

February 26, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-40204-P, Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

To Whom It May Concern:

**Re: Medicare Program: Appeal Rights for Certain Changes in Patient Status
CMS-4204-P, 88 Federal Register 89506 (December 27, 2023)**

These comments are submitted on behalf of the co-counsel organizations 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 **Center for Medicare Advocacy** is a national non-profit law organization that works to ensure access to Medicare, health equity, and quality health care. The organization provides education, legal assistance, research, and analysis on behalf of older people and people with disabilities. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation, and, when necessary, challenges patterns and practices that improperly deny access to Medicare and necessary care.
- **Justice in Aging** is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable healthcare, economic security, and the courts for older adults with limited resources. We focus our efforts primarily on those who have been marginalized and excluded from justice such as older adults of color, older women, LGBTQ+ older adults, older adults with disabilities, and older adults who are immigrants or have limited English proficiency. Justice in Aging has decades of experience with Medicare and Medicaid and improving both programs for people dually eligible.
- **Wilson Sonsini Goodrich & Rosati**, is the premier provider of legal services to technology, life sciences, and growth enterprises worldwide. The firm is internationally recognized as a leading provider to growing and established clients seeking legal counsel to complete sophisticated corporate and technology transactions; manage governance and enterprise-scale matters; assist with intellectual property development, protection, and IP-driven transactions; represent them in contested disputes; and/or advise them on antitrust

or other regulatory matters. Wilson Sonsini also has a premier Community Impact program, focused on access to justice and serving the underrepresented via *pro bono* and community service work. With deep roots in Silicon Valley, Wilson Sonsini has more than 950 attorneys and 19 offices across the United States, China, and Europe. For more information, please visit <https://link.edgepilot.com/s/59346f59/XK2wzfzau0UGkTqS27f9pDg?u=http://www.wsgr.com/>.

I. General Comments

We are generally supportive of the proposed procedures. Implementing the procedures as promptly as possible is of the utmost importance given the composition of the class and how long class members have had to wait for the vindication of their due process rights. Many class members have already died. Others have gone many years without urgently-needed reimbursement of funds they were forced to spend on hospital or skilled nursing facility (“SNF”) care that should have been covered by Medicare. Every day, more hospitalized Medicare beneficiaries enter the class when their patient status is changed from inpatient to outpatient receiving observation services. Without prospective appeal procedures in place, they may be forced to go without medically necessary SNF care because they cannot afford to pay for it out of pocket. In short, the faster the proposed procedures are implemented, the faster patients will be able to benefit from access to Medicare coverage for which they qualify by law.

As described in detail below, CMS must also provide more clarity in its notices and instructions, and in the standard of review for coverage. We also strongly urge CMS to ensure effective outreach to class members eligible for retrospective relief.

II. Provisions of the Proposed Regulations

a. Retrospective Appeals

We support the general approach CMS is proposing for retrospective appeals by eligible Medicare beneficiaries who experienced changes from hospital inpatient to outpatient status dating back to January 1, 2009. We agree that the retrospective appeal procedures should have substantial “similarities to the longstanding claims appeals procedures with which Medicare beneficiaries are familiar,” and we support basing the proposed regulations on existing provisions. 88 Fed. Reg. 89506, 89508 (Dec. 27, 2023). That approach is consistent with the court’s finding that “CMS already has in place the relevant procedural mechanisms,” noting the five-step appeals process and the analysis currently performed “in post-payment reviews and appeals therefrom.” *Alexander*, 613 F. Supp. 3d at 598. We appreciate the flow charts provided in Figures 1 and 2, which help clarify the proposed procedures and show their similarities to existing Medicare appeals.

We disagree with the proposal 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 recommend that CMS extend this filing period to two years (730 calendar days), in addition to the proposed**

allowance of extensions for good cause as specified in 42 C.F.R. §§ 405.942(b)(2)-(3).

