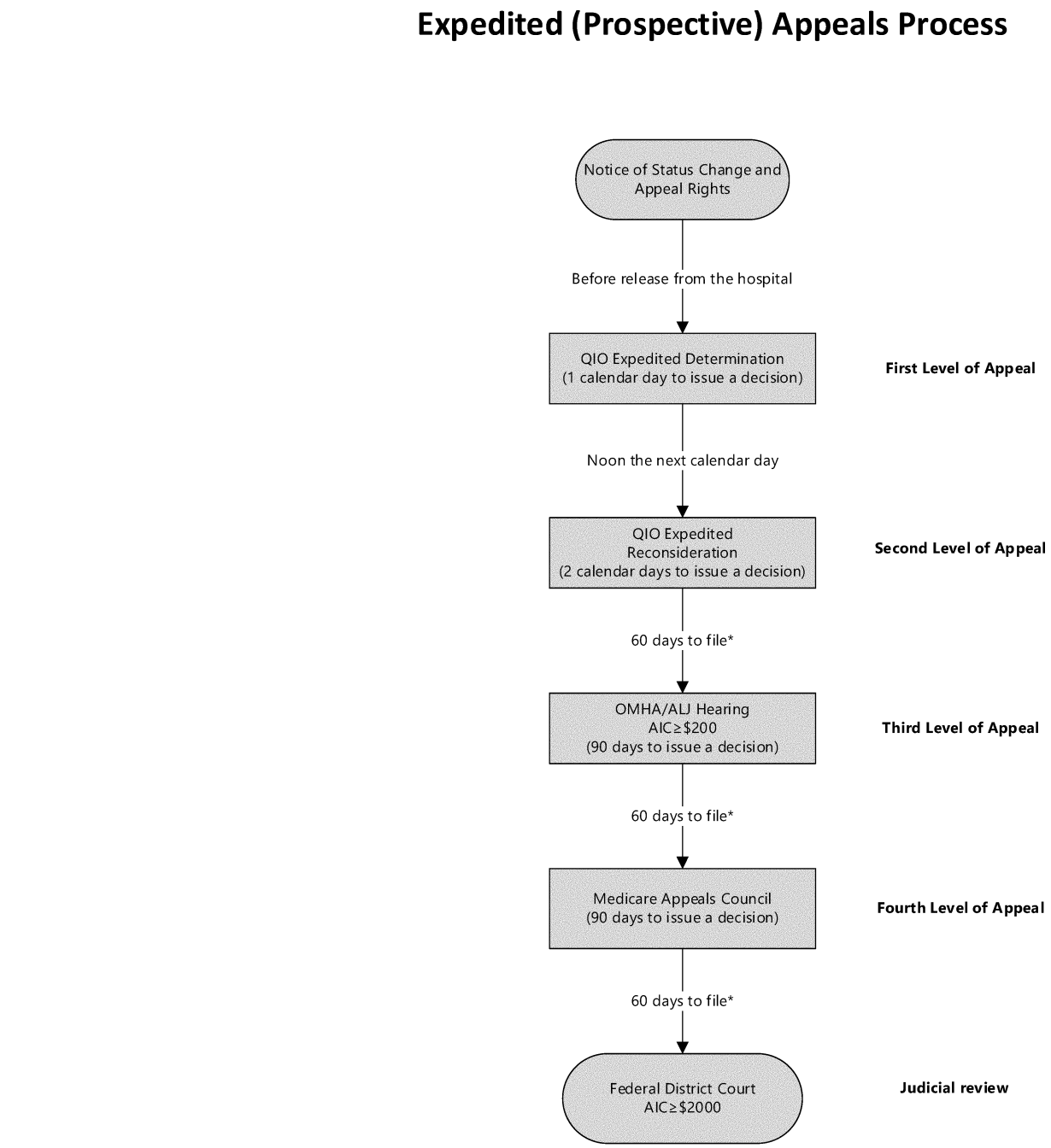


AIC = Amount In Controversy
ALJ = Administrative Law Judge
MAC = Medicare Administrative Contractor
OMHA = Office of Medicare Hearings and Appeals
QIC = Qualified Independent Contractor

*Filing deadlines are calendar days from date of receipt of the notice/decision (presumed to be 5 days from the date of the notice, unless evidence to the contrary).

**Eligibility determination timeframes may be longer if additional documentation is required (such as medical records or claims information).

***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 2025, and is subject to change each calendar year.



AIC = Amount In Controversy
ALJ = Administrative Law Judge
OMHA = Office of Medicare Hearings and Appeals
QIO = Quality Improvement Organization, a.k.a. Beneficiary Family Centered Care (BFCC-QIO)
*Filing deadlines are calendar days from date of receipt of the notice/decision (presumed to be 5 days from the date of the notice, unless evidence to the contrary).
NOTE: The Amount In Controversy for an ALJ Hearing and Judicial Review is not adjusted annually under Section 1155 of the Social Security Act.

BILLING CODE 4120–01–C

In the sections that follow, we provide an overview of the different appeal processes and describe the proposed provisions, the comments received on those provisions, and our response to those comments. We then indicate whether we are finalizing the provisions as proposed or with modifications.

III. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

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.[6] 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 proposed 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).

In § 405.931(b), we proposed 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 proposed 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 they meet the definition of a class member and is not eligible for an appeal, or the appeal request is not otherwise valid), we proposed 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), we proposed 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 otherwise proposed in § 405.932.

In § 405.934, we proposed 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 proposed that the QICs would generally utilize existing procedures that govern reconsiderations (42 CFR 405.960 through 405.978), as appropriate, except as we otherwise proposed in § 405.934.

Following a reconsideration, in § 405.936 we proposed 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.[7] In § 405.936(c), we proposed 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 proposed 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 proposed 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 would have afforded eligible beneficiaries ample time to gather necessary documentation in anticipation of filing appeal requests.

We received many comments in support of the overall process we proposed for retrospective appeals. In addition, we received several general comments on the scope and proposed procedures for the retrospective appeals process and several comments on the outreach efforts we proposed.

Comment: A commenter expressed concern that due to the length of the entire retrospective appeal process, eligible parties could experience delays in receiving coverage decisions for up to a year or more.

Response: We appreciate the concerns raised by the commenter. We

[6] 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.

[7] The amount in controversy requirement for CY 2025 is $190 for a hearing before an Administrative Law Judge, and $1,900 for judicial review. Notice of the updated minimum amounts for each 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.*

understand that beneficiaries and their families, in some cases, have waited for many years to access an appeals process for the issues addressed in these procedures. As we explained in the proposed rule, the new appeals procedures ordered by the court do not fit neatly into existing processes, but to the extent possible, we are mirroring existing appeals processes for these new appeals. This relative consistency in the processes will benefit individuals filing appeals as well as our contractors who process appeals. In some cases, decisions can be made in less time than the deadlines prescribed in the regulations. We believe these timeframes, which have been in place for existing appeals for 15 years, are reasonable and balance the need to resolve complex issues with the interests of appellants in receiving timely decisions.

Comment: A commenter requested that CMS clarify whether these new appeals procedures apply to persons enrolled in Medicare Advantage (MA) plans and consider extending these rights to the MA program.

Response: The retrospective appeals process (addressed in section III.A. of this final rule) and the prospective appeals process (addressed in section III.B. of this final rule) do not apply to the MA program and will not be available for MA enrollees. As we explained in the proposed rule, the terms of the court order refer to denials of Part A coverage. Consistent with the court order, we are creating a new appeals process for beneficiaries enrolled in Original Medicare. We further explained that the appeals processes proposed in this rule do not extend to enrollees in MA plans because we have determined that the considerations underlying the protections ordered by the court for beneficiaries enrolled in Original Medicare do not apply to MA plan enrollees. MA enrollees have rights and protections as set forth in 42 CFR part 422 Subpart M. Under the MA regulations at 42 CFR 422.566(b)(3), an MA plan's refusal 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 plan is an organization determination. If an MA plan enrollee disagrees with a plan's organization determination, the enrollee has the right to request a reconsideration of that decision under the rules at § 422.578. In the event an MA plan refuses to authorize an inpatient admission, this is an adverse organization determination and the enrollee may request a standard or expedited plan reconsideration (§§ 422.580 through 422.590, 422.633). If an MA plan upholds an adverse decision at the reconsideration level, the case is automatically sent to the Part C IRE for review (§§ 422.592 and 422.594). Additional levels of appeal that may be available to an MA enrollee include ALJ and Council review and judicial review (§§ 422.600 through 422.612). Because of these existing rights and protections afforded to MA enrollees, we did not propose any new procedures applicable to MA enrollees. To the extent we identify additional processes that may be necessary for the MA program, any such proposals would be subject to full public discussion through notice and comment rulemaking.

Comment: A commenter requested that we use ''provider-neutral language'' throughout the rule, for example, instead of using physician, we should consider using physician or otherwise qualified practitioner.

Response: We appreciate the suggestion from this commenter. We have reviewed the language in the proposed rule and found several instances where it would be more appropriate to use the phrase ''physician or other qualified practitioner'' consistent with the regulatory provisions regarding inpatient admissions in 42 CFR 412.3(a). We will use this terminology going forward.

Comment: A commenter requested that we amend the text of several sections of the proposed codified regulations text to include the word ''shall'' to strengthen and emphasize required actions.

Response: We appreciate the suggestion by the commenter. We drafted the regulation text for these new procedures to be consistent with existing regulation text in 42 CFR part 405 Subpart I. Those provisions also include required actions for contractors, but generally use ''must'' rather than ''shall'' to indicate a requirement. We reviewed the proposed regulation text and did not identify language that was vague or did not clearly indicate a requirement where we intended a requirement. Thus, we are not adopting the recommendations made by the commenter.

Comment: Many commenters expressed their support for the outreach and education that we plan to conduct following the issuance of the final rule as we implement these procedures. Commenters suggested additional means of educating beneficiaries and their representatives on the new appeal rights offered in this rule. For example, commenters recommended we include information in the Medicare & You handbook and with Medicare Summary Notices (MSNs) while the filing period is open and create new materials available to beneficiaries and advocates such as social workers and State Health Insurance Assistance Program (SHIP) counselors. Commenters also suggested that we provide translations of these materials into various languages.

Response: We appreciate the support of these commenters on our general approach to conducting education and outreach related to these new appeals procedures. We are committed to providing educational and training materials on our website for advocates to reference and provide to beneficiaries. We are also committed to creating new documents and publications, as well as updating current publications such as Medicare & You, that may be downloaded from *Medicare.gov* and/or *CMS.gov.* This includes the translation of materials into different languages as needed. We intend to train and provide information to customer service representatives at 1–800–MEDICARE to assist and inform beneficiaries with questions about these procedures. We also intend to provide information to SHIP counselors and other advocacy groups in providing updates on new and emerging programs in Medicare, such as these new appeal rights.

In addition, we will include a message regarding this new appeal right on beneficiary MSNs. This message will refer beneficiaries to the detailed information that will be included on *Medicare.gov* and/or *CMS.gov.*

Comment: A commenter suggested that we extend the date of receipt of notices or decisions sent by the eligibility contractor, processing contractor or other appeals adjudicators, to 30 calendar days following receipt of the notice.

Response: We appreciate the comment. Our longstanding policy presumes receipt of a notice in the appeals process is 5 calendar days after the date of the notice. We adopted this policy for these new retrospective appeals as we intended the process for these new appeals to mirror existing processes as much as possible. This presumption is rebuttable if the appellant can establish receipt outside of the 5-day window. The reason for this longstanding presumption is to account for the time between the printing and mailing of the notice receipt by the appellant and because filing timeframes at subsequent levels of appeal begin upon receipt of the decision at the previous level. Our longstanding experience is that this 5-day window for

receipt is generally consistent with postal delivery timeframes. We do not believe the time between mailing the notice and receipt would be as long as 30 calendar days. Thus, we are not adopting the recommendation made by the commenter.

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) we proposed 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 proposed 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 proposed to apply existing rules regarding appointed representatives and authorized representatives (see §§ 405.902 and 405.910) to these new appeals.[8] 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 proposed 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 proposed to exclude providers from representing beneficiaries in these new appeals, and we proposed to prohibit the assignment of appeal rights to providers as well. Since the decision to change a patient's status is made by the hospital, we had concerns that the interests of a class member could conflict with the interests of a hospital or SNF, and we were 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 had 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,[9] 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 believed 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.

We proposed 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 proposed 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 authorized representative as defined in § 405.902; [10] or (3) has appointed as its representative, a member of the beneficiary's family, a legal guardian, or

[8] 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.

[9] 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.

[10] 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 believed it was reasonable to treat appeals filed by authorized representatives, like other existing claim appeals filed by family members (that is, as if the appeal was filed by an unrepresented beneficiary).

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 also proposed 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 proposed 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 proposed 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 explained that for the purposes of determining eligibility for an appeal under these procedures, a beneficiary would be 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.

We received several comments regarding eligibility requirements for an appeal under these procedures and several comments regarding the limitation on provider representation of eligible parties.

Comment: A few commenters questioned the MOON being a determining factor for eligibility for an appeal under the new procedures. A commenter noted that the MOON was established in August 2015, but retroactive appeals are available to eligible beneficiaries with hospital admissions starting on January 1, 2009. Another commenter suggested that the proposed regulation in § 405.931(b) defining an eligible party requires the delivery of the MOON as a condition of eligibility for a retrospective appeal.

Response: We appreciate the commenter's observations regarding the implementation date of the MOON and the eligibility criteria under these appeal procedures. The federal district court order and our definition of an eligible party states that receipt of either an initial determination or a MOON would serve to meet one condition of eligibility for an appeal under these new procedures. For hospitalizations that predate the effective date of the MOON, a beneficiary's receipt of an initial determination for their hospital and/or SNF claim (that is, a Medicare Summary Notice resulting from processing a claim submitted by a provider) would serve to meet the requirement.

Comment: A commenter sought clarification on whether a beneficiary must receive observation services after the change in status from inpatient to outpatient in order to be eligible for an appeal under these new procedures.

Response: We appreciate the opportunity to provide this clarification. A beneficiary must receive observation services after the change in status from inpatient to outpatient in order to be eligible for an appeal under these new procedures. As explained in the proposed rule, consistent with the court order, the class members who are to be afforded an opportunity to appeal the denial of their Part A coverage include Medicare beneficiaries who, on or after January 1, 2009, have been or will have been subsequently reclassified by the hospital as an outpatient receiving observation services, and meet the other conditions specified in the order (88 FR 89506 (December 27, 2023)). We further stated in the proposed rule that, 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 (88 FR 89506).

Comment: Several commenters stated that the proposed rule does not address how beneficiaries who are eligible for a retrospective appeal will be identified and receive notice of the new appeal procedures that are available. A commenter suggested that CMS utilize claims data, hospital records, or beneficiary reports to identify eligible parties.

Response: We appreciate the commenter's suggestions. We considered this issue as we assessed how to implement the court order and determined that it would not be feasible to proactively identify eligible parties. Unfortunately, the claims data available to us do not align precisely with the eligibility criteria for these new appeals procedures. For example, the outpatient claim submitted by a hospital would not provide any indication of when observation services were furnished to a beneficiary. Thus, we could not discern between a beneficiary who received observation services prior to the inpatient admission (who would not meet eligibility criteria) and a beneficiary who received observation services after the change in status from inpatient to outpatient simply based on claims information. This aspect of eligibility for an appeal would only be available after a review of medical records, and we believe it would be inefficient and ineffective to request and review medical records for all potentially eligible beneficiaries (estimated to be over 32,000) in order to identify those beneficiaries who are, in fact, eligible for an appeal. Such attempts would cause undue burden on the program and would delay appeals due to the volume of records requests and resources needed to review every medical record. Instead, we will rely on education and outreach to alert beneficiaries to the availability of these new appeal procedures and the eligibility requirements to access these appeals established in this final rule.

Comment: A commenter questioned whether beneficiaries who were not enrolled in Medicare Part B at the time of their hospitalization but had other insurance coverage to cover outpatient services (such as a group health plan) would be eligible for an appeal.

Response: A beneficiary not enrolled in Medicare Part B who meets all stated eligibility criteria would be eligible for an appeal under these new procedures, even if the beneficiary had other insurance coverage that covered Part B outpatient hospital services. We would expect such appeals would be rare and would likely focus on noncovered SNF services that resulted in out-of-pocket expenditures by the beneficiary.

Comment: A few commenters disagreed with our limitation on provider representation for these new appeals as proposed in § 405.931. Generally, these commenters were concerned about the lack of support for beneficiaries to work through these appeals. A commenter stated that beneficiaries sometimes rely on provider staff to understand benefits and available coverage and requested clarification regarding whether provider staff may provide information and assistance to beneficiaries filing appeals. A commenter stated that SNFs should be able to file appeals on behalf of beneficiaries since SNFs have the motivation to ensure that they receive proper payment for the services they provide. A commenter expressed support for the definition of an unrepresented beneficiary and the rights it will extend to beneficiaries under 42 CFR part 405 subpart I.

Response: We appreciate the concerns raised by these commenters. While we generally agree that providers may provide valuable assistance to beneficiaries seeking appeals of denied services under existing procedures, we believe that in these new appeals, the circumstances warrant a different approach to appointed representatives. We note that beneficiaries entitled to an appeal under these new rules still have many options for obtaining assistance in their appeal. For example, friends and family members are eligible to be appointed as a representative. In each state, state health insurance assistance programs (SHIPs) are available to explain coverage and benefits and to represent and assist beneficiaries in appeals. Private advocacy groups are also available to assist and represent beneficiaries in Medicare appeals. Staff employed by providers may also assist beneficiaries by providing them with information and support in their appeals. These are just a few illustrative examples of persons and groups that may be available to assist beneficiaries, and we do not believe that precluding providers from representing beneficiaries for services, in some cases, furnished many years ago, will have a negative impact on beneficiary access or representation in these new appeals.

