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CENTER FOR MEDICARE

Medicare Appeal Rights for Certain Changes in Patient Status Proposed Rule (CMS-4204-P) Fact Sheet

On December 21, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would establish appeals processes for certain people with Medicare in Original Medicare who are initially admitted to a hospital as an inpatient but subsequently reclassified by the hospital as an outpatient receiving observation services during their hospital stay and meet other eligibility criteria.

The proposed rule can be downloaded from the Federal Register at: https://www.federalregister.gov/public-inspection/current.

Background

Alexander v. Azar was a nationwide class action case filed in 2011 that sought to require the Secretary of Health and Human Services to afford Medicare beneficiaries rights to a hearing to challenge their placement as outpatients receiving observation services. In March 2020, the United States District Court for District of Connecticut issued a decision explaining that beneficiaries were not entitled to appeal rights for their placement as outpatients receiving observation services. However, the court directed the Secretary of the Department of Health and Human Services to create additional appeals processes for a specified class of people with Medicare who were initially admitted as hospital inpatients but were subsequently reclassified by the hospital as outpatients receiving observation services and meet other conditions specified in the order. The government appealed and the United States Court of Appeals for the Second Circuit affirmed the district court's decision in January 2022.

Beneficiaries included in the class are those who either had, or will have, Part A benefits denied for hospital inpatient services and Skilled Nursing Facility (SNF) care as a result of the hospital's reclassification. The class also includes beneficiaries who did not have Part B coverage at the time of hospitalization.

The court ordered the Secretary to create additional appeals processes for such beneficiaries, including an expedited appeals process that is substantially similar to the existing hospital discharge appeals for class members who appeal while they are in the hospital, and a retrospective review process for beneficiaries who met the conditions for the class prior to the implementation of the prospective appeals process.

Proposed Rule Highlights

Expedited Appeals:
CMS is proposing in this rule an expedited appeals process for eligible beneficiaries who disagree with the hospital's decision to reclassify their status while they are still in the hospital from inpatient to outpatient receiving observation services (resulting in a denial of coverage for the hospital stay under Part A). These beneficiaries would be able to file an appeal with a Beneficiary & Family Centered Care - Quality Improvement Organization (BFCC-QIO). The BFCC-QIO would independently review the beneficiary's patient record to determine whether the inpatient admission satisfied the relevant criteria for Part A coverage. After receiving patient records from the hospital, the BFCC-QIO would render a determination within one day for timely requests.

Standard Appeals:
CMS is also proposing a standard appeals process for eligible beneficiaries who do not file an expedited appeal that would allow them to pursue an appeal 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). In some cases, this may happen after processing of the hospital's Part B outpatient claim and any denial of SNF coverage. This proposed process would follow similar procedures to the expedited appeals process but with longer timeframes to file and for the BFCC-QIO to make decisions.

Retrospective Appeals:
CMS is also proposing to establish a retrospective process that applies to beneficiaries with hospital admissions on or after January 1, 2009, involving status changes before the implementation of the prospective appeals processes discussed above. Consistent with the Court's order, the beneficiary must demonstrate eligibility for an appeal as a class member and show that the initial inpatient admission satisfied the relevant criteria for Part A coverage. Under this proposed process, CMS would use an "eligibility contractor," which would be an existing appeals contractor to serve as a single point of contact for incoming beneficiary retrospective appeal requests and as a gatekeeper in determining eligibility for an appeal. Beneficiaries would have a full year from the implementation date of the final rule to gather any related documentation and file an appeal request. Appeals following the eligibility determination would generally mirror the existing five level claim appeals procedures.

To conform with the appeals processes proposed above, CMS also proposed the following conforming changes:

- The delivery of a related appeals notice would be required as part of the Medicare provider agreement.
- The QIO regulations would be modified to specify that the QIO performs review functions for certain 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.

If finalized, these appeals processes would be available to beneficiaries after an operational implementation period.

made under Medicare. This flexibility allows CMS to establish and further define the types of reviews performed by the QIOs in order to meet evolving needs and issues pertaining to healthcare delivered under the Medicare program.