Importantly, the court imposed no deadline on the relief for class members whose due process rights had been violated before remedies were put into effect. Furthermore, as a practical matter, one year is too short given the composition of the class and how long they have had to wait as the underlying court case was litigated. While some eligible beneficiaries who were aware of the court order and awaiting this rulemaking will be equipped to file their appeal requests quickly, not all class members will be so well informed. Given that some of the changes in patient status underlying the relevant appeals occurred a decade or more ago, impacted individuals or their caregivers may no longer be alive or otherwise able to follow through with the new process. Their medical and other records from that time may be hard, if not impossible, to locate. It can take time to find and establish a relationship with an advocate who can help. Moreover, the particular individuals eligible for this relief are likely to experience the health and other complications that serve as the basis for good cause extensions under the applicable regulations. Extending the deadline for filing retrospective appeals requests to two years would minimize both the burden on beneficiaries to show good cause, and the burden on CMS to review requests for extensions.

Relatedly, **we also strongly urge CMS to conduct additional education and outreach to ensure affected enrollees and their representatives are aware of the retrospective appeal process. This is critical to comply with the court’s mandate to provide “effective notice” of the retrospective appeals. *Alexander*, 613 F. Supp. 3d at 632.** We support CMS’s plans to continue posting information on Medicare.gov and CMS.gov. However, this alone is not effective notice as affected class members may not be tech savvy and may not visit these websites. Moreover, if the beneficiary is deceased, it is particularly unlikely that their eligible representatives will be visiting these websites. We recommend including information about the retrospective appeal process on a separate page with the annual *Medicare & You* handbook, and with Medicare Summary Notices during the request filing period. CMS should also consider adding information about the new appeals processes to 1-800-MEDICARE hold messages and creating materials that social workers, SHIP counselors, SNFs, mainstream press, and advocates can use to inform individuals and families. The informational materials and model appeal request forms should be translated into other languages and accessible formats, and otherwise comply with regulations implementing Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973.

CMS should provide more clarity and guidance to beneficiaries about submitting their medical records as part of the retrospective appeal request and what they will need to show to be successful in their appeals. The model appeal form and instructions should encourage beneficiaries to submit their medical records with the retrospective appeal request if possible. It should also specify what the records should show, such as “the dates you were in the hospital, the doctors’ orders regarding your admission and care, and information about the care and treatment you received.” The instructions should also recommend which types of records beneficiaries should request and provide, if they are available, as likely containing information relevant to their appeal (e.g., emergency department notes, admission notes, physician orders, social work records, discharge notes and discharge summary, patient notices). The form should also explain how to obtain assistance from the eligibility contractor in getting their records (and

that such assistance is free of charge). The instructions must also make clear that Medicare beneficiaries can still submit retrospective appeal requests even if their medical records are unavailable and specify that in the absence of medical records, acceptable evidence would include things like written statements from beneficiaries, their family members, and their providers who are familiar with the facts giving rise to their appeal.

The instructions should also explain the relevant standard for coverage that beneficiaries will have to meet to obtain a favorable appeal decision, and this should be expressly noted in the final rule. For instance, the instructions could contain language to the effect of: “If we decide that you are eligible to appeal, what you will need to show to win your appeal depends on when you were hospitalized. If your hospitalization occurred from January 1, 2009 through September 30, 2013, to obtain Part A coverage of SNF care following your hospitalization, you will need to show that the doctor who ordered your inpatient admission had a reasonable expectation that you would require hospital care for at least 24 hours at the time of the inpatient order. If your hospitalization occurred between October 1, 2013 and [date of implementation of rule], to obtain Part A coverage of SNF care following your hospitalization, you will need to show that the doctor who ordered your inpatient admission had a reasonable expectation that you needed hospital care that would cross at least two midnights at the time of the inpatient order.”