As explained in the proposed rule, we are concerned about a provider acting as the appointed representative of a beneficiary in these new appeals. Appointed representatives play a significant role in a beneficiary's appeal. The representative is responsible for submitting forms, receiving and submitting information on behalf of the beneficiary, and making arguments on behalf of the beneficiary. While an appointed representative is acting on behalf of a beneficiary, the representative exercises control over most aspects of the appeal. In many of the appeals we expect under these new procedures, beneficiaries or family members reimbursed SNFs for the care that was furnished to the beneficiary. In some of these cases, we believe a SNF's interests could be at odds with the interest of the beneficiary. For example, a SNF could be motivated by maintaining the status quo with respect to payment already received for services in light of the burden associated with refunding payments and billing the Medicare program for payment for services furnished as many as 15 years earlier. We believe restricting formal provider representation in the appeals process, given the broad availability of other resources, affords beneficiaries the best opportunity for independent and unbiased assistance, if needed. While a provider may not act as an appointed representative for a beneficiary under these procedures, we believe it would be entirely appropriate for providers to lend assistance to beneficiaries in providing records, information, and advice about the appeal and the appeal process. Thus, we are not adopting the recommendation to allow providers to be appointed as a representative for an eligible party.

We would also like to clarify the scope of our proposal in adding a definition to the term unrepresented beneficiary in § 405.931(d)(5) for these new appeal procedures. As proposed in § 405.931(d)(5), a beneficiary who is an eligible party is considered unrepresented if the beneficiary meets one of several criteria specified in that section. As we explained in the introductory paragraph of § 405.931(d), the policies established in that section are for the limited purposes of these new appeal procedures, that is, appeals conducted under §§ 405.931 through 405.938. We did not intend to apply the definition of unrepresented beneficiary in § 405.931(d)(5) to claim appeals conducted under existing 42 CFR part 405 subpart I. The purpose in adding this definition is to help eligible parties who are considered unrepresented understand how certain existing procedural requirements, adopted for these new procedures, will apply. For example, in § 405.1018, there are specific requirements regarding the submission of evidence at an ALJ hearing that do not apply to an unrepresented beneficiary. For the purposes of appeals conducted under §§ 405.931 through 405.938, those requirements will not apply to an unrepresented beneficiary as defined in § 405.931(d)(5).

We appreciate the feedback that we received from commenters on eligibility requirements and policies regarding appointed representatives. Based on analysis of the public comments, we will be finalizing the proposals related to such procedures as proposed.

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

In § 405.932, we proposed to channel all retrospective appeal requests from eligible parties through a single point of contact, the eligibility contractor. We proposed, in § 405.932(a)(2) for a retrospective appeal, that the appeal request filed by an eligible party (or their representative) must be received by the eligibility contractor within 365 calendar days from the implementation date of these provisions which would be specified when this rule is finalized. We proposed that details regarding the filing of appeal requests would be posted to *Medicare.gov* and/or *CMS.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 believed 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 anticipated eligible parties (or their representatives) would 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 understood 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 proposed 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 proposed that eligible parties (or their representatives) provide, 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 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. 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 also proposed 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 calendar 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 § 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 proposed 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 did 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.[11] 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 proposed 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 proposed 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 proposed that individuals receiving a notice of denial of an 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 differed 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 was to keep these disputes with the eligibility contractor, requiring review by an individual not involved with the initial denial determination.

We received several comments regarding the proposed filing timeframes and procedures for retrospective appeals, the procedures for eligibility determinations, and the submission of medical records in support of an eligible party's appeal.

Comment: Several commenters recommended CMS extend the filing timeframes for retrospective appeals beyond the period of 1 year following the implementation of the final rule proposed by CMS, citing that beneficiaries may have trouble locating such dated medical records and that the process to determine eligibility could prove to be complex. Commenters varied in their recommendations, some suggested 2 years while another suggested 4 years. Commenters also recommended that CMS apply existing good cause rules that allow for exceptions to appeal filing deadlines.

Response: We believe the 1-year (that is, 365 calendar day) filing timeframe from the implementation date of the final rule affords eligible parties adequate time to submit appeal requests under these new procedures. The 1-year timeframe is twice as long as any other existing timeframe to file an appeal. Moreover, we note that general information regarding the forthcoming right to appeal has been posted on *Medicare.gov* and *CMS.gov* since 2021.[12] We also anticipate providing more detailed information regarding the appeals process online and in Medicare publications, including MSNs, in the time between publication of the final rule and the actual implementation of the provisions. Thus, we believe the time between publication of the final rule and the implementation date, and the 1-year timeframe to file from the implementation date will give eligible parties a reasonable amount of time to compile information necessary for their case, and to file an appeal (and as we explain in this final rule, Medicare contractors will assist in obtaining medical records if the records cannot be submitted with the appeal request). Accordingly, we are not adopting the recommendations made by the commenters to lengthen the filing timeframe for retrospective appeals. (We note that the procedures in § 405.932(a)(2)(ii) include an exception that allows the eligibility contractor to accept an untimely filed appeal request

[11] 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.

[12] See *https://www.medicare.gov/providers-services/claims-appeals-complaints/appeals/original-medicare* and *https://www.cms.gov/medicare/appeals-grievances/fee-for-service.*

if the eligible party establishes good cause under the existing appeal provisions in § 405.942(b)(2) and (3).)

Finally, we are making an editorial revision in § 405.932(a)(2)(ii) to insert the word calendar after the number 365 for clarity and to be consistent with existing language regarding timeframes being measured in calendar days, both in these procedures and in our existing appeals procedures.

Comment: A commenter recommended that CMS create an online portal for the submission of appeal requests and supporting documentation.

Response: We appreciate the recommendation submitted by commenter to create an online portal for the submission of appeal requests and supporting documentation. We considered this option as we began to plan for implementation of this new appeals process, but ultimately found this approach to be impracticable due to a variety of time, cost, and security considerations. The length of development time, testing, and sheer level of effort required to implement a secured beneficiary-facing portal is at odds with the complex security environment and the need to implement these new procedures as quickly as possible. Moreover, we are committed to mirroring existing appeal procedures as much as possible for these new appeals. Therefore, we are not adopting the recommendation made by the commenters. We believe it is appropriate for beneficiary appeal requests to continue to be submitted via mail. CMS will provide clear instructions to beneficiaries on where to mail their requests.

Comment: A commenter suggested that we consider having beneficiaries file appeals with the health plan and have the plan conduct the initial eligibility determination in addition to the appeal. Other commenters supported our proposal to use a single point of contact for receiving appeals and making eligibility determinations.

Response: We appreciate the comments and support for our use of an eligibility contractor. We considered having MACs conduct the appeal intake and make eligibility determinations. However, as we explained in the proposed rule, we are establishing a single point of contact, the eligibility contractor, to receive these new appeals and to make eligibility determinations. We believe a single point of contact will relieve beneficiaries of the burden of determining which MAC would be responsible for performing an appeal under these new procedures. In addition, we believe a single contractor making eligibility determinations will promote consistency in such determinations. Following the determination of eligibility, the processing contractor (the MAC) will conduct the appeal. We also note that, as explained in the proposed rule, these new appeals are limited to beneficiaries in Medicare Part A and B (''Original Medicare''). Claims processing and first level appeals in Original Medicare are conducted by MACs and not health plans. Thus, we are not adopting the recommendation to use a health plan or the MACs to make eligibility determinations.

Comment: Many commenters supported the availability of a model form that could be used to file an appeal request. Commenters suggested that we make the form available in multiple languages, including an ASL interpretation of the form.

Response: We appreciate the support of the commenters regarding our proposal for a model form that beneficiaries may use to submit an appeal request. We plan to translate the form into different languages as needed.

Comment: Several commenters requested that we provide more information about the submission of medical records as part of the retrospective appeal request and what types of records and information would be needed as part of the appeal. Commenters also suggested that we provide eligible parties with instruction about how to seek assistance from the eligibility contractor in obtaining records and suggested other information that we should consider including in our instructions for filing appeal requests (for example, the types of records that would be helpful, the dates spent in the hospital, orders regarding admission and care, etc.).

Response: We appreciate the recommendations submitted by commenters for the content of instructions related to filing appeal requests. We intend to carefully consider these recommendations for the online educational materials we intend to publish prior to implementation of the new procedures. We agree that as part of our educational efforts, it will be helpful to provide beneficiaries with information about the types of records needed for these new appeals and suggestions for how to get access to them.

We would like to emphasize, as we did in the proposed rule, that we strongly encourage beneficiaries or their representatives to submit with their appeal request all available medical records related to the hospitalization and, as applicable, SNF services, and documentation of amounts paid out of pocket for care that was not covered under Part A. However, in these new appeals, we understand the difficulty some beneficiaries may have in obtaining records for services furnished many years ago. For that reason, we will require the eligibility contractor to work with the appropriate MAC to request all relevant records that are needed to establish eligibility for an appeal from the appropriate providers if some, or all, of those records are not submitted with the appeal request. In addition, as necessary, the eligibility contractor and MAC will request missing records related to the hospital, and as applicable, SNF services furnished to the beneficiary to determine whether coverage under Part A is warranted. Such records should be comprehensive with respect to the treatment and services received and would include, but are not limited to, hospital records that document admission as an inpatient, orders for observation services, diagnosis and treatment notes, orders and results of testing, discharge planning notes, as well as records from services furnished by the SNF (as applicable). In addition, beneficiaries should submit information related to the out of pocket payments that were made for the services at issue in the appeal, particularly SNF services for which a provider refund is sought. Such information could include provider bills and/or invoices, proof of payment in the form of a copy of a cashed check, credit card statement, etc.

Comment: A commenter requested clarification on how contractors will request additional information from providers related to an appeal request, and who within the provider's organization would be authorized to share patient information with the contractor.

Response: Providers have a longstanding obligation to provide requested information related to services furnished to a beneficiary under section 1815(a) of the Act. MACs will utilize existing methods for requesting additional documentation and records, that is, the Additional Documentation Request (ADR) process, where a letter outlining the requested records and dates of service is mailed to the provider. Providers that have registered to receive ADRs and submit records in response electronically may use the existing system (for example, the Electronic Submission of Medical Documentation (esMD) system). Providers should follow existing privacy protocols for the submission of records requested by the MAC for these appeals in the same manner as they would for

other records requests by a MAC or other contractor.

Comment: Several commenters recommended that we give individuals and providers additional time to submit records requested for an appeal. The commenters stated that the 60-day timeframe in the proposed rule is inadequate and suggested we allow 120 calendar days for the submission of missing information. A commenter expressed concern about the impact of records requests on providers. Some commenters also recommended that we also allow extensions of the timeframe for good cause. Commenters also expressed concern about whether providers would be penalized for being unable to locate records that are older than existing record retention requirements and urged CMS to ensure contractors are aware of record retention requirements.

Response: We understand and appreciate the concerns of the commenters regarding the potential issue some individuals or providers may have in locating and producing records for services furnished many years ago, and the burden of these requests on providers. While we are concerned that extended timeframes to respond to records requests may cause delays in establishing eligibility of the beneficiary in order to adjudicate valid appeals, we agree with the commenters that affording up to 120 calendar days to submit records to the eligibility contractor is reasonable. Accordingly, we are revising § 405.932(c)(2) to provide that the eligibility contractor will allow up to 120 calendar days for submission of missing information.

However, in light of the 365-calendar day filing timeframe to request an appeal under these procedures and the additional 60 calendar days we are granting to submit records, we believe it is also reasonable not to include extensions to the 120-calendar day timeframe in which records must be submitted to the eligibility contractor. It is important to balance the interests in affording individuals adequate time to obtain records with the interests in avoiding extended delays in processing appeals. We believe the 365-calendar day filing timeframe to request an appeal provides individuals with adequate time to obtain the necessary documentation to support their appeal. Should the eligibility contractor still need additional information, we believe allowing up to another 120 calendar days is reasonable. If an individual or provider cannot meet the deadline, the eligibility contractor will make a decision based on the information in the record. If the information in the record does not establish the individual's eligibility, then the eligibility contractor will issue a denial notice. The individual (or their representative) may request a review of the eligibility contractor's denial in accordance with the procedures outlined in § 405.932(e) and may submit any records subsequently obtained that serve to establish eligibility and/or coverage of services.

We acknowledge the concerns raised by commenters about the extended lookback period for retrospective appeals and the ability of providers to locate medical records for services that were furnished on dates that are not covered by existing record retention requirements. Medicare requires records be retained by providers for 7 years from the date of service (42 CFR 424.516(f)). While providers are not required to maintain records beyond the 7-year timeframe specified in regulations, we encourage providers to make reasonable efforts to search for and furnish any records in their possession, including those outside the record retention requirements. However, contractors are aware of existing record retention requirements, and we will not penalize providers who cannot locate records for dates of service that are beyond the record retention timeframe.

Comment: Several commenters stated that we should advise beneficiaries in our instructions for these new appeals that they may still submit retrospective appeal requests even if their medical records are unavailable. The commenters also requested that we specify that in the absence of medical records, acceptable evidence for the determination of Part A coverage would include written statements from beneficiaries, family members and providers who are familiar with the facts giving rise to the appeal.

Response: We agree with these commenters that beneficiaries may submit a retrospective appeal request without medical records. Consistent with the proposed rule, under this final rule we will require the eligibility contractor and the appropriate MAC to coordinate with providers to obtain necessary medical records to determine eligibility and to process the appeal regarding the denial of Part A coverage. Written statements from a beneficiary or family member regarding hospital services and, as applicable, SNF services furnished to a beneficiary may be submitted as evidence in the appeal. However, we believe an adjudicator will need some form of documentary evidence, such as medical records, to determine whether specific aspects of eligibility are met (for example, whether the hospital in fact admitted a patient as an inpatient and subsequently changed their status, or whether observation services were furnished after such change in status to outpatient). The adjudicator will also need to determine whether services meet Part A coverage requirements (for example, with hospital admissions subject to the original two-midnight rule from 2013, whether the patient is reasonably expected to require a stay of at least two midnights, and where the medical record includes information to support the physician's or otherwise qualified practitioner's expectation that the patient would require a stay of at least two midnights). Thus, testimonial evidence, such as statements from a beneficiary or provider regarding the care or treatment received will be accepted and considered in an appeal. However, without corresponding medical documentation, such statements by themselves may be insufficient to establish eligibility and/or determine if Part A coverage requirements were met. Thus, we decline to adopt the recommendation made by the commenters.

Comment: Several commenters recommended that our instructions for filing appeals and other guidance regarding the new appeals procedures explain the relevant standard for coverage that beneficiaries will have to meet in order to demonstrate that their hospital stay met the relevant Part A coverage criteria for inpatient hospital services.

Response: We appreciate this recommendation, and we agree that guidance regarding the coverage standards for inpatient admissions will be important information for beneficiaries eligible for an appeal. We intend to provide information regarding the relevant standards for inpatient hospital coverage and the applicable timeframes in materials we will publish on our websites.

Comment: A few commenters contended that the regulatory text in the proposed rule did not provide sufficient detail regarding the information contained in the notice related to a denial of eligibility for an appeal. The commenters suggested that the eligibility denial notice should contain specific information to assist beneficiaries in understanding the reason for the denial as well as what information is necessary to cure the denial.

Response: We appreciate the suggestions made by the commenters. We believe the regulatory language regarding the content of the denial notice in § 405.932(d)(3)(ii) is sufficient

with respect to specifying the reason for denial of the appeal request (''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).''). However, we agree that it would be appropriate to specify that the denial notice include a statement about the information needed to cure the appeal request to establish eligibility. We view this as implied in providing the reason(s) for the denial but also see the value of including this additional requirement in the denial notice prepared by the eligibility contractor. Therefore, we are revising § 405.932(d)(3)(ii) to state that the denial notice explains that the request is not eligible for an appeal, the reason(s) for the denial of the appeal request, the information needed to cure the denial, and the process for requesting a review of the eligibility denial under § 405.932(e). We appreciate the feedback that we received from commenters on eligibility determinations and filing appeals under these new procedures. Based on analysis of the public comments, we will be finalizing the proposals related to such procedures as proposed with the exception of the amendments to §§ 405.932(c)(2) and 405.932(d)(3)(ii), described previously.

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 proposed 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 proposed 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 believed the procedures for the new retrospective appeals would need to differ from existing claims appeals procedures, we proposed new processes. For example, in § 405.931(b) and (c), we proposed that party status for these appeals be limited to the eligible class members (or their authorized representatives).

In § 405.932(f)(1), we proposed 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 proposed 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 proposed that the processing contractor would make a decision based on the information available.

In proposed § 405.932(f)(3), we required 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 proposed 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-calendar day adjudication timeframe. If the requested information is not sent to the processing contractor, then we proposed that the time afforded by the contractor for submission of the information would not count towards the adjudication timeframe. In effect, the 60-calendar 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 proposed 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 section 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 proposed 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 proposed 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 of the regulations, 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 proposed 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 proposed 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 believed 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 [13]). 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 proposed 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 also proposed 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 the eligible party.

In addition, if a favorable appeal decision includes eligible SNF services that are covered, in § 405.932(h)(2)(i), we proposed 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 also proposed 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.

If the processing contractor determines that the hospitalization did not meet applicable Part A inpatient coverage requirements, we proposed 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 also proposed 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.

We received several comments regarding the processing of retrospective appeals and the effectuation of favorable or partially favorable appeals.

Comment: A commenter requested clarification regarding coordination among MACs if a hospital claim and SNF claim are processed by different MACs. The commenter questioned how the MAC processing the appeal would get information about the SNF. The commenter also inquired about the process for handling requests from the eligibility contractor that are sent to the wrong MAC.

Response: We appreciate the commenter's questions about how contractors will coordinate activities to ensure appropriate information is available to the eligibility and processing contractors. We considered the concerns raised by the commenter as we were developing the procedures in the proposed rule and we intend to include a process for contractors to coordinate with each other and with CMS in the rare case of different contractors having responsibility for the SNF claim and the hospital claim. This will ensure information needed to request documentation will be made available to the appropriate contractor. We will also instruct contractors to work with CMS in the event that the eligibility contractor sends requests to the incorrect MAC. In turn, CMS will assist the eligibility contractor, as needed, to determine the appropriate processing contractor so the appeal will be handled in a timely manner.