As discussed in sections II. and III.A. of this rule, a recent court decision requires the Secretary to implement an appeal process for certain Medicare beneficiaries that is substantially similar to the existing hospital discharge appeals conducted by QIOs under §§ 405.1205 through 405.1208. See *Alexander* v. *Azar,* 613 F. Supp. 3d 559 (D. Conn. 2020)), *aff'd sub nom., Barrows* v. *Becerra,* 24 F.4th 116 (2d Cir. 2022). These new review and appeals activities are within the scope of the Secretary's authority under section 1154(a)(18) of the Act to contract with QIOs to perform additional activities that are not already specified in section 1154 of the Act or other provisions. Section 1155 of the Act governs appeals of QIO determinations that are made under Title XI, subpart B, which includes section 1154 of the Act. Therefore, the proposed new QIO determinations, performed under section 1154(a)(18) of the Act, are subject to the appeal process specified in section 1155 of the Act.[14] Based on the QIOs' expertise and longstanding performance of similar functions, CMS has determined that the QIOs are the most appropriate entity to perform beneficiary-initiated appeals of hospital reclassifications of inpatients to outpatients receiving observation services proposed in §§ 405.1211 through 405.1212.

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

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

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

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

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

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

[14] 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 proposed appeals, section 1155 of the Act authorizes the QIO to conduct a reconsideration of its expedited determination regarding the hospital reclassification under proposed § 405.1211 to determine if an eligible beneficiary is entitled to coverage under Part A of the program.

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

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

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

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

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

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

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

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

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

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

(2) An eligible party (or the party's representative) who satisfies the amount in controversy requirement in § 405.936(c) and the requirements to escalate a case from the Council in § 405.1132 may request judicial review in Federal district court under the procedures set forth in § 405.1136.

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

Subpart J—Procedures and Beneficiary Rights for Expedited Determinations and Reconsiderations When Coverage Is Changed or Terminated

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) Any other information required by CMS.

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

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

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

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

{Insert contact information here}

Medicare Change of Status Notice

Patient name: **Patient number:**

Your hospital changed your status from inpatient to outpatient receiving observation services. This means:

- Your hospital bill might change depending on the Part B coinsurance you'll owe as an outpatient. If your Part B coinsurance is less than the Medicare inpatient hospital deductible, you'll get a lower bill. If your Part B coinsurance is higher than the inpatient deductible, you'll get a higher bill. Check with your hospital for more detailed billing information.
- You won't have Medicare coverage in a skilled nursing facility (SNF) after you leave the hospital.

Your Right to Appeal This Decision:

- You have the right to an immediate, independent medical review (appeal) of the hospital's decision to change your status. Medicare authorized an independent Quality Improvement Organization (also known as a QIO) to perform this review.
- If you choose to appeal, the QIO will ask for your opinion. The QIO will also look at your medical records and/or other relevant information. You don't have to prepare anything in writing, but you have the right to if you'd like.
- If the QIO disagrees with your status change to an outpatient receiving observation services, you may qualify for a Medicare-covered SNF stay after you leave the hospital. You'll be responsible for the Medicare inpatient hospital deductible.
- If the QIO agrees with your status change to an outpatient receiving observation services, you won't qualify for a Medicare-covered SNF stay after you leave the hospital. You'll be responsible for Medicare Part B copays.

How to Appeal your Status Change:

- Call your QIO at: {insert QIO name and toll-free number of QIO}, or if you have questions.
- You should ask for an appeal as soon as possible and before you leave the hospital.
- The QIO will notify you of its decision as soon as possible, usually within 1 day of getting all the necessary information.

See page 2 of this notice for more information.

If You Miss the Deadline to Appeal, You May Have Other Appeal Rights:

- Call the QIO listed on Page 1.

You have the right to get Medicare information in an accessible format, like large print, braille, or audio. You also have the right to file a complaint if you feel you've been discriminated against. Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice, or call 1-800-MEDICARE (1-800-633-4227) for more information. TTY users can call 1-877-486-2048.

Additional Information (Optional):

Please sign below to indicate you received and understood this notice.

I have been notified of my change in status from a hospital inpatient to a hospital outpatient receiving observation services. I understand I may contact my QIO to appeal this decision. I also understand if I win my appeal, my hospital charges will be different, and possibly higher.

Signature of Patient or Representative

Date / Time