CMS should allow more time for submission of missing information. We appreciate that CMS recognizes the “challenges beneficiaries and their representatives may face in obtaining and producing” documentation for their appeals “where significant time may have passed since a beneficiary was hospitalized.” 88 Fed. Reg. at 89513. It is therefore important to provide flexibility and generous time for individuals and providers to submit supporting information for appeal requests. Federal law currently allows covered health care entities up to 30 days to respond to individuals’ requests for records, and entities can extend that time by another 30 days. 45 C.F.R. § 145.524 (b)(2). Laws vary from state to state on the circumstances under which providers may charge individuals for copies of their medical records. Thus, we are concerned to see provisions such as “[t]he eligibility contractor allows up to 60 calendar days for submission of missing information” in proposed § 405.932(c)(2); and “[t]he processing contractor allows the provider or eligible party...up to 60 calendar days to submit missing information” in proposed § 405.9032(f)(1)(i). **Sixty days is not sufficient given the realities of requesting and obtaining medical records. We suggest allowing up to 120 calendar days (with extensions allowed for good cause) for the submission of missing information.**

After the time for submission of missing information has elapsed (which should be longer than 60 days), the proposed regulations direct the eligibility and processing contractors to make determinations “based on the information available.” §§ 405.932(c)(3), 405.932(f)(1)(ii). It should be specified in the regulatory text that, as noted above, the attestation of the beneficiary, family members, providers, or others who are familiar with the facts giving rise to the appeal, is acceptable evidence where medical records are not reasonably available or obtainable. CMS should explain that the contractors and adjudicators involved in the appeals processes should not require beneficiaries (or their representatives) to take anything more than reasonable steps under the circumstances to obtain medical records. We also recommend additional information and guidance to beneficiaries, contractors, and adjudicators on situations in which the relevant

hospital or SNF may have changed ownership or closed since the stays in question. Again, only reasonable steps should be required to obtain records.

We strongly agree with the need for contractors and adjudicators to take an active role in obtaining appropriate information throughout the proposed appeals processes. This should be further emphasized. In addition to the steps listed by CMS (such as working with the appropriate MAC, the provider, or the party to obtain medical records), we also recommend that they help by obtaining CMS claim records showing the hospitalization in question. (For instance, if the beneficiary cannot obtain records of the hospitalization, CMS should have records of Part B claims from the hospital.) Also, the language in the preamble and the regulation establishing the contractors' obligation to work with eligible parties should be strengthened. The regulations should state that if contractors determine there is information missing from the request, the contractor "shall work" (as opposed to "works") with the appropriate MAC and "shall attempt" (as opposed to "attempts") to obtain the information from the provider or the eligible party, or both as appropriate. *See, e.g.,* proposed §§ 405.932(c)(2), 405.932(f)(1). Similarly, the preamble language currently reads "the eligibility contractor would work with MACs, eligible parties, and providers, whenever necessary, to attempt to obtain the information needed...." 88 Fed. Reg. at 89513. "Whenever necessary" is excessively subjective as a standard. The language should state that the eligibility contractor "shall work" with the MACs, eligible parties, and parties, and providers to attempt to obtain the information needed.

We are concerned that neither the preamble nor the proposed regulatory language provides sufficient specificity regarding the information to be contained in a notice of denial for eligibility for appeal, especially as compared to what is required in a denial by the processing contractor on the merits. The proposed regulation states that the denial notice regarding eligibility "explains...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)." It is particularly important that "the reason(s)" be sufficiently specific to allow individuals to cure their appeal request given the proposal that an affirmation of the initial denial is "binding and not subject to further review." §405.932(e)(8). **The denial should explain what is necessary to cure the appeal request with as much specificity as possible.** *Cf.* proposed § 405.932(g)(3)(i)-(iv) (requiring, a summary of the facts, a summary of any clinical or scientific evidence used in making the determination, and an explanation of how pertinent regulations, rules, and policies apply to the facts of the case).

The preamble specifies that existing procedures for "incorrect collections" will be used to govern refunds to beneficiaries from SNFs and hospitals to beneficiaries who succeed in their appeals. 88 Fed. Reg. at 89514. These procedures call for "prompt" refunds, set-asides if such refunds cannot be made in 60 days, and other protections. 42 C.F.R. §§ 489.41(a)-(c). The proposed regulations also state that hospitals and SNFs 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. § 405.932(h)(3). We support these protections for beneficiary refunds, but rather than merely cross-referencing other regulatory provisions without mentioning their substance, **CMS should expressly state in the final rule that the intent of application of the provisions in part 489 Subpart D is that providers must issue refunds promptly (generally within 60 days of a binding favorable decision) to**

beneficiaries with favorable appeal decisions, and comply with existing legal protections.