Comment: A commenter expressed concern about estate recovery under the Medicaid program in situations under these new procedures where a beneficiary could not obtain Medicare coverage of SNF services, but ultimately received coverage of SNF services from Medicaid. The commenter suggested that CMS encourage states to use hardship waiver authority to relieve individuals of estate recovery for portions of SNF stays that Medicare should have covered.

Response: We appreciate the concerns raised by the commenter. If a State Medicaid agency determines that a deceased beneficiary may be subject to estate recovery, it may only make recoveries from the beneficiary's estate under certain circumstances, including when recovery would not create an undue hardship for survivors. States are required by section 1917(b)(3) of the Act to have procedures to waive estate recovery where it would create an undue hardship for the deceased Medicaid recipient's heirs. States have flexibility and discretion to design reasonable criteria for determining what constitutes an undue hardship and who may be afforded protection from estate recovery in such instances. The State plan needs only specify the criteria for waiver of estate recovery claims due to undue hardship. Individuals will need to work directly with their State Medicaid Agency to file an undue hardship claim.

Comment: Several commenters suggested CMS clarify that due to the COVID–19 public health emergency (PHE) and the waivers implemented by CMS with respect to the 3 consecutive day qualifying hospital stay (QHS) eligibility requirement for SNF benefits, that there should be no appealable SNF stays for the period in which the PHE waivers were in effect.

Response: We appreciate the commenters' suggestions on this issue. Under the terms of the court order and the proposed rule establishing eligibility for retrospective appeals (§§ 405.931 through 405.938), an eligible party may appeal the denial of Part A coverage. We anticipate an overwhelming majority of appeals filed under these new provisions will focus on denials of Part A SNF coverage due to financial liability for the denied SNF services. We

[13] 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).

agree with the commenter that appeals under these new provisions should not include SNF services that were paid by Medicare as the result of a SNF invoking the COVID–19 PHE waiver authority for a QHS (or services paid by a third-party payer as noted in § 405.932(b)(2)). Nevertheless, we would like to clarify that we are not restricting an eligible party's right to appeal the denial of Part A coverage for hospital services under these procedures even if the SNF services were covered by Medicare or a third-party payer; we do not believe that such a restriction is consistent with the court order in *Alexander.* However, following the clarifying order by the court which does not require the unwinding or adjustment of the Part B outpatient hospital claim following a favorable appeal decision, we do not expect many appeals to be filed if the beneficiary's SNF services were covered.

Comment: A few commenters suggested that we clarify how the new appeals process will interact with existing claims appeals processes. A commenter requested that we address situations where a hospital is pursuing a claim appeal under the existing claims appeals process and then an eligible party initiates a retrospective appeal under these new procedures. The commenter acknowledged there would likely be few such cases.

Response: We agree with the commenter that we expect very few, if any, situations where a claim for hospital outpatient services is pending in the claims appeal process and then an eligible party files an appeal for Part A coverage under the new process. However, in that unlikely situation, the determination of coverage under Part A for the hospital claim would be conclusive with respect to the hospital services and would be binding for purposes of the beneficiary's hospitalization.

To illustrate, under existing procedures in § 405.940, *et seq.,* if the hospital appealed a denial of coverage of outpatient hospital services for not being medically reasonable and necessary under section 1862(a)(1)(A) of the Act, that appeal would only address the coverage and payment of the outpatient services on the hospital's Part B claim submitted to Medicare. An appeal filed by a hospital under existing procedures would not address whether coverage under Part A would have been appropriate. However, if an eligible party filed an appeal for the denial of Part A coverage under the provisions in §§ 405.931 through 405.938, then that determination would be conclusive for the purposes of coverage for the hospital services. Adjudicators deciding an appeal of the Part B outpatient claim would be bound by the determination with respect to Part A coverage as a result of an appeal under §§ 405.931 through 405.938. Similarly, if the appeal under §§ 405.931 through 405.938 involves coverage of SNF services, the determination would be binding on any pending claims appeal under existing procedures.

In order to address the issue raised by the commenter, we are revising § 405.931 to add new paragraph (i) to explain that the determination of Part A coverage made in an appeal decision under these procedures is conclusive and binding with respect to coverage of such services under Part A for any other appeal under Part 405 Subpart I. Specifically, § 405.931(i) would be added to state that, for the purposes of appeals under §§ 405.931 through 405.938, the determination with respect to coverage under Part A is conclusive and binding with respect to the services furnished and shall be applied to any existing appeals with respect to coverage and payment for hospital services under Part B and SNF services (as applicable).

Comment: Several commenters expressed support for the process outlined in the proposed rule regarding applicable refunds to beneficiaries for out-of-pocket payments made following a favorable or partially favorable appeal decision. A commenter suggested that CMS clarify that ''family member'' in the context of out-of-pocket payments include individuals who are not biologically related to the eligible party. A commenter requested that CMS state that the application of 42 CFR part 489 Subpart D with respect to handling incorrect collections means that providers must issue refunds promptly (generally within 60 days of a binding favorable appeal decision) and must comply with existing legal protections. A commenter also suggested that CMS provide additional explanation for situations where a provider has changed ownership or has closed, and a refund is owed to a beneficiary. A commenter also indicated that CMS should consider how refunds will get to the appropriate individual, particularly with respect to appeals filed on behalf of deceased beneficiaries.

Response: We appreciate the commenters' support and suggestions on this issue. Our goal in creating this new retrospective appeals process is to implement the court order in a way that provides class members with a meaningful opportunity to appeal the denial of Part A coverage that is similar to the existing claim appeal process and provide a remedy for those class members who endured uncompensated or undercompensated care at SNFs. At the same time, there are limits on our authority to fashion remedies in effectuating favorable appeal decisions. For example, payment for hospital and SNF services may only be made to providers following submission of a claim by the provider. Section 1814(a)(1) of the Act; 42 CFR 424.33 and 42 CFR 424.51. In addition, existing policies for handling incorrect collections of funds from a beneficiary (42 CFR part 489 Subpart D) do not authorize the program to reimburse beneficiaries directly except in very limited circumstances (see § 489.42(a)). For this reason, we must rely on providers and the terms of their provider agreement to issue refunds to beneficiaries where applicable.

In the proposed rule, we explained that we are limiting our review of SNF services in these new appeals to situations where the beneficiary or a family member paid out-of-pocket for the SNF services (42 CFR 405.932(b)(2)). We explained that payments, including cost sharing payments, made by a third-party payer do not constitute out-of-pocket payments made on behalf of the eligible party. We agree with the commenter who suggested that for the purposes of determining whether there were out-of-pocket payments made for SNF services, we consider payments made by individuals who are not biologically related but who paid out-of-pocket expenses on behalf of a beneficiary to be considered as out-of-pocket payments made by a family member. This could include, for example, close family friends, a former spouse, a roommate, or other individuals who would not have a legal or contractual obligation to pay for a beneficiary's care. We are revising § 405.932(b)(2)(iii) to state that payments made by a family member (including payments made by an individual not biologically related to the beneficiary) for an eligible party's SNF services are considered an out-of-pocket payment for the eligible party.

With respect to the comments received about the timing of refunds that may be required following a favorable or partially favorable appeal decision, we reiterate our position as explained in the proposed rule that providers have an obligation to comply with applicable statutory and regulatory requirements with respect to charging for covered services. In the proposed rule (88 FR 89514), we stated that providers are reminded that under sections 1814 and 1866 of the Act, 42 CFR 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. Refunding amounts previously paid for services determined to be covered following an appeal is the responsibility of the provider, and must be made consistent with the provisions in part 489 Subpart D. We expect that the provider will promptly refund amounts incorrectly collected, meaning the refund should be issued within 60 days of receipt of the decision letter to avoid the set aside requirements in 42 CFR 489.41(b).

With respect to concerns about refunds getting to the appropriate individual in the case of deceased beneficiaries, we note that an appellant would need to establish authority to file on behalf of a deceased beneficiary as they do under existing appeals procedures (see 42 CFR 405.906(a)(1)). Coordination of any refund owed by a provider following a favorable appeal decision is a private matter between the provider and the individual entitled to a refund, and state law would govern in the case of a refund owed to a deceased beneficiary or their estate, or refunds owed by a provider that is no longer operating. CMS has limited authority under the statute to intervene. CMS may only make payment to an individual in situations where the provider invokes the set aside provision in § 489.41 and fails to issue a refund. CMS would then determine whether payment of an amount equal to the incorrect collection should be made under § 489.42. However, failure to issue a refund and retain funds from sources other than Medicare for covered services would constitute a violation of section 1866(a)(1)(A) of the Act and the terms of the entity's provider agreement.

Finally, in situations where there is change of ownership for a provider, obligations of the previous entity are generally transferred to the new owners. In rare situations where the new owners do not accept assignment of the provider agreement, including prior obligations, or in cases where the provider is no longer in operation, state law would apply with respect to the entity's obligations to remedy a debt.

Comment: A commenter indicated that the proposed rule did not consider the implications for the Medicare Secondary Payer (MSP) program and the impact on other insurers or payers involved in the beneficiary's insurance coverage.

Response: We appreciate the concern raised by the commenter. In the retrospective appeals process, we explained that following a favorable decision, to prevent duplicate payment, a provider who wishes to submit a claim for Part A payment would be obligated to refund amounts previously collected for Part B services determined, on appeal, to be covered under Part A. Providers would follow existing procedures for making refunds of amounts previously collected for such Part B services prior to submitting a Part A claim for payment as the services are considered non-covered under Part B. Then providers could collect payment for the covered Part A services based on the beneficiary's insurance coverage at the time the services were furnished. However, consistent with the court's clarifying order issued on December 9, 2022, with respect to appeals involving beneficiaries enrolled in both Medicare Part A and B at the time of hospitalization, we remind hospitals that they are not required to submit a claim for Part A hospital services. Absent a Part A claim, we will not reopen or unwind previous Part B outpatient hospital payments in order to make payment for any SNF services determined to be covered under Part A.

Comment: A few commenters requested that CMS allow providers up to 1 year, as well as extensions for good cause or hardships, to file a claim following a favorable appeal decision. Commenters also requested that CMS consider all options to facilitate the submission of claims for Part A services following a favorable retrospective appeal decision. A commenter suggested that the decision itself could be sufficient to adjudicate a Part A claim for payment. A commenter questioned whether hospitals could collect the Part A hospital inpatient deductible following refund of any Part B payments collected and submission of a Part A claim.

Response: We appreciate the concerns raised by commenters about billing for services following a favorable or partially favorable appeal decision. We acknowledge that submitting a claim may be complicated in situations where services were furnished many years ago, and in developing the procedures to implement the court order, we considered options with respect to claims for newly covered Part A services. As we stated in the proposed rule, under section 1814(a)(1) of the Act, and §§ 424.33 and 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. In addition, under section 1815(a) of the Act, providers must furnish information as requested in order to determine the amounts due for Part A services. Thus, while the coverage determination with respect to the Part A services is conclusive based on the appeal decision, we would not make payment for covered Part A services solely based on a favorable or partially favorable appeal decision without a Part A claim for payment from the provider, in light of section 1814(a)(1) of the Act. Moreover, an existing Part B outpatient claim cannot be ''adjusted'' into a Part A inpatient claim due to the different characteristics and requirements of inpatient and outpatient claims. (See 78 FR 50917, 50926 (August 19, 2013) where we explained that we could not ''adjust'' a Part A inpatient claim into a Part B claim for the purposes of Part B inpatient billing.) We are currently developing instructions for submission of these claims and will have a process approved and finalized shortly after this final rule is published.

However, we agree that extending the timeframe for providers to submit claims in response to a favorable or partially favorable decision is warranted in light of the complexities that may surround such submissions. Thus, we are adopting the commenters' suggestion to extend the deadline for providers to file a claim(s) from 180 calendar days to 365 calendar days from the date of receipt of the notice of a favorable or partially favorable appeal decision. Specifically, we are revising §§ 405.932(h)(2)(i), 405.932(h)(2)(ii), 405.934(d)(2)(i), 405.934(d)(2)(ii), 405.936(e)(2)(i), 405.936(e)(2)(ii), 405.938(d)(2)(i), and 405.938(d)(2)(ii) to replace ''180 calendar days'' with ''365 calendar days''. We note that this 365-calendar day timeframe to submit a claim is established solely in furtherance of implementing operational aspects of the court order in the *Alexander* case and is unrelated to existing rules for timely filing of claims in section 1814(a)(1) of the Act and 42 CFR 424.44. As suggested by commenters, we will also permit extensions to the claims filing deadline upon establishment of good cause. In determining whether a provider has established good cause when requesting an extension for filing a claim following a favorable or partially favorable appeal decision under these procedures, we will apply the provisions in § 405.942(b) and (c) to the provider's request.

We also remind hospitals that submission of a claim for Part A payment of inpatient hospital services is not required under these procedures, nor is submission of a claim prohibited. Hospitals may have received payment for Part B outpatient services at the time these services were furnished. As a

result of the clarifying order issued by the court, for beneficiaries who were enrolled in both Part A and Part B at the time of hospitalization, Medicare will not immediately unwind previously paid Part B outpatient claims in the case of a favorable or partially favorable appeal decision for Part A coverage of the hospital services. However, if a hospital chooses to submit a Part A inpatient claim for payment following a favorable or partially favorable decision, in order to prevent duplicate payment for services, we will unwind the Part B claim (by canceling the claim) before processing the Part A claim, and recover any monies paid to the hospital. The hospital would also need to refund any other payments collected for the outpatient services, including payments collected from any source related to coinsurance and deductibles for the outpatient services prior to submitting the Part A inpatient claim. Hospitals may then collect applicable cost sharing based on the beneficiary's insurance coverage at the time of hospitalization in accordance with the processed Part A claim.

In order to clarify these points, we are amending §§ 405.932(h)(1)(ii), 405.934(d)(1)(ii), 405.936(e)(1)(ii) and 405.938(d)(1)(ii) to state that following a favorable appeal decision, a prior Part B outpatient hospital claim will not be reopened and revised (that is, unwound) unless a hospital submits a Part A claim for inpatient services. These sections will be revised to read as follows: For the purposes of effectuating a favorable [decision type], unless a Part A claim is submitted by a hospital, 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.

We are amending §§ 405.932(h)(2)(ii), 405.934(d)(2)(ii), 405.936(e)(2)(ii) and 405.938(d)(2)(ii) and we are adding §§ 405.932(h)(2)(iii), 405.934(d)(2)(iii), 405.936(e)(2)(iii) and 405.938(d)(2)(iii) to clarify that if a hospital chooses to submit a Part A inpatient claim following a favorable appeal decision for any eligible party, the hospital must refund any payments collected for the outpatient hospital services prior to submitting a Part A inpatient claim in order to prevent receipt of duplicate payment, and to clarify that a refund of payments collected for the outpatient hospital services is required if the favorable or partially favorable appeal decision involves a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization even if the hospital does not submit a Part A inpatient claim for payment. While we do not anticipate hospitals will submit Part A claims in situations where they previously received Part B payment for an outpatient claim, a refund would be required before the submission of a Part A inpatient claim submitted for any eligible party, and not limited to situations where a beneficiary was not enrolled in Part B at the time of hospitalization.

Accordingly, these sections are being revised to state that a hospital that furnished services to any eligible party (including those enrolled in both Medicare Part A and Part B at the time of hospitalization) must refund any payments collected for the outpatient hospital services prior to submitting a Part A inpatient claim for such services, and that the claim must be submitted within 365 calendar days of receipt of the notice of a favorable decision. These revisions also clarify that if a favorable or partially favorable decision is issued to a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization, a refund is required for any amounts collected for the outpatient hospital services even if a Part A inpatient claim for payment is not submitted to the program.

Finally, we are adding §§ 405.932(h)(2)(iii), 405.934(d)(2)(iii), 405.936(e)(2)(iii) and 405.938(d)(2)(iii) to differentiate appeals involving beneficiaries who were enrolled in Medicare Part B at the time of hospitalization in order to clarify that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services following a favorable or partially favorable decision for these beneficiaries, and the timeframe to submit such claims (365 calendar days).

Comment: Several commenters raised questions about billing for services following a favorable or partially favorable appeal decision. A commenter questioned how a favorable decision with respect to Part A coverage for both the hospital and SNF services would be effectuated with respect to the SNF if the SNF had previously submitted and received payment for Part B services, and now decides to submit a claim for covered Part A services. Commenters also raised questions about specific condition codes to be used in billing for services, how Common Working File (CWF) edits would be implemented to accommodate these new claims, and how these new claims would be identified by the MAC. The commenters requested that CMS acknowledge the complexity of billing for SNF services furnished prior to FY 2020 and that CMS address how this will be resolved in the final rule.

Response: Following a favorable appeal decision and after issuing a refund to the beneficiary for any out of pocket payments made for SNF services, if a SNF decides to submit a claim for covered Part A services, then in order to avoid duplicate payment, Medicare would recover the funds paid to the SNF for the Part B services to the extent such Part B services are included in the payment made for Part A services. Medicare would then process the Part A claim and make the appropriate payment to the SNF for covered services.

We appreciate the comments about the complexity of this billing process and understand the complexity involved not only in billing, but also in processing these claims manually. We anticipate that each situation will involve subtle differences that will need to be addressed on a case-by-case basis. We are currently working to make the necessary system changes to accommodate these claims and to create billing instructions that will be approved and finalized shortly after publication of this final rule. That will give providers some advance time to work internally and/or with billing agents to be able to submit claims following a favorable appeal. We will be working to implement condition codes and remarks codes to be used on claims submitted following a favorable decision so those claims may be identified by the MAC. We anticipate the process will be similar to the Part B inpatient rebilling process (*https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM8185.pdf*) implemented in response to CMS Ruling CMS–1455–R and the provisions in the Fiscal Year 2014 Hospital Inpatient Prospective Payment System final rule (CMS–1599–F, *https://www.govinfo.gov/content/pkg/FR-2013-08-19/pdf/2013-18956.pdf*). But we are unable to incorporate this operational guidance into this rulemaking.

Finally, we note that we agree with commenters who expressed similar concerns about the complexity of this process. As explained earlier, we are extending the time period to submit claims in response to a favorable or partially favorable decision to 365 calendar days from the date of receipt of the appeal decision and MACs will provide support, as needed, to providers who wish to submit Part A claims.

We appreciate the feedback that we received from commenters on the

procedures for appeals conducted by processing contractors. Based on analysis of the public comments, we will be finalizing the proposals related to such procedures as proposed except for the addition of §§ 405.931(i) and 405.932(h)(2)(iii), and the amendments to §§ 405.932(b)(2)(iii), 405.932(h)(1)(ii) and 405.932(h)(2)(i) and (ii), described previously.

5. Conduct of Reconsiderations by Qualified Independent Contractors

In § 405.934(a), we proposed that the second level of retrospective appeals be performed by QICs. As with the first level of appeal, we proposed 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 proposed 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 proposed 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 also proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 also proposed 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 proposed 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 also proposed 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 proposed 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 also proposed 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.

We did not receive any comments on the proposed policies related to QIC reconsiderations. We are finalizing our policies as proposed with the exception of the following modifications, described in section III.A.4. of this final rule:

- Amending § 405.934(d)(1)(ii) to clarify that existing outpatient claims will not be unwound unless the hospital files a Part A inpatient claim following a favorable appeal decision.
- Amending §§ 405.934(d)(2)(i) and (ii) to extend the time for providers to file claims following a favorable decision to 365 calendar days.
- Adding § 405.934(d)(2)(iii) to clarify that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services following a favorable or partially favorable appeal decision for beneficiaries who were enrolled in Medicare Part B at the time of hospitalization.

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 proposed 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 proposed that these elements would mirror existing requirements for appeal requests in § 405.1014(a)(1). We also proposed 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 the 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 proposed 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.[14] 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 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 did 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 believed it was 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 proposed including those charges in calculating the amount in controversy for a hearing before an ALJ and for judicial review in federal district court. We emphasized that, as explained in section III.A.4. of this 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 proposed 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 proposed 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 did not reduce 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 did we factor 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 did 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 proposed 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 believed 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, were 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

[14] For calendar year 2025, the minimum amount in controversy for a hearing at the OMHA level is $190, and for judicial review the minimum amount in controversy is $1,900. These amounts are calculated annually in accordance with section1869(b)(1)(E) of the Act and notice of the updated minimum amounts for each 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.*

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 proposed 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 explained 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 proposed 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 proposed 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 proposed 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 specified 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 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 proposed 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 proposed 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 proposed 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 also proposed 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 proposed 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 also proposed 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 proposed 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 also proposed 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 proposed 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.

We did not receive any comments on the proposed policies related to ALJ hearings and decisions by ALJs or Attorney Adjudicators. We are finalizing our policies as proposed with the exception of the following modifications, described in section III.A.4. of this final rule:

- Amending § 405.936(e)(1)(ii) to clarify that existing outpatient claims will not be unwound unless the hospital files a Part A inpatient claim following a favorable appeal decision.
- Amending § 405.936(e)(2)(i) and (ii) to extend the time for providers to file claims following a favorable decision to 365 calendar days.
- Adding § 405.936(e)(2)(iii) to clarify that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services following a favorable or partially favorable appeal decision for beneficiaries who were enrolled in Medicare Part B at the time of hospitalization.

7. Conduct of Review by the Medicare Appeals Council

Under § 405.938, we proposed 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 proposed to use the existing requirements for requests for Council review in § 405.1112. We proposed that untimely or incomplete requests would be handled under existing procedures in §§ 405.1100 through 405.1116.

We proposed 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 proposed 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 proposed 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 proposed that a decision would contain information regarding the effect of a favorable decision. In the case of an unfavorable or partially favorable decision, we proposed that the Council include information about filing a request for judicial review under existing procedures in 405.1136. We also explained 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 proposed 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 proposed 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,[15] 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 explained 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 proposed 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.

We did not receive any comments on the proposed policies related to Appeals Council review. We are finalizing our policies as proposed with the exception of the following modifications, described in section III.A.4. of this final rule:

- Amending § 405.938(d)(1)(ii) to clarify that existing outpatient claims will not be unwound unless the hospital files a Part A inpatient claim following a favorable appeal decision.
- Amending § 405.938(d)(2)(i) and (ii) to extend the time for providers to file claims following a favorable decision to 365 calendar days.
- Adding § 405.938(d)(2)(iii) to clarify that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services following a favorable or partially favorable appeal decision for beneficiaries who were enrolled in Medicare Part B at the time of hospitalization.

8. Judicial Review

We proposed 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.

We did not receive any comments on the proposed policies related to judicial review. We are finalizing our policies as proposed.

We appreciate the support and feedback we have received from the commenters on our proposals related to the retrospective appeals process. After review and consideration of all comments, we are finalizing the regulations for the retrospective appeal procedures as proposed with the following modifications:

- We are adding § 405.931(i) to clarify that the coverage decision for a retrospective Part A patient status appeal is conclusive for any pending claim appeal.
- At § 405.932(b)(2)(iii) we are clarifying that a family member may include individuals who are not biologically related to the beneficiary (solely for the purpose of determining whether out of pocket payments were made for SNF services, making those services eligible for an appeal).
- At § 405.932(c)(2) we are extending the timeframe for providers to respond to a request for medical records to aid in establishing a beneficiary's eligibility for an appeal from 60 calendar days to 120 calendar days.

[15] 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.

• At § 405.932(d)(3)(ii) we are requiring that the eligibility contractor's notice of denial of eligibility will also include an explanation of the information needed to cure the denial.

• At §§ 405.932(h)(1)(ii), 405.932(h)(2)(ii), 405.934(d)(1)(ii), 405.934(d)(2)(ii), 405.936(e)(1)(ii), 405.936(e)(2)(ii), 405.938(d)(1)(ii) and 405.938(d)(2)(ii) we are revising the regulation text to clarify that in the case of a favorable appeal decision, a hospital who chooses to submit a Part A inpatient claim must refund any payments received for the Part B outpatient claim before submitting the Part A inpatient claim. If a Part A claim is submitted, the previous Part B outpatient claim will be reopened and canceled, and any Medicare payments will be recouped to prevent duplicate payment. In addition, we are revising the regulation text to clarify that in the case of a favorable decision for a beneficiary who was not enrolled in Medicare Part B at the time of hospitalization, the hospital must refund any payments collected for the outpatient services even if the hospital chooses not to submit a Part A claim for payment to the program.

• At §§ 405.932(h)(2)(i) and (ii), 405.934(d)(2)(i) and (ii), 405.936(e)(2)(i) and (ii) and 405.938(d)(2)(i) and (ii) we are amending the content of decision letters to specify that a provider's claim filing timeframe will be 365 calendar days following a favorable or partially favorable decision under the retrospective appeals process.

• We are adding §§ 405.932(h)(2)(iii), 405.934(d)(2)(iii), 405.936(e)(2)(iii) and 405.938(d)(2)(iii) to clarify the effect of favorable appeals involving beneficiaries who were enrolled in Medicare Part B at the time of hospitalization to explain that hospitals must refund any payments collected for the outpatient hospital services only if the hospital chooses to submit a Part A inpatient claim for such services.

In addition, in drafting this final regulation we identified several erroneous cross-references in the proposed regulations text that we will be correcting. Specifically—

• In proposed § 405.931(a)(1), the reference to § 405.931(b)(1) is revised to read § 405.931(b);

• In proposed § 405.932(c)(2), the reference to § 405.931(b)(1) is revised to read § 405.931(b);

• In proposed § 405.932(d)(2)(ii), the reference to § 405.932(e) is revised to read § 405.932(f); and

• In proposed § 405.932(f)(3), the reference to paragraph (e)(1) is revised to read (f)(1).

After publication of this 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 §§ 405.1210 through 405.1212). We will announce the implementation dates on *cms.gov* and/or *Medicare.gov.*

B. Prospective Appeal Rights

1. Overview

This final rule also establishes and implements 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 expedited appeals process parallels the process in effect for inpatient hospital discharge appeals set forth at §§ 405.1205 and 405.1206, 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 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.[16] Based on the QIOs' expertise and longstanding performance of similar functions, CMS has determined that the QIOs are the most appropriate entity to perform beneficiary-initiated appeals regarding hospital reclassifications of inpatients to outpatients receiving observation

[16] Under section 1155 of the Act, a beneficiary who is entitled to benefits under title XVIII (that is, a Medicare 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 appeals, section 1155 of the Act authorizes the QIO to conduct a reconsideration of its expedited determination regarding the hospital reclassification under § 405.1211 to determine if an eligible beneficiary is entitled to coverage under Part A of the program.

services proposed in §§ 405.1211 through 405.1212.

We proposed an expedited appeals process that would be available to beneficiaries [17] 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, received observation services following the reclassification, and met one of the following two criteria:

- Their stay in the hospital was at least 3 days but they were an inpatient for fewer than 3 days.
- They 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 proposed 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 proposed 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).[18] 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 final rule for details on how to obtain a copy of the MCSN.[19]

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 proposed 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 SNF coverage following the hospital stay. We believed 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.

We 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 was 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 proposed 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 release from the hospital. For beneficiaries with Part B, we proposed 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 proposed 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 believed the approach we proposed 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 was modeled after the existing hospital discharge appeals notice (IM), and like that notice, does not require extensive time for hospitals to prepare and deliver to beneficiaries. We believed 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

[17] 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.

[18] OMB control number 0938–1467.

[19] Section IV.D. of this final rule states that to obtain copies of the supporting statement and any related forms, individuals should visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing.*

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 under this new appeals process beneficiaries will not have financial liability protection for hospital services received while their appeal is adjudicated. 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 proposed that the 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. We stated that if the proposed rule was finalized, we would 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 proposed 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 be referred to herein as a standard or untimely appeal.

Comment: The vast majority of commenters supported the proposed prospective appeals process that would provide eligible beneficiaries with the right to pursue an appeal regarding a hospital reclassification from inpatient to outpatient receiving observation services. Many commenters stated the policy would protect beneficiary access to medically necessary post-acute care services, specifically skilled nursing and occupational therapy services. Several commenters noted appreciation that the prospective appeals process would protect beneficiaries from the potentially detrimental effects of hospital status changes. A few commenters believed the appeals process would increase transparency for beneficiaries receiving hospital care.

Response: We appreciate the commenters' support for the proposed prospective appeals process.

Comment: Multiple commenters strongly recommended CMS finalize and implement the proposed prospective appeals process as soon as possible, with a commenter suggesting beneficiaries have lacked recourse to hospital reclassifications for too long already. Conversely, several commenters requested CMS delay implementation of the prospective appeals process for at least 1 year to allow hospitals to better understand their responsibilities and have time to integrate the appeals processes into existing workflows, with a commenter urging CMS to not finalize the proposed rule without addressing commenters' concerns and reducing the potential administrative burden the process would place on hospitals. Lastly, a commenter sought clarification on the implementation timeline and whether the prospective appeals process would be permanent.

Response: We appreciate the commenters' perspectives on the policy's implementation schedule. When considering the implementation timeline, we are balancing the need to provide beneficiaries access to the prospective appeals process as soon as possible with the time needed for finalizing guidance and notices and educating the industry on the new requirements, as well as the time needed by hospitals to integrate the new process into their existing workflows. We believe scheduling implementation as soon as operationally feasible not only meets the Court's order but strikes the proper balance between ensuring beneficiaries are adequately protected and providing hospitals sufficient lead time to prepare for and comply with the new requirements.

Comment: Multiple commenters strongly recommended CMS monitor hospital compliance with the prospective appeals process after implementation and to identify unintended consequences and make updates to the appeals process as necessary. A commenter suggested specifically monitoring the impact the prospective appeals process may have on SNF intake and hospital length of stay statistics. Another commenter suggested CMS monitor the impact the prospective appeals process may have on quality improvement reporting programs.

Another commenter suggested CMS coordinate and align the proposed appeals process with the Medicare Secondary Payer (MSP) program and ensure beneficiaries rights and benefits are not adversely affected. Another commenter predicted hospital inpatient admissions would decrease as a result of the proposed prospective appeals process because hospitals would want to avoid having their reclassifications effectively overturned.

Response: We appreciate the input from commenters and the suggested areas for increased monitoring as we implement the new prospective appeals process. While we did not propose to establish any oversight programs specific to the new appeals process, we plan to utilize existing program oversight authorities related to Medicare provider agreements to ensure industry compliance. We note, however, as explained in the proposed rule, the class of beneficiaries eligible to appeal a denial of Part A coverage relating to a hospital reclassification from inpatient to outpatient receiving observation services in any given year is relatively small (we estimated hospitals will deliver 15,655 beneficiary notices and the QIOs will process approximately 8,000 appeals, per year). Because of the relative few numbers of appeals, and proportionally fewer anticipated appeal

overturns, we do not believe this new appeals process will have a disruptive effect on other areas of the Medicare program, including the MSP program operations. Similarly, we do not believe approximately 8,000 annual appeals will meaningfully affect the regimented decision-making currently used by hospitals when determining the medical necessity of inpatient admissions for millions of beneficiaries annually. Nevertheless, if in our monitoring, we identify the new appeal process having unintended adverse consequences on the Medicare program, beneficiaries, or the hospital industry, we will respond with additional rulemaking or guidance, as we deem appropriate.

Comment: Multiple commenters urged CMS to conduct education and outreach to ensure impacted beneficiaries and their representatives are aware of the new prospective appeals process. A commenter suggested outreach efforts should specifically focus on culturally diverse populations, beneficiaries with limited English-speaking, and beneficiaries with visual or hearing impairments. The commenter also suggested CMS educate SHIPs and other beneficiary-assistance programs on the finalized prospective appeal procedures. In addition, several commenters suggested CMS also ensure the hospital industry is properly educated on the requirements of the new appeals process. Lastly, a commenter suggested CMS provide beneficiaries with educational material on Medicare inpatient coverage criteria and the reasons hospitals decide to reclassify them from inpatient to outpatient receiving observation services.

Response: We appreciate the commenters' suggestions for ensuring beneficiaries, associated assistance programs, and the hospital industry are properly informed of their respective rights and requirements of the prospective appeals process. As we finalize the prospective appeals requirements, we plan to add information on the appeals process to Medicare publications, manuals, and websites, as necessary and appropriate. Through this process we can explore whether providing information related to criteria for Medicare Part A coverage of inpatient admissions and common rationales for hospitals reclassifying certain beneficiaries from inpatient to outpatient receiving observation services will help beneficiaries understand the new prospective appeals process. Beneficiaries do not need prior knowledge of their appeal rights in order to avail themselves of the prospective appeals process, as relevant appeal submission information will be included in the Medicare Change of Status Notice (MCSN).

Comment: A commenter sought clarification whether the prospective appeals process requirements apply to MA enrollees with several commenters recommending that CMS expand the prospective appeals process to the MA program.

Response: The retrospective appeals process (addressed in section III.A. of this final rule) and the prospective appeals process (addressed in section III.B. of this final rule) do not apply to the MA program and will not be available for MA plans for MA enrollees. We did not propose extending application of the prospective appeals requirements to the MA program. We explained in the proposed rule that the terms of the court order refer to denials of Part A coverage. Consistent with the court order, the appeals processes in this rule do not extend to enrollees in MA plans. MA plan enrollees have existing rights that afford enrollees the ability 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 (see 42 CFR 422.562(b)(4)). 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 pursuant to §§ 422.578 through 422.590, and 422.633. As such, we are declining commenters' suggestions to extend the prospective appeals processes in this rule to MA enrollees. To the extent we identify additional processes that may be necessary for the MA program, any such proposals would be subject to notice and comment rulemaking. We note that MA enrollees do have access to QIO reviews of quality of care concerns, hospital discharges, and terminations of services furnished by home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) that is similar to the QIO reviews available for Original Medicare beneficiaries. *See* §§ 422.562(a)(2)(ii), 422.564(c) and (e)(3), 422.622 through 422.626.[20]

Comment: A few commenters requested that CMS define certain terms related to the prospective appeals process. A commenter requested that CMS explain ''what is considered a change in patient status'' and how such a change must be documented. Another commenter requested that CMS define a ''formal admission.'' The same commenter also requested that CMS clarify when a beneficiary is considered discharged or released from the hospital.

Response: We proposed at § 405.1210(a)(2) that, for purposes of the prospective appeals process, a change of status occurs when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services (as defined in § 405.931(h)). As we discussed in the proposed rule, hospitals are already required to deliver the written Condition Code 44 notification to enrollees whose status is changed from inpatient to outpatient after review by a hospital utilization review committee and the entire episode will be billed as outpatient. As this process is already in place, we did not propose any new documentation requirements related to a beneficiary's change in status and will not be making any modifications in this final rule.

We did not propose specific definitions for the terms ''formal admission'' or ''discharge'' since these terms are frequently used in the healthcare industry and, as used in the preamble of the proposed rule and at proposed §§ 405.1210(a)(3)(i) (for ''formally admitted'') and 405.1210(a)(3)(iv) (for ''discharge''), their meaning should be ascribed to their common usage and parlance in the healthcare context. Therefore, we decline the commenter's suggestion to establish these definitions in this final rule.

Comment: A commenter disagreed with CMS's proposal to allow hospitals to bill beneficiaries for reasonable costs associated with duplicating and delivering documentation provided to the QIO, when requested by the beneficiary, believing it was extremely burdensome on the beneficiary.

Response: We proposed at § 405.1211(d)(2) a requirement for hospitals, upon request, to provide a beneficiary with any documentation, including written records of any information provided by telephone, it provides to the QIO. We explained in the proposed rule that we intended for § 405.1211(d)(2) to operate the same way as the existing regulation at § 405.1206(e)(3), specifically that the hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating and delivering the requested materials. We note that the proposal mirrors an existing policy that has been in effect for many years, and from our

[20] The Independent Review Entity (IRE) referenced in §§ 422.624 and 422.626 is the BFCC–QIO.

programmatic experience, it has not shown to be burdensome on beneficiaries. Thus, we do not agree with the commenter that the proposed regulation is unduly burdensome and are finalizing § 405.1211(d)(2) as proposed.