Also as noted above, additional explanation or clarification of situations where a hospital or SNF has changed ownership or closed would be beneficial as it applies to beneficiary refunds.

Regarding circumstances where a third-party payer (other than a family member) or insurer covered all of the cost of SNF services for an eligible party, we are concerned about situations where a beneficiary who could not obtain Medicare coverage of her SNF services ultimately received coverage of her SNF care from Medicaid. In that case the beneficiary could be subject to additional estate-recovery amounts from the Medicaid program. Medicaid estate recovery has important health equity implications, with the burden falling disproportionately on families of color. It also perpetuates wealth inequities tied to historical and contemporary structural racism.

We suggest 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.

b. Prospective Appeals

We agree with the general approach to establishing the expedited and standard appeals processes for individuals whose hospital status is changed from inpatient to outpatient going forward. We urge CMS to act efficiently to finalize and implement these processes for beneficiaries as soon as possible.

i. Medicare Change of Status Notice (MCSN)

We agree with CMS's proposal to require hospitals to timely deliver a standardized notice to individuals who are eligible to appeal their change from inpatient to outpatient. We appreciate CMS's intention and effort to develop the Medicare Change of Status Notice (MCSN) in a format and manner that effectively conveys information about status change and appeal rights. Presenting the information in a way that is easy to understand is especially vital, given the personal challenges that patients and their representatives may be experiencing when they receive the notice, and the time constraints faced by hospital staff tasked with issuing the notice. CMS estimates and expects hospital staff to spend a total of no more than 10 minutes to complete and deliver the notice, which includes explaining its contents to the beneficiary (or representative) and obtaining their signature. In light of this, we urge CMS to revise the draft MCSN to ensure its purpose is clearer and that it accurately describes the benefits as well as the risks of appeal. We offer the following recommendations:

a) **Include dates of status orders.**

The draft instructions for completing the MCSN require the hospital to fill in the patient's name and identification number. We recommend that the hospital also be directed to fill in the date of the patient's formal inpatient admission and the effective date of their status change to outpatient with observation status. We believe these are details that staff will need to initially verify in any case when completing the notice, and so it will not impose an extra burden to inscribe them on the notice itself. In fact, it may save staff time in the

end, since the patient or their representative may ask for this key information. Having the status order dates on paper will be useful to patients, who may have lost sense of time in the hospital, and may not have been told or may have forgotten when they were formally admitted as an inpatient. The information may inform their decision whether to appeal and also facilitate clearer communication with the QIO about the details of their situation.

b) Lead with information about SNF coverage rather than the hospital bill.

The draft MCSN lists the ramifications of the status change in the following order:

- 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.

We strongly suggest placing the implications for SNF coverage ahead of the lengthier and more complex explanation regarding how the hospital bill could be affected. One reason is that the impact of the status change on eligibility for SNF coverage has potentially greater financial and time-sensitive *health* ramifications than changes to a patient's hospital bill. The inability to access covered post-acute care could factor heavily in whether a patient decides to appeal the status change and whether to initiate an expedited appeal. On the other hand, the difference between having to pay the Part A inpatient deductible or Part B coinsurance for their hospital stay may not be a significant factor for many Medicare beneficiaries. Most in traditional Medicare (to whom these appeals apply) have supplemental coverage through a self-purchased plan (32.9%), employer-sponsored insurance (27.4%), Medicaid (17.6%) or other supplemental coverage, that will cover some or all of their cost-share regardless of how their hospital stay is classified and ultimately billed.