Comment: A commenter requested the QIOs publish detailed annual reports on the new appeals process, including data on the number of appeals, the appeal dispositions, the general geographic location area of appeal requests, and information confirming whether beneficiaries are being reimbursed upon a successful appeal. Another commenter recommended CMS publish statistics on the number of times the ALJ overturns a QIO decision under the new appeals process. The commenter suggested to apply the data as a quality measure when considering renewing the QIO contracts.

Response: We did not propose and are not finalizing a process to publicly disclose any data related to the new prospective appeals process. CMS routinely tracks the timeliness of resolving beneficiary appeals for internal monitoring and evaluation purposes, and will do so for these new prospective appeals. We appreciate the commenters' interest in program transparency and may consider requiring such data disclosures at a later time.

We appreciate the comments received on the general structure of the proposed prospective appeals process. After consideration of the comments, we are finalizing these provisions as proposed.

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 discussed previously, we proposed to revise Subpart J of 42 CFR 405 to add new §§ 405.1210 through 405.1212. These new proposed regulations were 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) set 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 proposed 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 addressed 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 was 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 also proposed 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 meant 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 beneficiaries about inpatient hospital discharges. We proposed 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 proposed 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 release from the hospital. For beneficiaries with Part B, we proposed 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 proposed 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)) 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 SNF after the hospital stay.

Proposed new § 405.1210(b)(3) and (4) provided 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.

We received the following comments regarding our proposed requirements related to notification of appeals rights.

Comment: Multiple commenters were supportive of our proposal to require hospitals to deliver a standardized notice to eligible beneficiaries, informing them of the change in their hospital status, the resulting effect on Medicare coverage of their stay, and their appeal rights.

Several commenters approved of the proposed requirement for hospitals to deliver the standardized notice as soon as possible after a beneficiary becomes eligible for the appeal process. A commenter agreed that timely notice will provide beneficiaries with an opportunity to properly evaluate whether they want to pursue an appeal relating to their status change before leaving the hospital, consider whether to enter a SNF for post-acute care, and resolve questions about liability for their hospital stay. Lastly, another commenter agreed that a targeted appeals notice, delivered only to those eligible to appeal, would be the most effective and efficient means of informing eligible beneficiaries of their appeal rights.

Response: We appreciate the commenters' support and agree that it is imperative eligible beneficiaries receive notice of the change in their hospital status, the resulting effect on Medicare coverage of their stay, and information on their appeal rights in a format and manner that is readily understandable.

Comment: Many commenters urged CMS to apply specific revisions to the proposed MCSN. A few commenters suggested we ensure the final MCSN clearly describes, using plain language, the fact that the beneficiary was reclassified from inpatient to outpatient receiving observation services and the availability of appeal rights. Other commenters requested CMS ensure the finalized MCSN accurately describes the benefits and risks of the proposed appeal process.

A commenter suggested we incorporate check boxes to the list of ramifications for hospitals to use when completing the MCSN. The commenter believes the check boxes will assist beneficiaries in identifying the information that is relevant to them and may reduce hospital burden when delivering the MCSN by reducing the number of beneficiary questions. The same commenter suggested we add a new section explaining that beneficiaries without Part B may be charged for the full cost of their stay. Another commenter felt the MCSN is directed to a broader class of beneficiaries than set forth at § 405.1210(a) and suggested all the elements from § 405.1210(a) be listed on the MCSN.

Several commenters suggested we remove from the beneficiary acknowledgement and signature block the statement ''I also understand if I win my appeal, my hospital charges will be different and possibly higher.'' The commenters found the tone of this language alarming and believe the statement may act to deter beneficiaries from appealing their reclassification when, in many cases, the beneficiary's risk of higher hospital charges is relatively low.

Other commenters recommended we add a disclaimer to the proposed MCSN explaining beneficiaries do not have financial liability protection while their appeal is pending. Several commenters requested we add a statement to the proposed MCSN advising beneficiaries that leaving the hospital will not impact a pending appeal and they will still receive notice of the appeal decision. Similarly, a commenter predicted beneficiaries would be concerned about the impact leaving the hospital would have on a pending appeal.

A commenter suggested we reorder the list of potential ramifications from a status reclassification, found in the introductory paragraph, to have information related to SNF coverage precede, rather than follow, information related to changes to the beneficiary's hospital bill. The commenter reasoned SNF eligibility is relevant to all beneficiaries that receive the MCSN, has a greater financial impact, and has a more immediate impact on a beneficiary's health than potential changes to a beneficiary's hospital charges.

Response: We appreciate the commenters' support and wide range of suggested modifications for the proposed MCSN [21] and we will be incorporating several commenters' suggested edits to the proposed MCSN that we believe will increase beneficiary understanding of the status change and the potential ramifications.

We added check boxes to the list of potential ramifications for the hospital staff to indicate which items apply to the beneficiary receiving the notice. We also added an explanation that eligible beneficiaries without Part B may be charged for the full cost of the outpatient stay, due to the hospital status change. Further, we simplified and streamlined language throughout the notice, including in the list of potential ramifications, to increase readability.

We also revised the MCSN to confirm that a beneficiary may initiate a standard appeal after leaving the hospital and to clarify that a beneficiary who requested a timely expedited determination will receive notice of the QIO decision even if they leave the hospital before the decision is made. We agree with commenters on the importance of including these clarifications on the MCSN to enhance beneficiaries understanding and comfortability with the new appeals process.

In addition, we added text to the MCSN to explain if the beneficiary remains in the hospital during the appeals process and they receive an unfavorable appeal decision, the beneficiary could be responsible for the cost of the Part B coinsurance and applicable deductible for any covered services and the full cost of any non-covered services received during the appeals process. We agree with commenters on the importance of beneficiaries understanding that the appeals process does not provide the same liability protections afforded when being discharged from a covered inpatient stay. However, we did not add an explanation that a hospital could release a beneficiary during an appeal, as suggested by some commenters, because hospital decisions related to safely releasing patients following treatment falls outside the scope of this appeals process. Hospitals must continue to assess the appropriateness of release by applying the beneficiary's particular medical circumstances, using their usual operating procedures, and in accordance with all applicable laws.

We have removed from the beneficiary acknowledgement and signature block text stating beneficiaries may face higher hospital charges upon a successful appeal. We agree with commenters that some beneficiaries could be alarmed by such a warning and potentially not proceed with an appeal they otherwise would want to pursue.

We did not believe it necessary or prudent to add details on the criteria necessary for a beneficiary to receive the MCSN and pursue an appeal relating to their hospital status reclassification. We believe including such detailed information about the appeals criteria would likely be confusing to beneficiaries and is unnecessary for them to decide whether to appeal. Importantly, the MCSN will only be

[21] Section IV.D. of this final rule states that to obtain copies of the supporting statement and any related forms, individuals should visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing.*

delivered to those beneficiaries eligible to appeal.

Finally, while we agree that Medicare not covering a SNF stay following a status change from inpatient to outpatient receiving observation services is an important ramification for beneficiaries, we did not reorder the list in the notice to reflect this. Through the course of consumer testing of the MCSN after reordering the notice to list SNF coverage information before information on potential hospital coverage, it was apparent that discussing SNF coverage after discussing the hospital coverage was confusing to beneficiaries.[22]

Comment: A commenter suggested the proposed MCSN be further developed with beneficiary input to ensure that the information conveyed by the notice is accessible and understandable to beneficiaries.

Response: We agree seeking beneficiary input is vital when developing new notices and that it is essential for the MCSN to clearly inform the beneficiary of their change in status and related financial implications as well as how they may appeal this change. To that end, we edited the proposed MCSN to use research-based plain language that should be more understandable to beneficiaries. In addition, before distribution, the MCSN will have undergone consumer testing. We will also continue to refine the notice for future revisions.

Comment: A commenter recommended we require hospitals specify the exact appeal timeframes and deadlines for each beneficiary that receives the MCSN.

Response: We appreciate the commenter's intent to have beneficiaries receive as personalized a notice as possible. We proposed for the MCSN to contain a statement that, if a beneficiary wishes to pursue an appeal, the beneficiary should request an appeal as soon as possible and before leaving the hospital, which is the proposed deadline for an expedited determination. We believe such a statement is preferable to a customized notice as it sufficiently advises beneficiaries of their appeal timeframes while not further increasing the burden that would come from hospitals having to customize each notice before delivery. We also are hesitant to create a notice with a glut of dates and information that could inadvertently lead to beneficiary confusion and may detract from other important and actionable material on the MCSN. We note this level of information is consistent with similar appeals notices, such as the IM, that have not elicited complaints related to uncertainty of when to appeal.

Comment: A few commenters asserted that hospitals only change a beneficiary's status from inpatient to outpatient when they are certain the change is appropriate and that the guidelines for inpatient versus outpatient coverage and payment are complicated. The commenters suggested the MCSN include specific information on the criteria for Medicare inpatient coverage and medical review for inpatient admissions to inform beneficiaries. One of the commenters also suggested such information and additions to the MCSN would assist preventing potential overuse of the proposed appeals process.

Response: We appreciate the commenters' perspective on the appropriateness of hospital decisions to change a beneficiary's status from inpatient to outpatient receiving observation services. However, the purpose of the proposed prospective appeal process is not to validate the hospital change of status decision, but to provide beneficiaries with the ability to pursue an appeal relating to a change in a beneficiary's status, when certain criteria are met, because of the substantial impact these decisions may have on beneficiaries. We believe a core component of creating an effective appeals process is to ensure ease of access and understanding for Medicare beneficiaries. We do not believe including detailed coverage criteria in the MCSN would promote beneficiary understanding on the effect of their change in status or their right to appeal such change. Indeed, considering the commenters' acknowledgement that coverage and medical review criteria are complicated, we believe including this information on the MCSN would only risk confusing beneficiaries and possibly dissuading them from requesting appeals.

Lastly, we are unclear of the commenter's meaning when they expressed concern of potential overuse of the appeals process. In accordance with the Court's order, access to the prospective appeals process is limited to eligible beneficiaries. Once the appeal process is established, we strongly believe all eligible enrollees who wish to pursue a valid appeal should have the ability to do so with reasonable ease. We believe including complex coverage criteria on the notice, with a stated purpose to dissuade otherwise valid appeals, would be antithetical to the Court's order and our proposed goals. Therefore, we decline the commenter's suggestion to include material in the MCSN when the inclusion is intended to reduce otherwise valid appeals.

Comment: Multiple commenters provided feedback on the proposed requirements related to the timing of delivery of the notice. A few commenters were uncertain when the MCSN must be delivered, some commenters requested that hospitals be given more time for delivery, and another commenter requested a flexible delivery timeframe. Commenters based their feedback on wanting to minimize the risk of confusion on the part of the beneficiary, reduce provider burden, and not wanting to delay hospital releases (and affecting beneficiary options for SNF placement).

Response: We proposed a requirement at § 405.1210(b) that hospitals would be required to deliver a standardized notice informing eligible beneficiaries of their right to appeal a denial of Part A coverage relating to a hospital's decision to reclassify them from inpatient to outpatient receiving observation services. We proposed at § 405.1210(b)(1) to require hospitals to deliver the notice to eligible beneficiaries as soon as possible after the beneficiary is eligible for this process per § 405.1210(a)(2) and (3) and no later than 4 hours prior to release from the hospital. This means, for beneficiaries with Part B, the notice must be delivered as soon as possible after the hospital reclassifies the beneficiary from inpatient to outpatient receiving observation services and after the beneficiary has been in the hospital for 3 consecutive days. For beneficiaries without Part B, 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 to appeal.

We believe the MCSN delivery timeframes, as with other beneficiary notices, appropriately balance the interests of beneficiaries with the necessary burden placed upon hospitals. As we explained in the proposed rule, we reviewed the notice delivery procedures for other beneficiary notices, specifically the IM notice related to inpatient hospital discharges, and have mirrored those processes for delivery of the MCSN, wherever possible. Accordingly, the timeframe to deliver the MCSN is 4 hours prior to a beneficiary's scheduled release time from the hospital, as is existing practice for the IM. We believe it impractical to expect a beneficiary to understand the ramifications of their status change and have time to fully

[22] This testing methodology is set forth and approved in OMB collection 0938–1382 Gen IC #11.

consider whether they wish to file an appeal before leaving the hospital if the notice were to be given closer to the beneficiary's release.

Comment: Several commenters questioned the hospital's role in delivering the MCSN. A commenter requested that CMS provide clear directives for hospitals to operationalize the delivery of the MCSN and integrate the notice into existing hospital workflows.

Commenters also requested clarification in the following areas:

- Is a hospital required to verbally explain the MCSN to beneficiaries and, if so, specify how detailed the explanation must be?
- When must a hospital deliver the MCSN in circumstances where a beneficiary's hospital status is reclassified shortly after their formal inpatient admission and then remains in outpatient receiving observation for 3 days?
- Must a beneficiary receive 4 hours of observation services after receiving the standardized notice?
- Should hospitals document when a beneficiary voluntarily leaves the hospital less than 4 hours from receiving the MCSN?
- To what extent are hospitals required to document delivery of the MCSN when a beneficiary refuses to sign the notice?

A few commenters suggested that CMS prohibit hospitals from filling in the date and time in the beneficiary signature block because it may result in inaccurate information. Another commenter supported CMS' proposal for hospitals to annotate the MCSN if a beneficiary refuses to sign or acknowledge receipt.

Response: We proposed at § 405.1210(b)(3) that a hospital's delivery of the notice is considered valid when the hospital issues the notice timely, in accordance with § 405.1210(b)(1), the notice contains all required elements, in accordance with § 405.1210(b)(2), and the eligible beneficiary or their representative signs and dates the notice to indicate receipt and comprehension of its contents.

We did not propose to require hospital staff to orally convey the information on the MCSN to eligible beneficiaries. Instead, the hospital is only required to complete and timely deliver the MCSN while ensuring the beneficiary can comprehend its contents. As we explained in the proposed rule, as with existing beneficiary notice requirements, hospitals generally would need to determine whether a patient is capable of comprehending and signing the MCSN. We continue to believe that the clinicians treating a beneficiary are in the best position to determine whether their patients are capable of receiving and comprehending a notice, and whether a representative should be contacted. It would not be practicable to establish specific criteria to ascertain whether a hospital properly assessed beneficiary 'understanding' for the purposes of receiving the MCSN. The determination should fall within the practiced day-to-day assessments a hospital is making when communicating with, and providing care to, beneficiaries.

We note, the proposed requirement at § 405.1210(b)(1) only governs the timeframes in which hospitals must deliver the MCSN to eligible beneficiaries. We did not propose to require hospitals to render observation services during that timeframe nor did we propose to restrict beneficiaries from choosing to leave the hospital earlier than their scheduled release time. Instead, we expect for hospitals to build this relatively brief 4-hour window into their standard patient release planning processes, as appropriate, for beneficiaries receiving the MCSN, and for delivery to occur, no later than, 4 hours from the anticipated end of medically necessary services. Hospitals are already adept at timing the issuance of other beneficiary notices to correspond with the end of medically necessary services. In the event a beneficiary voluntarily leaves the hospital prior to the hospital's schedule time of release, the hospital may document the time of and circumstances surrounding the beneficiary's departure on their copy of the MCSN.

If the beneficiary or their representative refuses to sign the notice, we proposed at § 405.1210(b)(4) to permit a hospital to annotate its copy of the notice of the beneficiary's refusal to sign. The hospital would be required to maintain a copy of the signed or annotated notice as part of its records regarding the stay, pursuant to federal and state law. In the December 2023 proposed rule (88 FR 89521), we further explained that a hospital would need to determine whether the beneficiary is capable of comprehending and signing the notice in the same manner as existing beneficiary notice requirements.

As suggested by some commenters, the proposed delivery requirements do not permit hospital staff to prefill the date and time elements of the beneficiary receipt acknowledgement section before delivery of the MCSN. Proposed § 405.1210(b)(3)(A) states valid delivery of the MCSN only occurs when, among other criteria, an ''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 [or when annotated if the beneficiary refuses to sign the notice].'' Because a beneficiary's acknowledgement of receipt and comprehension is recorded through their (or their representative's) signing and dating the document, hospital staff must not prefill these sections before delivery. Our proposed rules do not prevent hospital staff from assisting beneficiaries with completing the necessary elements after delivery.

We agree with commenters that the hospital responsibilities for delivering the MCSN should be delineated as clearly as possible and appreciate the interest in appropriately implementing the MCSN into hospital workflows. Following finalization of this rule, we plan to issue sub-regulatory guidance to further explain specific operational practices as we have for other beneficiary notices.

Comment: A commenter sought clarification on the consequences hospitals would face for failing to deliver the MCSN in accordance with the proposed requirements.

Response: We did not propose and are not finalizing new consequences or penalties for hospitals that specifically fail to comply with the prospective appeal requirements. Hospitals will continue to be subject to existing enforcement actions related to non-compliance with Medicare conditions of participation. As always, we would determine the degree and manner of any potential enforcement action on a case-by-case basis.

Comment: Multiple commenters suggested the proposed MCSN should not be finalized because the notice was too confusing for beneficiaries and hospitals. Several commenters worried the proposed MCSN would confuse beneficiaries by unnecessarily adding to the amount of documentation beneficiaries already receive.

A few commenters suggested the proposed MCSN might confuse beneficiaries in situations where the beneficiary receives notice of their right to appeal, through the proposed MCSN, before they receive notice of their reclassification. (The commenters incorrectly inferred the purpose of the MOON is to notify beneficiaries that they have been reclassified from inpatient to outpatient receiving observations services.)

Some commenters expressed concern that the MCSN could be confused with other existing standardized notices,

such as the MOON and other commenters suggested CMS not create a new standardized notice but, instead, incorporate language on hospital status reclassifications into the MOON or, in the alternative, require delivery of the new notice at the same time as the MOON.

Response: We appreciate and share the commenters' mindfulness for avoiding beneficiary and hospital confusion related to the proposed MCSN. We explained in the proposed rule that after determining the need for beneficiaries to receive notice of their right to appeal, we considered several options and, ultimately, decided the creation of a new standardized notice that would only be provided to eligible beneficiaries would be the least confusing and burdensome option available. In addition, we mirrored the notice delivery procedures to the IM notice procedures, a beneficiary notice with which hospitals are already familiar. We believe this approach balances a beneficiary's need to be informed of their appeal rights in an appropriate and timely manner, without imposing unnecessary burdens on hospitals.

We do not agree with commenters that merely creating a new beneficiary notice will inevitably lead to beneficiary confusion. While CMS has several beneficiary notices that must be delivered by hospitals, each has a discrete purpose and not all are provided at one time. As we have explained, the MCSN is a dedicated notice that will only be provided to the relatively few eligible beneficiaries who have the right to appeal based on a hospital reclassification from inpatient to outpatient receiving observation services. This means most beneficiaries will not receive the notice, drastically reducing the risk of beneficiary confusion. In addition, to enhance comprehension, we derived much of the verbiage used on the MCSN from other consumer-tested CMS beneficiary notices. Because of the narrow scope of the MCSN, the limited audience that will receive the notice, and our focus to use clear and concise language to convey the purpose of the notice, we believe we have taken all necessary steps to limit beneficiary and hospital confusion.

We explained in the proposed rule that we considered alternatives to creating a new notice for this process, including adding appeals information to the MOON or other existing beneficiary notifications. However, as discussed in the proposed rule, the vast majority of beneficiaries receiving the MOON will not be eligible for an appeal under this new process. Therefore, we believe using the MOON instead of, or in addition to, the MCSN, would be confusing to the nearly 600,000 beneficiaries receiving the MOON per year who would not be eligible for this appeal process.

Further, the MOON is only required for beneficiaries who have been outpatients receiving observation services for more than 24 hours. We proposed, however, the prospective appeals process would be available to eligible beneficiaries that received observation services for any amount of time after their reclassification from inpatient to outpatient. Therefore, because the MOON is not required for observation stays shorter than 24 hours, using the MOON, or attaching delivery of the MCSN to delivery of the MOON, would result in eligible beneficiaries not receiving notification of their right to appeal regarding a hospital status reclassification.

We also do not agree that beneficiaries will be confused if they receive the MCSN before the MOON. The MOON does not indicate whether the hospital has changed the beneficiary's status from inpatient to outpatient receiving observation services and, importantly, would not be required to be delivered to beneficiaries that have had their status changed and receive less than 24 hours of observation services. Instead of the MOON, hospitals are currently required to provide a written Condition Code 44 notification 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.

We decided against adding information on the prospective appeals process to the Condition Code 44 notice, however, because the number of beneficiaries eligible for this new appeals process would only be a small subset of the population receiving the existing Condition Code 44 notification. Therefore, we believe the MCSN and Condition Code 44 notification have distinct roles that will also provide complementary information to beneficiaries eligible for this appeals process.

Comment: Multiple commenters generally asserted the requirement for hospitals to deliver a new standardized notice specific to beneficiaries reclassified from inpatient to outpatient receiving observation services is too burdensome for hospitals and recommended against finalizing the policy. A commenter suggested the new delivery requirement, combined with existing workforce issues, would create an undue burden for hospitals and would be logistically almost impossible for hospitals to comply. Another commenter suggested hospitals already struggle with the timely delivery of the MOON and IM and adding another notice with a shorter deadline would compound an already administratively burdensome process. A commenter asserted the notice requirement would be an enormous burden on hospitals for what is estimated to be a small volume of appeals.

A commenter predicted the notice requirement would exacerbate hospital nursing shortages because the QIOs will need to hire new staff, thereby decreasing the pool of hirable nurses. A few commenters recommended CMS minimize the role of providers in delivering the proposed MCSN to protect the providers' patient care time. However, another commenter recommended CMS require hospitals use clinical staff to deliver the notice.

Response: We estimated in the proposed rule that hospitals would be required to give 15,655 MCSNs to beneficiaries each year, which we acknowledged is likely an overestimation based on limitations to our data collection. The current number of Medicare-certified hospitals in the country is approximately 6,162. Therefore, we estimate a single Medicare-certified hospital would deliver on average fewer than 3 notices, per year. While we understand the act of delivering new notices, even in a low volume, is an appreciable increase in responsibilities for hospitals, we do not believe the new appeals process will significantly affect operations or staffing within hospitals.

As we explained in the proposed rule, when considering developing the MCSN we needed to balance hospital burden with the need to appropriately notify beneficiaries of their appeal rights. We strongly believe the use of a dedicated, standardized notice, delivered by hospital staff to patients while still in the hospital is the most efficient and effective manner by which to inform beneficiaries of their appeal rights. We considered but ruled out adding the appeals language to existing beneficiary notices because, primarily, the appeals information would not be applicable to most beneficiaries receiving those notices. In addition, we are wary of adding too much information onto a single notice as consumer research consistently demonstrates that beneficiaries are not adept at self-selecting information. We, therefore, believe using a notice exclusively for those beneficiaries eligible to pursue an appeal relating to a hospital status

reclassification will ensure beneficiaries understand their appeal rights and how to exercise them.

The proposed delivery requirements for the MCSN were derived from the existing procedures hospitals must follow when delivering the IM. Our intention for mirroring the delivery processes was to leverage the familiarity that existing hospital processes and staff have with the IM procedures to more easily incorporate the new MCSN delivery requirements. Further, we developed the new MCSN to be a largely generic notice that would only require hospital staff to complete a few fields before delivering to the beneficiary. We strongly believe that considering the limited estimated volume of MCSNs hospitals would need to deliver annually, the similarity between the IM and new MCSN delivery procedures, and the familiarity existing hospital processes and staff have with the IM, will allow for hospital compliance with very limited increase in burden.

Finally, while we used a registered nurse's hourly rate to compute our burden calculation, we would like to clarify that there is no requirement for hospitals to use clinical personal to deliver the MCSN. As with similar notices, such as the IM and MOON, we do not feel it appropriate or necessary to regulate which hospital staff are capable of delivering the MCSN. Such decisions are best left to hospitals to make based on their internal protocols and staffing requirements. In regard to the impact the new appeals process will have on QIO-hiring demands, we estimated that the QIO will receive an estimated 8,000 appeals per year. While we do anticipate the QIO will need to hire additional clinical staff to review the increasing appeal volume, we do not anticipate an impact on hospital hiring practices on a national level. Thus, we do not foresee this new appeals process having a significant impact on clinical care resources or the demand for nurse labor.

We appreciate the feedback we received from commenters on the notification requirements. We will be finalizing the proposals at § 405.1210 as proposed. (We note that changes to the MCSN will be reflected in OMB control number 0938–1467 which is discussed in section IV.B.2. of the final rule.)

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 new expedited QIO review leading up to issuance and effect of the QIO's determination. We stated in the proposed rule that proposed § 405.1211 would establish the responsibilities of the hospitals, QIOs, and beneficiaries relative to the process.

Proposed § 405.1211(a) described 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 proposed 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 stated that we intended 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 proposed 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 did not propose any parameters of what a request in writing would constitute, but it could be an email or fax transmitted to the QIO. We also proposed 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) explained 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 also proposed, 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 (2 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 proposed 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 are 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) described the procedures that the QIO would be required to follow in performing the expedited determination. We proposed 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. The 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) addressed 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 1 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 did 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 SNF should they obtain a favorable decision by the QIO. A Medicare covered SNF 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) provided 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 2 calendar days after the QIO receives all requested information that the hospital must provide per proposed § 405.1211(d)(1).[23] 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.

In § 405.1211(c)(7) we proposed 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 2 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 proposed 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) set forth the responsibilities of hospitals in the expedited appeals process. Section 405.1211(d)(1) provided 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 also proposed 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) required 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 proposed that this obligation work the same way that it does under § 405.1206(e)(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 proposed 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 proposed only that the hospital may not bill the beneficiary until after the QIO has issued its determination. This proposal mirrored 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) set 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.

We received the following comments regarding our proposed requirements related to the prospective appeal determination procedures.

Comment: Many commenters expressed approval that the proposed prospective appeals process would be available to all beneficiaries who have been reclassified by a hospital from an inpatient to an outpatient receiving observation services, rather than limiting the class of eligible beneficiaries to those who receive a MOON, which is only required to be delivered when outpatient services reach 24 hours in duration. Multiple commenters strongly supported that beneficiaries with Part A but not Part B would not need to remain in the hospital for at least 3 days in order to be eligible for an appeal.

Response: We thank the commenters for their support of the proposed prospective appeals policy and our expansion of the population of beneficiaries eligible for an appeal.

Comment: Multiple commenters sought clarification on the criteria required for beneficiaries to access the proposed prospective appeals process. A few commenters questioned whether a beneficiary who is reclassified from inpatient to outpatient but does not receive observation services may appeal the reclassification. A few commenters questioned whether it was CMS's intent to require a beneficiary to receive the MOON in order to be eligible to appeal regarding a hospital status reclassification.

A commenter questioned whether a beneficiary may use the proposed appeals process when they have been reclassified from inpatient to outpatient receiving observation services, do not

[23] The proposed regulations text at § 405.1211(c)(6)(ii) contained a typographical error that stated that the QIO must render a decision for untimely requests within 1 day. This was an error that will be corrected in this final rule.

have Medicare Part B, but have other insurance coverage for outpatient observation services. A few commenters questioned whether a beneficiary must specify they are seeking SNF care in order to request an appeal. A commenter questioned how the proposed appeals process would be affected if a beneficiary exhausts their Medicare inpatient coverage and whether beneficiaries, in those circumstances, could pursue an appeal under the proposed prospective appeals process.

Response: We proposed at § 405.1211(a) that a beneficiary has the right to request an appeal by a QIO when they are reclassified by their hospital from an inpatient to an outpatient receiving observation services, and the beneficiary meets the eligibility criteria established in § 405.1210(a)(3). Pursuant to proposed § 405.1210(a)(3), an eligible beneficiary would be one who was formally admitted as a hospital inpatient, was subsequently reclassified as an outpatient receiving observation services, and either was not enrolled in Medicare Part B at the time of the beneficiary's hospitalization or stayed in the hospital for 3 or more consecutive days but was classified as an inpatient for fewer than 3 days.

We explained in the proposed rule the provisions of the prospective appeals process 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 Court's order required new appeal procedures be afforded to a specific class of Medicare beneficiaries who, among other criteria, have or will have been subsequently reclassified by the hospital as an outpatient receiving observation services. In accordance with the court order, we established the beneficiary eligibility criteria for this new appeal process at § 405.1210(a)(3), which requires eligible beneficiaries to have been reclassified by their hospital to an outpatient receiving observation services, among other criteria. We defined the phrase ''outpatient receiving observation services'' at proposed § 405.931(h) to mean when the hospital changes the 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. Thus, we believe it to be explicitly clear that a beneficiary must have received at least some observation services after being reclassified from an inpatient to outpatient in order to be eligible for the proposed appeals process.

As discussed in the proposed rule, a beneficiary does not need to receive the MOON in order to be eligible to request a prospective appeal. The MOON is a beneficiary notice furnished by a hospital to beneficiaries who receive observation services as an outpatient for more than 24 hours. However, in accordance with the proposed § 405.1210(a)(3) beneficiaries are eligible for the prospective appeals process after being reclassified from inpatient to outpatient receiving observation services if any time is spent in observation following the reclassification. Thus, the MOON is not required to be received by, and likely would not be received by many, beneficiaries in order to be eligible to appeal regarding a hospital status change under the new process. We acknowledge, as we did in the proposed rule, that this policy expands the population of beneficiaries eligible for an appeal beyond the class defined by the court in *Alexander.*

As we have previously explained, eligible beneficiaries include those whose hospital status was changed from inpatient to outpatient receiving observation services and were not enrolled in Medicare Part B at the time. We did not propose to include consideration of non-Medicare insurance among the required elements for appeal eligibility and do not believe it is prudent to do so now for several reasons. First, we do not believe verifying non-Medicare insurance in real-time during a fast-moving expedited process would be practical without risking delays to the appeal decisions if the QIO must first confirm a beneficiary does not have other outpatient insurance coverage. In addition, a beneficiary's possession of non-Medicare outpatient insurance does not actually guarantee coverage in all circumstances. Such decisions would be made on a case-by-case basis by the other insurer. Lastly, the Medicare program does not limit a beneficiary's appeal eligibility based on having outside insurance in other circumstances. Thus, we do not believe it reasonable to limit a beneficiary's right to appeal under the prospective appeals process merely because they may possess outpatient insurance coverage from another source.

Similarly, we did not propose at § 405.1210 (a), establishing the scope of prospective appeals process, a requirement for beneficiaries to request SNF services to be eligible to pursue an appeal regarding a hospital reclassification from inpatient to outpatient receiving observation services. While we expect SNF coverage to be a driving factor for many beneficiaries considering whether to pursue a prospective appeal, this is not the only reason an appeal might be warranted. For example, a beneficiary may want to appeal because they expect that their out-of-pocket costs would be lower as an inpatient or, in another case, the beneficiary may not have Part B and would want to appeal in order to not be liable for the full cost of the hospital stay. More importantly, some beneficiaries may not want to enter post-acute SNF care and, in those cases, we do not feel it would be just to condition a beneficiary's ability to pursue an appeal regarding a hospital reclassification on the requirement that they seek SNF care. Thus, while eligibility for a covered SNF stay is an important consideration for many beneficiaries considering an appeal, we believe it would be improper to significantly limit the class of eligible beneficiaries by requiring a beneficiary to seek SNF care as a prerequisite for appealing based on a hospital reclassification.

Finally, an implicit requirement for beneficiaries seeking inpatient coverage through the prospective appeals process is having available Medicare Part A benefits. The proposed appeals process, as with other similar appeals processes, does not override statutory benefit limits, such as the availability of inpatient hospital days. Should a beneficiary begin an appeal and it becomes evident that inpatient days are exhausted, the appeal decision will be unfavorable. Even if the QIO is unaware that the beneficiary had exhausted their inpatient days, the usual claim edits would trigger, and coverage would not be available to the beneficiary upon the submission of a claim. This appeals process does not confer benefits in excess of Medicare statutory limits.

Comment: A commenter recommended CMS permit SNF staff to file appeals under the prospective appeals process on behalf of eligible beneficiaries. The commenter asserted beneficiaries often lack the necessary support to work through appeals processes on their own and SNFs would be motivated to ensure they receive proper payment for services they render. Another commenter questioned whether hospital staff may assist a beneficiary in the proposed appeals process by answering questions and guiding the beneficiary through the appeals process.

Response: We appreciate the commenter's suggestion to permit a SNF to file an appeal on behalf of an enrollee; however, we do not agree that

party status should be extended to providers for the new appeals process. The prospective appeals process, proposed at §§ 405.1210 through 405.1212, is available to eligible beneficiaries who, after formally being admitted as an inpatient, have subsequently been reclassified by the hospital as an outpatient receiving observation services. We explained in the proposed rule that the court order specifically required the provision of appeal rights to a defined set of class members, and that definition did not include the provider of services (that is, hospitals and SNFs). Accordingly, we proposed limiting party status for these new appeals to the defined class members. The same limitation currently exists for hospital discharge appeals procedures in §§ 405.1205 and 405.1206, where a provider of services does not have party status.

While we are not extending party status to SNFs or other provider types, we are not modifying existing rules related to appointed representatives who may act on behalf of a beneficiary, nor have we restricted hospital or provider staff from assisting beneficiaries as they navigate their status reclassification and appeals process. We believe hospital and other provider staff already routinely engage in support activities for beneficiaries in their care and we endorse providers extending such support to eligible beneficiaries appealing based on a hospital reclassification. We do not believe it is necessary to strictly define or limit the type of support that may be provided to an eligible beneficiary but believe such support could include answering questions, providing explanations on the reclassification and appeals process, or assisting the beneficiary or their representative in contacting a State Health Insurance Program, 1–800–MEDICARE, or the QIO. We note that we do not believe support includes hospital staff completing the beneficiary specific portions of the MCSN that document the beneficiary's comprehension of the notice and the date/time of receipt before delivery to the beneficiary.

Comment: Multiple commenters commended CMS for not placing a deadline on when an eligible beneficiary may submit an appeal request to the QIO after leaving the hospital. A few commenters sought clarification on whether there is a deadline for eligible beneficiaries to submit an appeal to the QIO after leaving the hospital.

Response: We thank commenters for their support on the proposed appeal submission timeframes and for recognizing our intent to afford beneficiaries maximum flexibility when considering whether to request an appeal under the prospective appeals process. We proposed in § 405.1211(b)(5) that an eligible beneficiary may file a request for review by the QIO regarding their change in hospital status after the deadline established for expedited determinations, at proposed § 405.1211(b)(1). More specifically, the beneficiary may file an appeal request after they are released from the hospital. In addition, we proposed that these untimely appeal requests, which we also referred to as ''standard'' appeal requests, may be made ''at any time.'' We did not propose a deadline for these appeal requests in order to afford beneficiaries flexibility when exercising their appeal rights, especially those who may have had a SNF stay following their change in status from inpatient to outpatient receiving observation services. We continue to believe beneficiaries should have the maximum opportunity to pursue an appeal regarding their status change and potentially obtain coverage for SNF services which they may have paid out-of-pocket.

Comment: A commenter suggested CMS extend the timeframe for eligible beneficiaries to request an expedited determination to 48 hours after leaving the hospital. The commenter explained that an extended submission timeframe would better protect a beneficiary's rights by affording the shortest appeal decision timeframe available.