We further suggest presenting the information about SNF coverage first because it is applicable to patients enrolled in Parts A and B, as well as to those patients who only have Part A. By contrast, the current bullet point about Part B coinsurance will not be relevant to individuals who do not have Part B, and may even confuse them since the wording appears to assume they have Part B. To be sure, **patients without Part B need to be correctly informed that the status change means that the hospital can charge them for the *full cost* of their outpatient hospital stay.** This would no doubt be an important consideration in their decision about whether to appeal. **The current draft of the MCSN does not provide that key information, and we firmly feel it should be added.**

c) Simplify language and employ check boxes to provide clarity.

In light of the concerns expressed in the previous section, changes should also be made to the introductory section of the MCSN that set forth the consequences of a status change in a way that minimizes confusion. **We respectfully recommend that check boxes be employed to highlight to individuals only the consequences that actually apply to them.** We suggest an expanded description of SNF care, since many patients are more familiar with the concept of “needing to go to rehab for therapy” after a hospital stay than of going to a “skilled nursing facility.” We also recommend simplifying and shortening the information about how one’s hospital bill may change. Further, we request the addition of information specific to individuals without Part B coverage. We suggest language with check boxes along the lines of the following:

- ☐ Medicare will not pay for your stay in a skilled nursing facility (SNF) if you need daily skilled rehabilitation (e.g., therapy) or nursing care in a SNF after you leave the hospital.

Depending on your coverage, the following may also apply to you if there is a check mark (ask the hospital for clarification):

- ☐ Your hospital stay will be billed to Medicare Part B instead of Part A. Depending on the Part B coinsurance you will owe as an outpatient, your hospital bill may be either lower or higher than the Part A inpatient deductible. Check with your hospital for more detailed billing information.
- ☐ Because you do not have Medicare Part B, the hospital may charge you for the full cost of your outpatient hospital stay.

We believe that requiring hospitals to check the boxes that apply to a patient will not be burdensome since the staff member who delivers the notice will already be required to explain the notice and answer questions that the patient or representative may have. Simplifying and highlighting the relevant information will serve to minimize confusion and the need for clarification from hospital staff.

d) Remove deterrent language.

CMS should remove the final sentence in last section where the patient or representative acknowledges receipt and understanding of the notice by applying their signature. It reads: “I also understand if I win my appeal, my hospital charges will be different and possibly higher.” We are concerned that this sentence may discourage appeals by warning of potentially higher hospital charges if an appeal is won, when there is little or no risk of such an outcome for most beneficiaries (e.g., those who have supplemental insurance, those without Part B). The statement neither explains that the hospital charge would vary depending on an enrollee’s particular situation, nor counterbalances by pointing out the potential benefits of appealing. We feel the statement is prejudicial and

could deter people from appealing even when an appeal may be low-risk and in their best interest.

e) Reinforce timely delivery of notice.

We praise and support CMS's proposal to instruct hospitals to have the patient or representative not only sign and date the MCSN, but also denote the actual time when they received the notice. We are pleased that the draft MCSN specifically prompts this information *from the beneficiary or their representative*. This measure and protocol will help ensure that patients timely receive the MCSN, as it could affect their ability to make a meaningful decision about appealing and timely initiate an expedited appeal before they leave the hospital. Hospitals should explicitly advise staff that it is unacceptable for them to prefill the date and time on the notice when preparing the MCSN, since that would not reflect the actual time that the patient acknowledged receipt and understanding of the notice.

f) Comply with Section 1557 Notice of Availability Requirements.

We appreciate that the draft MCSN includes instructions on how to get the notice in alternate formats. This language should be updated and translated to comply with the Notice of Availability requirements in the forthcoming 1557 rule. Requiring a Notice of Availability in at least the top 15 languages in the state would align with CMS's approach in the Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program proposed rule.

ii. Expedited and Standard Appeals

a) Quality Improvement Organizations (QIOs) to conduct reviews

We endorse CMS's determination 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. We believe that the QIOs have the requisite capacity and expertise to carry out these reviews because of their longstanding experience in performing similar reviews, namely in conducting patient status reviews of short stay hospital claims, as well as expedited reviews of hospital discharge appeals. We feel that adding this new review activity to the current contracts with the QIOs is a logical decision and should facilitate the smooth, swift, and effective implementation of the court-mandated appeals process, which beneficiaries have been waiting on for a very long time.