Response: We understand and appreciate the commenter's intent to provide beneficiaries with as long as possible to request and receive an expedited determination from the QIO. When proposing the expedited appeal submission timeframe, we weighed the benefit of providing beneficiaries ample time to submit an appeal request with ensuring beneficiaries submit the appeal request as soon as possible. Because there is no liability coverage during the proposed appeals process, we believe it is in beneficiaries' best interest to receive an appeal decision as soon as possible. In addition, we believe rapid decisions will provide beneficiaries with a more accurate picture of their inpatient coverage status and better inform their future financial and health care decisions, such as electing post-acute care services. If a beneficiary obtains a favorable decision from the QIO, a rapid decision will also maximize their potential for coverage in a SNF or other post-acute care facility.

We believe the proposed policy requiring beneficiaries to submit an expedited appeal before leaving the hospital strikes an effective balance that incentivizes beneficiaries to submit appeals quickly, so to receive a faster appeal decision, with ensuring untimely appeals are still processed expeditiously. An expedited appeal timely submitted to the QIO will be decided within 1 calendar day of receiving all relevant requested information. An untimely expedited appeal submission to the QIO will be decided within 2 calendar days of receiving all relevant requested information. This policy, while slightly slower than the expedited determination timeframes, still provides beneficiaries with a decision far sooner than if they had to request an appeal under the standard claims appeal timeframes (60 days at the first level of the claims appeals process).

Comment: Multiple commenters sought clarification from CMS on whether the proposed regulations require hospitals to retain beneficiaries for the duration of an expedited QIO review. A few commenters suggested CMS clarify that the QIO must continue to process an expedited determination request whether the beneficiary is present in the hospital or not. Several commenters recommended CMS permit hospitals to discharge or release beneficiaries from the hospital, as reasonable and necessary, during the pendency of an expedited determination. Other commenters warned the proposed policy will needlessly delay beneficiaries' safe release from hospitals and warned that requiring hospitals to keep beneficiaries in the facilities would increase the risk of beneficiaries contracting hospital infections and may lead to increased mortalities.

Response: We did not propose and are not finalizing a requirement that would restrict hospitals from safely releasing eligible beneficiaries that are awaiting a decision from the QIO on an expedited determination request. We explained in the proposed rule that the court in *Alexander* indicated that HHS should use a process for expedited appeals regarding hospital status changes that is ''substantially similar'' to the existing process for expedited hospital discharge appeals at §§ 405.1205 through 405.1208. While we believe we have appropriately followed the direction of the court, we noted in the proposed rule that there are certain differences between the proposed expedited determination process and the existing hospital discharge appeals process. Most notably, we explained that the proposed expedited determination process does not afford beneficiaries

protection from financial liability for services furnished during the pendency of the QIO's review. Instead, we proposed that the hospital may not bill the beneficiary until after the QIO has issued its expedited determination or issued a decision in response to a timely reconsideration request, as applicable. We noted that this billing protection does not extend coverage to beneficiaries during the appeal, which is consistent with § 405.1202(g).

Although we believed the policy was clearly described in the proposed rule, as several commenters had similar misunderstandings, we explicitly state here that the new appeals process does not direct hospitals to house or treat a beneficiary with medically unnecessary care during the pendency of their appeal. Hospitals should continue to follow all existing federal, state, and local rules and internal standard operating procedures when considering the release of a beneficiary who no longer requires hospital services. The only interaction this appeals process has with an eligible beneficiary's release from the hospital is the proposed requirement for hospitals to deliver the MCSN no later than 4 hours before the beneficiary's release from the hospital. We continue to believe that hospitals are equipped to accurately estimate, to within 4 hours, when an enrollee will cease to need medical care and should be able to comply with the MCSN delivery requirement.

Because we did not propose and are not finalizing a requirement that restricts hospitals from releasing eligible beneficiaries during an appeal, we do not believe we need to address the comments related to unnecessarily housing patients that do not need hospital-level care in hospitals.

Comment: Multiple commenters requested CMS clarify whether enrollees receive financial liability protection for services received while their appeal is pending. Several commenters urged CMS to hold beneficiaries harmless for the costs of services received while an expedited appeal is pending. These commenters suggested CMS will violate the court's direction that CMS should use a process for the expedited appeals that is ''substantially similar'' to the inpatient hospital discharge appeals process if beneficiaries are not held financially harmless while an expedited appeal is pending.

Several commenters requested guidance on how to code and bill beneficiaries for time spent in the hospital during their appeal. These commenters incorrectly believed the hospital could not release patients during the appeals process and suggested the hospital would need to bill for custodial care. Similarly, other commenters questioned how to properly inform a beneficiary that they will be financially liable for services received during their appeal.

Response: We appreciate the commenters' concerns and interests in protecting beneficiaries' financial liability during the expedited appeals process. As we previously explained, we believe the proposed structure of the expedited appeals process complies with the court order indicating we should use a process for expedited appeals regarding hospital status changes that is ''substantially similar'' to the existing process for expedited hospital discharge appeals at §§ 405.1205 through 405.1208. Nevertheless, there are certain important differences between the two appeals processes. Most notably, the proposed expedited determination process does not afford beneficiaries protection from financial liability for services furnished during the pendency of the QIO's review. As discussed in the proposed rule, Section 1869(c)(3)(C)(iii)(III) of the Act (by 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)) provides beneficiaries with coverage during the inpatient hospital discharge appeal process. However, this statute only applies to beneficiaries being discharged from a Medicare covered inpatient hospital stay. Under the proposed appeals process, beneficiaries are eligible to appeal based on a hospital's reclassification of their inpatient status to outpatient receiving observation services. Because the new appeals process is not an appeal of a covered inpatient hospital discharge, section 1869(c)(3)(C)(iii)(III) is inapplicable to the new appeals process. Thus, we did not propose and are not finalizing financial liability protections for eligible beneficiaries that appeal regarding a hospital reclassification from inpatient to outpatient receiving observation services.

We note that most of the commenters requesting guidance on notification and coding related to billing beneficiaries during the appeals process seem to misinterpret our proposed regulations to require hospitals to retain beneficiaries during the appeals process even if they no longer meet the requirements for medically necessary care. As we addressed in a previous comment, the proposed appeals procedures do not prevent hospitals from safely releasing beneficiaries based on their particular medical circumstances. Therefore, hospitals should continue to follow all existing federal, state, and local requirements for providing, and notifying beneficiaries of their financial liability related to non-covered care.

Comment: A few commenters urged CMS to grant beneficiaries presumptive SNF coverage from the date a prospective appeal is requested to at least the date of the QIO decision.

Response: While we appreciate the commenters' suggestion, we decline to create a policy that would provide presumptive SNF coverage for the days in which a prospective appeal is being adjudicated by the QIO. To qualify for SNF services coverage, section 1861(i) of the Act requires Medicare beneficiaries to have a medically necessary 3-consecutive-day inpatient hospital stay within 30 days of admission to a SNF. However, beneficiaries eligible for the proposed prospective appeals process had their hospital status changed from inpatient to outpatient receiving observation services. This means the beneficiaries may not have acquired the necessary 3-day stay to qualify for SNF coverage. Indeed, this is one of the primary reasons the court in *Alexander* directed CMS to create an expedited determination process for eligible beneficiaries. Therefore, in order to meet the 3-day stay requirement, as established by statute, most eligible beneficiaries would have to receive a favorable decision from the QIO. If CMS were to provide presumptive SNF coverage for the days in which a QIO is adjudicating a prospective appeal, but then a beneficiary did not receive a favorable decision from the QIO, the SNF stay would likely result in non-covered SNF care, with potentially significant beneficiary out-of-pocket expenses, regardless of any previous presumption of coverage. We believe the commenters' suggestion would, therefore, lead to inequitable outcomes for beneficiaries that receive unfavorable QIO decisions.

Comment: Multiple commenters supported our proposed requirement prohibiting hospitals from billing eligible beneficiaries until the expedited determination and reconsideration, when applicable, processes are complete. A commenter sought clarification on the appropriate time to bill a beneficiary for services after an expedited determination has been made. The commenter also questioned whether the hospital should rescind a bill issued to a beneficiary in the time between when the beneficiary received an expedited determination and requested a timely reconsideration. Separately, a few commenters requested

CMS extend the beneficiary billing protections for expedited appeals to untimely appeals.

Response: We appreciate the commenters support for our proposal. We proposed in § 405.1211(e) that a hospital may not bill a beneficiary who requested a timely appeal for any services at issue in the appeal until the expedited determination process (and reconsideration process, when applicable) is complete. This policy mirrors existing procedures for appeals related to the termination of non-hospital services found at § 405.1202(g). If a hospital inadvertently bills a beneficiary during a period in which the proposed requirements restrict hospital billing, we agree with the commenter that the hospital should immediately rescind the bill.

With respect to extending beneficiary billing protections for untimely appeals, we appreciate the commenters' suggestion and interest in enhancing beneficiary protections. However, pursuant to our proposed policy, eligible beneficiaries may at any time request a standard (that is, untimely) appeal relating to a hospital's decision to reclassify their status from inpatient to outpatient receiving observation services. While this policy provides beneficiaries with maximum flexibility when considering an appeal relating to a hospital reclassification, the timing of appeal requests could be unpredictable and, in some cases, a standard appeal request could be submitted after a beneficiary receives a hospital bill. We believe adopting such a proposal would be administratively impractical for hospitals to comply with as they could not be expected to reasonably anticipate when they would be barred from billing a beneficiary.

Comment: A commenter suggested the adjudication timeframes for ''regular appeals'' could result in financial uncertainty for hospitals as organizations could wait 2 years before the issuance of a final decision.

Response: We are unclear how the commenter estimated hospitals may have to wait 2 years before receiving a final decision. We posit the commenter considered the potential cumulative adjudication times if an eligible beneficiary appealed an adverse expedited reconsideration decision to the ALJ or beyond. Nevertheless, as stated in the proposed rule at §§ 405.1211(e) and 405.1212(e), a hospital is only prohibited from billing a beneficiary during the expedited levels of the determination and reconsideration processes. However, hospitals are permitted to bill beneficiaries after the QIO expedited determination and reconsideration levels of appeal are complete. As with other Medicare expedited and claim appeal processes, the higher levels of administrative appeal may not conclude until well after the service and billing are completed. Even so, we do not believe the proposed appeals adjudication timeframes would introduce significant financial uncertainty for hospitals due to the very low anticipated first level appeals volume of around 8,000 appeals nationally, per year.

Comment: Multiple commenters sought clarification on the impact of a beneficiary receiving a favorable expedited or standard determination from the QIO. Their questions were as follows:

- Upon the QIO issuing a favorable expedited determination to a beneficiary who remained in the hospital during their appeal, is the hospital required to present the IM before the beneficiary may be discharged?
- Would a beneficiary in that scenario be able to appeal the hospital inpatient discharge to the QIO, if desired?
- Upon a successful appeal, must a new inpatient order be entered or is the hospital reclassification decision considered null and void?
- Must the inpatient order be revised if a beneficiary received a favorable standard appeal decision and already released from the hospital?
- May a hospital collect the Part A deductible from the beneficiary upon a favorable determination by the QIO? (The commenter also wanted CMS to understand that some beneficiaries may have higher out-of-pocket costs when they receive a favorable appeal, due to the higher Part A deductible.)
- Must hospitals use a specific condition code when rebilling a Part A claim after a favorable standard appeal decision that was requested after the hospital had billed Part B?

Another commenter suggested hospitals should not have to refund to an eligible beneficiary any payments collected prior to the beneficiary receiving a favorable standard appeal decision from the QIO. The commenter suggested the Part B claim should be reopened instead and the hospital should be paid any remaining balance before the hospital is required to refund the beneficiary, as necessary.

Response: We did not propose and are not finalizing any changes to other hospital notice delivery requirements. If a beneficiary is still present in the hospital when a hospital's reclassification is reversed by a QIO, the beneficiary would again be deemed an inpatient under the original hospital admission order for purposes of Medicare Part A coverage. Hospitals would then be required to follow all applicable Medicare inpatient requirements when treating and discharging the beneficiary to include following the standard IM delivery guidelines set forth at § 405.1205(1). However, we expect most beneficiaries will receive their appeal decisions after being released from the hospital as hospitals historically have reclassified beneficiaries close to termination of hospital services. We will issue instructions for the submission or adjustment of claims affected by a disregarded reclassification in program instructions following this rule. The instructions will make use of existing standard claim coding and submission processes familiar to the affected providers.

We appreciate the feedback we received from commenters on the expedited determination procedures. Based on analysis of the public comments, we will be finalizing these provisions as proposed.

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 proposed to set forth the procedures for the new expedited reconsideration process. Proposed § 405.1212 contained the responsibilities of the hospitals, QIOs, and beneficiaries relative to the reconsideration process.

Proposed § 405.1212(a) described 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 proposed a process for beneficiaries to request an expedited reconsideration by a QIO. Proposed paragraph (b)(1) provided 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 explained 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) stated 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) described the procedures that the QIO must follow in performing the expedited reconsideration. Specifically, we proposed 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) provided that the QIO must render a decision and notify all relevant persons and entities within 2 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 SNF stay must begin within 30 days of a beneficiary's discharge from a hospital. To that end, we proposed 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) provided 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 2-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) set 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 QIO's [24] required timeframes of 2 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 (§ 405.1204(e)).

In § 405.1212(e) we proposed 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) set 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 or Part B, 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.[25] Our proposal followed that process.

We received the following comments regarding our proposed requirements related to the prospective appeal reconsideration procedures.

Comment: Several commenters supported the proposed reconsideration procedures when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services. A commenter believed the proposed timelines for beneficiaries to request, and QIOs to render, a reconsideration decision were reasonable and would protect the ability of beneficiaries to potentially obtain SNF benefits within the 30-day period following release from a hospital.

Response: We thank the commenters for their support.

Comment: A commenter suggested CMS harmonize the proposed prospective appeals procedures with existing Parts A and B claims appeal procedures because the commenter believed the proposed appeal procedures do not clearly identify if beneficiaries may continue to appeal after receiving an unfavorable QIO reconsideration decision.

Response: We explained in the proposed rule that a beneficiary who is dissatisfied by a QIO's reconsideration of its initial determination may seek additional administrative review and, ultimately, judicial review, if the amount-in-controversy limits are met. This means a beneficiary may appeal an adverse QIO reconsideration decision to an ALJ, if the amount in controversy is $200 or more, then to the Medicare Appeals Council (MAC), and, if the MAC denies the request for review or issues an unfavorable decision, to

[24] We referred to ''BFCC–QIO'' in the proposed rule but note that we are making a technical change at § 405.1211(d) to change to ''QIO'' so that it comports with all other references to the QIO in this subpart.

[25] 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.

federal district court, as long as the amount in controversy is $2,000 or more.

Comment: A commenter asserted beneficiaries should be given up to 24 hours to request an appeal of a QIO expedited determination, rather than noon of the next day, as was proposed in § 405.1212 (b). The commenter was concerned that beneficiaries may not understand the appeals process in time to receive an expedited reconsideration. Another commenter generally suggested beneficiaries receive more time to request an expedited reconsideration.

Response: We appreciate the commenters' interest in providing beneficiaries sufficient time to request a timely reconsideration. We proposed the expedited reconsideration request timeframes to mirror appeal submission timeframes for similar processes, such as inpatient hospital discharge appeals. In our experience, beneficiaries have sufficient opportunity to request an expedited reconsideration under the proposed timeframes. Additionally, when a QIO provides an expedited determination by phone, the QIO personnel will ask the beneficiary, or their representative, if the beneficiary would like to request an expedited reconsideration during the same phone call. This means a beneficiary, or their representative, may immediately request a second-level appeal (an expedited reconsideration) at the time they receive their first-level decision (expedited determination), without having to take any additional actions.

We note that even if the beneficiary fails to timely request an expedited reconsideration, the QIO will process an untimely request and the beneficiary will receive a decision in 3 calendar days (instead of 2 calendar days, which is the expedited processing timeframe).

Comment: A commenter requested that CMS acknowledge that hospitals may submit claims and receive Part A payment for services that are on appeal to an ALJ under the proposed prospective appeals process.

Response: We believe the commenter meant to request that CMS confirm that hospitals may bill Medicare and receive Part B payment while an appeal regarding a hospital status change is pending before an ALJ. If a hospital decides to reclassify a beneficiary from inpatient to outpatient receiving observation services, then the hospital would only bill Medicare under Part B. Nevertheless, we confirm that a hospital may bill Medicare for covered services while an appeal is pending at the ALJ.

Comment: A commenter requested CMS clarify which beneficiary notice a hospital must deliver to a beneficiary to notify them of their financial liability following an unfavorable expedited reconsideration decision.

Response: We proposed at § 405.1212(c)(4)(i) through (iv) that a QIO reconsideration decision must include, among other items, the potential financial ramifications, such as deductible and coinsurance for the beneficiary. Thus, the QIO is responsible for informing a beneficiary of their potential financial liability related to an unfavorable reconsideration decision.

We appreciate the feedback we received from commenters on the expedited reconsideration procedures. Based on analysis of the public comments, we will be finalizing these provisions as proposed.

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 proposed to make conforming changes to a related existing regulatory provision. We proposed to amend the provider agreement requirements in § 489.27(b) to cross-reference the proposed notice requirements. Thus, proposed § 489.27(b) specified that delivery of the proposed appeals notice was required as part of the Medicare provider agreement. Lastly, to account for this conforming change, we proposed 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.

We did not receive any comments on the proposed changes related to these conforming changes. As a result, we are finalizing our policies as proposed.

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

We also proposed 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 regarding hospital reclassifications of a fee-for-service beneficiary's inpatient status to that of outpatient receiving observation services when the eligibility requirements to file a prospective appeal being finalized in this rule are met. The beneficiary eligibility requirements for filing expedited appeals and the required processes for those appeals are described in sections III.B.1. through III.B.5. of this final rule. This proposed amendment to the QIO regulation specified that QIOs 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 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.

We stated in the proposed rule that 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 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 discussed in section III.B. of this final rule and appear at §§ 405.1210 through 405.1212.

The proposed amendment to the QIO regulations, as previously discussed, applied to the processes and timeframes

for the new appeals discussed in section III.B. of this final rule, which have been designed to meet the needs of beneficiaries who have had their inpatient status reclassified to outpatient receiving observation services.

In general, we received comments that were supportive of having the BFCC–QIOs conduct the new expedited and standard appeals and reconsiderations as a new type of QIO review under proposed § 476.71(a)(9), and for which QIOs would follow the processes specified under §§ 405.1211 and 405.1212.

Comment: Commenters indicated that QIOs' expertise conducting similar types of beneficiary appeals as well as reviewing patient status under the 2-midnight rule places them in an ideal position to review the new appeals under the prospective appeals process.

Response: We thank the commenters for their recognition of the QIOs' experience with beneficiary appeals and ability to conduct these new beneficiary appeals. QIOs have been performing expedited reviews for beneficiaries appealing inpatient discharges and termination of provider services in non-hospital settings for decades. We believe placing responsibility for reviewing the new prospective appeals with the QIOs will ensure consistent and timely review.

CMS is finalizing the conforming change to the QIO regulation as proposed, which adds the new prospective appeals to the enumerated list of QIO review responsibilities under § 476.71(a)(9).

A few commenters requested further clarification on specific topic areas which we address below.

Comment: A few commenters requested clarification on the decision-making criteria that would be used by the BFCC–QIOs for whether an inpatient admission order was valid; citing the potential for uncertainty, inconsistency and discretion in medical decision making.

Response: Consistent with existing CMS medical review guidance, in determining whether an initial inpatient admission met the criteria for Part A coverage, the QIOs would only consider the medical evidence which was available to the physician at the time an admission decision was made. Information which became available only after admission (for example, test results) would not be taken into consideration ''except in cases where considering the post-admission information would support a finding that an admission was medically necessary'' as stated in the Medicare Benefits Policy Manual, Ch. 1, § 10.

Comment: A commenter requested clarification regarding whether the QIOs will be staffed over weekends and holidays to conduct appeals and whether hospitals are expected to respond to requests from QIOs for patient records (as described in proposed § 405.1211(d)(1)) over weekends.

Response: We clarify that pursuant to their contracts, BFCC–QIOs are required to maintain operations 24 hours a day, 7 days a week. Should a beneficiary file a request for an expedited appeal over a weekend or holiday, the QIO will proceed with contacting the hospital to notify the hospital of the request and obtain medical documentation for the appeal. The hospital is required to respond by noon of the calendar day after the QIO notifies the hospital of the request for an expedited appeal.

However, should a beneficiary or their representative request that the hospital provide them with a copy of the records it provided to the QIO for the appeal, the hospital will be required to provide the records by no later than close of business of the first day after the material is requested by the beneficiary or the beneficiary's representative under 42 CFR 405.1211(d)(2). We clarify that for administrative functions ''close of business'' generally means 5:00 p.m. in the hospital's time zone.

Comment: A few commenters requested clarification on how the QIO will communicate decisions to the hospital and to the beneficiary.

Response: QIOs employ multiple modes of communication with beneficiaries and providers during current expedited appeals processes under 42 CFR 405.1202 and will do so for the expedited appeals finalized in this rule. These multiple modes of communication are used by the QIOs to ensure timely intake, patient record requests, and communication of decisions to both beneficiaries and providers. Currently a beneficiary appeal may be initiated via phone but would be formalized in writing by the QIO as required for expedited appeals under 42 CFR 405.1202(e)(8). QIO patient record requests for appeals, and appeal status tracking typically occur via web-based systems and phone. Under §§ 405.1211 and 405.1212, QIOs are required to notify the eligible beneficiary, the hospital, and SNF, if applicable, of their decision by telephone and issue written decisions for both initial determinations and reconsiderations.

Comment: Commenters suggested that CMS provide clear and objective guidelines for the BFCC–QIOs to follow when conducting the new appeals to ensure consistency.

Response: We appreciate the commenters' suggestion and will consider developing further implementation guidance for the BFCC–QIOs.

Comment: A commenter suggested that the BFCC–QIOs should issue written notices of their decisions to both the beneficiaries and the hospitals that contain the reasons and evidence for their determinations.

Response: We appreciate the need for beneficiaries and hospitals to understand the basis and rationale for the QIO's decision. Under §§ 405.1211 and 405.1212, QIOs are required to issue written decisions for both initial determinations and reconsiderations. These written decisions contain the reasons for their decision-making and the content that was evaluated to make their decisions.

Comment: A commenter suggested that CMS track the timeliness of the BFCC–QIOs in adjudicating the appeals and to report information on these and other appeals to the public.

Response: CMS routinely tracks the timeliness of resolving beneficiary appeals and will do so for these new prospective appeals. We appreciate the public's interest in ensuring accountability for the timely conduct of these appeals and may consider additional reporting in the future.

Comment: A few commenters suggested that CMS establish an electronic means for the BFCC–QIO to provide updates on appeals to hospitals.

Response: The QIOs currently maintain electronic/web-based means of communicating with providers for beneficiary appeals—both for patient record requests, and for appeal decisions.

Comment: A commenter expressed concern that the BFCC–QIOs may not have adequate resources to conduct these reviews, and this may divert resources from other areas like quality improvement and quality reporting. The BFCC–QIOs may need to hire a large number of clinical staff for these appeals, thus contributing to healthcare workforce shortages. Another commenter was concerned that the new appeals could negatively affect the QIOs' ability to work on quality reporting and improvement programs for hospitals.

Response: We do not believe the new appeals process will significantly affect operations or staffing within hospitals due to the low annual volume anticipated. While we anticipate the BFCC–QIOs will need to hire additional

clinical staff to review the additional appeals, we do not anticipate this would have an impact on the clinical workforce on a national level. Thus, we do not foresee this new appeals process having a significant impact on clinical care resources.

We thank the commenters for their feedback and recommendations for the prospective appeals process. After consideration of the public comments, we will be finalizing our policies as proposed. However, we note that we are making the following editorial/technical corrections:

- In § 405.1211(c)(6)(ii), we are correcting a typographical error in the proposed regulations text and stating that for untimely requests, the QIO must make a determination within 2 calendar days.
- In § 405.1211(d), we are changing ''BFCC–QIO'' to ''QIO'' to comport with all other references to the QIO in this subpart.
- In § 405.1211(d)(7), we are making technical edits for clarity.
- In § 405.1212 —

++ In paragraph (c)(3)(i), we are revising the phrase ''A timely request from in accordance'' to ''A timely request in accordance'';

++ In paragraph (c)(4), we are revising the phrase ''When the QIO issues an reconsideration'' to ''When the QIO issues a reconsideration'', and

++ In paragraph (d), we are revising the phrase ''beyond that furnished to the BFCC–QIO'' to ''beyond that furnished to the QIO'' to be consistent with other references to the QIO.

- In § 476.71(a)(9), we are correcting the cross-reference in the last sentence of the paragraph to refer more broadly to ''§ 405.1212''.

As noted previously, after publication of this 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 §§ 405.1210 through 405.1212). We will announce the implementation dates on *CMS.gov* and/or *Medicare.gov.*

C. Other/Out of Scope Comments

We also received comments that are outside the scope of this rulemaking, summarized as follows.

Comment: Several commenters urged CMS to address policy issues related to outpatient stays and observation services and the impact on SNF coverage for Medicare beneficiaries. Some commenters recommended that CMS count all time in the hospital towards satisfying the requirement of a 3-day qualifying inpatient hospital stay for SNF coverage. A commenter suggested that CMS directly address the issue of long outpatient stays with hospitals to avoid the need for beneficiaries to use an appeals process when they disagree with their outpatient status. The commenter suggested that CMS should implement policies to prohibit or severely restrict hospital reclassifications from inpatient to outpatient and long outpatient stays, and further suggested that hospitals should bear the burden of justifying long outpatient stays (lasting more than two-midnights).

Response: We appreciate the concerns raised by commenters related to observation services and long outpatient stays. This final rule implements the court order in *Alexander* v. *Azar* for the limited purpose of establishing appeal 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. It is beyond the limited scope of this rule to address the concerns raised by commenters regarding observation services, the counting of all hospital days towards satisfying the statutory requirement of a 3-day qualifying inpatient hospital stay for SNF coverage, and restricting hospital decisions regarding the length of outpatient stays or reclassifications. CMS acknowledges this feedback and may further consider it in future policymaking.

D. Severability

The various provisions of this final rule are intended 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). As detailed in the preamble, this final rule establishes processes for retrospective appeals and prospective appeals (standard prospective appeals and expedited prospective appeals). To the extent a court may enjoin any part of this final rule, the Department intends that other provisions or parts of provisions remain in effect. For example, the portions of this rule addressing retrospective appeals and prospective appeals are mutually severable from each other. Per the court order, the retrospective appeals process applies to class members whose due process rights may have been violated prior to the availability of the procedural protections set forth in the prospective appeals process, whereas the prospective appeals process applies to class members whose due process right may be violated in the future. In addition to applying to different beneficiaries, the retrospective and prospective appeals processes involve different timeframes for the reviews to take place, different contractors to perform the reviews, and potentially different claims. The existence of the prospective appeals process does not depend on the existence of the retrospective appeals process, and vice versa. These distinct processes can function independent of each other and are thus mutually severable. This example is not intended to be exhaustive and should not be viewed as an intention by HHS to consider specific provisions of the rule as not severable from other provisions of the rule. To the extent a court enjoins any part of this final rule, the other provisions of the rule would still further the purpose of implementing the court order and establishing appeals processes for qualifying beneficiaries.

We did not receive comments on this issue, and we intend to apply the concept of severability to this final rule as described.

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 final 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements and

comments are responses are discussed in the following.

A. Wage Estimates

1. Private Sector

To derive average costs, we used wage data from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/2023/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	45.42	45.42	90.84

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.

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $23.18/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [26] 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 $1,117 [27] for 2022, divided by 40 hours to calculate an hourly pre-tax wage rate of $27.93/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.75/hr ($27.93/hr × 0.17), resulting in the post-tax hourly wage rate of $23.18/hr ($27.93/hr − $4.75/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.

[26] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[27] *https://fred.stlouisfed.org/series/LEU0252881500A.*

B. Information Collection Requirements (ICRs)

This final 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. *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 or otherwise qualified practitioner 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 final rule. 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 provisions in new § 405.932 were submitted to OMB for review under control number 0938–1466 (CMS–10885). 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. of this final rule, § 405.932 establishes 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* and/or *CMS.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.[28] Assuming that 20 percent of

[28] 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

individuals (6,579 = 32,894 × 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 $76,262 (3,290 hr × $23.18/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 provisions in new § 405.1210 were submitted to OMB for review under control number 0938–1467 (CMS–10868). 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 requires hospitals to deliver, prior to release from the hospital, 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 Medicare Change of Status Notice (MCSN) is new and is intended to be furnished only to those beneficiaries eligible for this specific new appeal process. The 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 will 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 will 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 $90.84/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.[29] With regard to this final 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 × 0.1667 hr/notice) at a cost of $237,092 (2,610 hr × $90.84/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 final rule for information on how 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 final rule, we provided that the QIOs will 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 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 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 final rule, hospitals will be required to submit patient records to the QIOs for prospective expedited appeals under § 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 preamble 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 final rule, we established 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 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

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.

[29] 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.

the PRA as stipulated under 5 CFR 1320.4(a)(2).

C. Summary of Annual Burden Estimates for Changes

TABLE 2—ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Regulation section(s) under Title 42 of the CFR	OMB Control No. (CMS ID No.)	Respondents	Total responses	Time per response (hours)	Total time (hours)	Labor cost ($/hr)	Total cost ($)
§ 405.932	0938–1466 (CMS–10885)	32,894 beneficiaries	6,579	0.5 (30 min)	3,290	23.18	76,262
§ 405.1210	0938–1467 (CMS–10868)	6,162 hospitals	15,655	0.1667 (10 min)	2,610	90.84	237,092
Total		39,056	22,234	varies	5,900	varies	313,354

D. Submission of Comments

We have submitted a copy of this final 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 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.

Comment: Multiple commenters believed CMS underestimated the burden estimates related to hospitals timely delivering the new MCSN. A commenter believes the estimated annual volume of expedited appeals is generally understated because it failed to include appeals from beneficiaries with Part A but without Part B. Another commenter suggested CMS should be able to easily calculate the average annual number of eligible beneficiaries without Part B and should publish the number.

Another commenter disputed our estimate that the MCSN would take hospital staff 10 minutes to prepare and deliver because it does not account for any time the staff will need to answer beneficiary questions upon delivery. Another commenter stated the burden estimate failed to account for the hospital time and resources needed, including the hiring of new personnel, to establish a new workflow, to provide requested records to the QIO, and to rebill claims and refund beneficiaries who obtained a successful appeal.

Response: We acknowledge that the proposed rule estimates did not include hospital reclassifications of beneficiaries from inpatient to outpatient receiving observation services for beneficiaries that did not have Medicare Part B. Based on certain data collection limitations, it is not possible for CMS to fully estimate the number of beneficiaries with Part A but not Part B who are eligible to appeal in this process. Hospital stays for this population without Part B coverage who were changed from inpatient to outpatients receiving observation services are not reflected in Medicare claims data, as non-covered Part B claims are generally not submitted to Medicare. Nevertheless, we did attempt to obtain estimates from the data that was available and only a handful of such non-covered Part B claims existed per year.

In the proposed rule, we estimated the time it would take a hospital registered nurse to complete the MCSN to be 10 minutes as this is the longstanding estimate for delivery of the IM, a very similar notice. Throughout multiple public comment periods as part of the PRA renewal process, we have not received any comments or concerns regarding delivery of the IM or our estimated time to complete delivery of the notice. We also cannot account for all circumstances and our estimates only represent the average time we expect for notice preparation and delivery. We note that because this is a new appeals process, we must provide these estimates in the absence of historical data. However, we will update these estimates in each MCSN PRA renewal cycle. Finally, we acknowledge we did not provide burden estimates for hospital activities beyond delivering the new notice. We have not previously calculated the burden of activities ancillary to the appeals process, such as rebilling or submitting documentation to the QIO, for the IM or the Notice of Medicare Non-Coverage, which have similar notice and appeals processes for termination of coverage of sub-acute care. Therefore, we do not have data available to utilize for such an estimate. Even if we were to attempt such an estimate, we believe it would be impossible to provide an accurate estimate due to the variation in hospital size and workflow approaches. Nevertheless, we believe the financial impact and resource expenditure for hospitals delivering the MCSN to be minimal as hospitals already have processes and personnel in place that regularly deliver beneficiary notices with similar delivery requirements of the MCSN. We expect hospitals can incorporate this new notice into their well-established practices for pre-release paperwork delivery by caseworkers and other hospital staff.

Comment: A commenter requested CMS provide guidance in the final rule on the expected impact to Medicare Supplement Insurance plans serving FFS beneficiaries, including impacts on cost-sharing, due to the proposed appeals processes.

Response: We do not anticipate the proposed prospective appeals process will impact existing policies related to Medicare Supplement Insurance plans. We acknowledge that a beneficiary's cost-sharing may at times increase or decrease due to a favorable QIO decision, which in turn may potentially affect the amounts covered by an enrolled Medicare Supplement Insurance plan. However, we do not have the historical data necessary to accurately estimate any potential change in total payments made by Medicare Supplement Insurance plans.

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), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and

equity). 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 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 for the retrospective process is 32,894.[30] 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 basis. We estimate that around 15,655 notices informing beneficiaries of their change in status and informing them of their right to appeal will be delivered annually.[31] We are estimating an appeal rate of 50 percent, which would result in about 8,000 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.

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 604 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 final 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 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 2024, that threshold is approximately $183 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 final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 27, 2024.

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 amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 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:

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

[30] 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.

[31] 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.

hospital stays on or after January 1, 2009, for a specified class of beneficiaries under certain conditions (defined in § 405.931(b)) 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.

(i) *Conclusive effect of a Part A coverage determination.* For the purposes of appeals under §§ 405.931 through 405.938, the determination with respect to coverage under Part A is conclusive and binding with respect to the services furnished and must be applied to any existing appeals with respect to coverage and payment for hospital services under Part B and SNF services (as applicable).

§ 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 calendar 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 paragraph (d)(3) of this section, 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 (including payments made by an individual not biologically related to the beneficiary) 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) 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 120 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 paragraph (f) of this section.

(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, the information needed to cure the denial, and the process for requesting a review of the eligibility denial under paragraph (e) of this section.

(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 paragraph (f) of this section.

(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 (f)(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, unless a Part A claim is submitted by a hospital, 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 365 calendar days of receipt of the notice of a favorable decision.

(ii) In the case of 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. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision.

(iii) In the case of a beneficiary 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 only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(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, unless a Part A claim is submitted by a hospital, 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 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of 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. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary 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 only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(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, unless a Part A claim is submitted by a hospital, 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 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of 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. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary 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 only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(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, unless a Part A claim is submitted by a hospital, 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 365 calendar days of receipt of the notice of a favorable decision;

(ii) In the case of 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. After the refund is issued, the hospital may then submit a Part A inpatient claim for such services within 365 calendar days of receipt of the notice of a favorable decision;

(iii) In the case of a beneficiary 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 only if the hospital chooses to submit a Part A inpatient claim for such services. The deadline for submitting a Part A claim for such services is 365 calendar days after receipt of the notice of a favorable decision, and the hospital must refund any payments collected for the outpatient services before submitting the Part A inpatient claim.

(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, 405.1211, 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 this section and §§ 405.1211 and 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 this section and §§ 405.1211 and 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 this section and §§ 405.1211 and 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, 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) An 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 untimely expedited QIO determination at any time. The QIO issues a decision in accordance with paragraph (c)(6)(ii) of this section, but the billing 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 2 calendar days 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 specified in paragraph (d)(1)(i) of this section, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the requested 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 and, if applicable, delivering 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 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 a 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 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 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 or 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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–23195 Filed 10–11–24; 4:15 pm]

BILLING CODE 4120–01–P