b) Expansion of population eligible to request appeals

We appreciate CMS's recognition that certain patients who are switched from inpatient status to outpatient receiving observation services may not receive a MOON (Medicare Outpatient

Observation Notice), which is only required to be given for observation stays longer than 24 hours, and therefore do not fall within the class entitled to request appeal as defined by the court in *Alexander* even if they may otherwise meet the eligibility requirements for appeal (i.e., hospital stay for 3 or more consecutive days, not enrolled in Part B). We applaud CMS's proposal not to limit eligibility for appeal only to beneficiaries who have received a MOON, but to recognize eligibility if any amount of time is spent in observation following the status change. If finalized, the proposal would expand the population of beneficiaries eligible for an appeal beyond the class as defined by the court in *Alexander*. Such action is eminently fair and well within the agency's discretion, and we agree that requiring issuance of the MCSN to all beneficiaries who have been reclassified and meet the eligibility requirements (regardless of whether they have received a MOON notice) would be "the most effective and efficient means of informing eligible beneficiaries of their appeal rights."

We also strongly support CMS's proposal to extend eligibility for *expedited* appeals to individuals who lack Medicare Part B coverage, but who have not stayed in the hospital for three or more consecutive days. This is appropriate because such individuals are personally liable for the cost of their hospital stay as an immediate result of their status change and should have the right to request a fast appeal. We believe that allowing such a request is not only fair, but will minimize confusion and make the process easier to implement in that anyone who is eligible to appeal their change in status can access the expedited process.

c) Timing of delivery of notice

We are pleased that CMS proposes to require hospitals to deliver the MCSN as soon as possible after a beneficiary is eligible for the appeal process (i.e., after the hospital reclassifies the beneficiary and the third day in the hospital is reached), but no later than 4 hours prior to discharge. Likewise, we are pleased that delivery of notice to beneficiaries without Part B must take place as soon as possible after a hospital changes their status from inpatient to outpatient receiving observation services. We believe that providing these clear directives to hospitals about when notice must be issued is vital to ensuring access to due process. Timely notice will allow beneficiaries to more properly evaluate whether they want to challenge their status change. By timely exercising their right to an expedited appeal before leaving the hospital, they can gain some clarity about whether they can enter a SNF for post-acute care and resolve questions about their liability for their hospital stay.

It is not uncommon, based on what we have been told, for patients to learn that they have been switched from inpatient to outpatient on observation status shortly before or right at the point when they are being discharged from the hospital, with little or no explanation. We also hear of patients who only find out when they arrive at the SNF, or days later at home when they look through their pile of discharge papers, that their hospital stay had been reclassified as outpatient on observation. To avoid these unpleasant discoveries and delays in seeking expedited appeal, we urge CMS to finalize its proposal to require timely issuance of the MCSN.

d) Allowance for untimely requests for expedited appeal

Because there will be circumstances in which eligible beneficiaries leave the hospital before requesting an expedited appeal, we are grateful that CMS is proposing that “untimely requests may be made at any time in order to afford maximum opportunity for beneficiaries to exercise their appeal rights.” We praise CMS for recognizing that beneficiaries who entered a SNF following a hospital stay in which they were reclassified as outpatients receiving observation services, “should have the maximum opportunity to appeal and potentially obtain coverage for what might have been a costly out-of-pocket outlay.” The importance of an expedited appeal may be equally critical to those who require SNF care but cannot enter the SNF unless they obtain some reassurance soon that their stay could be covered by Part A.

We understand the agency’s decision to allow QIOs an extra day to render decisions for untimely requests over the required timeframes for timely requests. We appreciate the tradeoff that “Keeping untimely appeals with the QIO will provide beneficiaries with a decision far sooner ... (two calendar days), than if ... provided with the timeframes set forth in the standard claims appeals (60 days).

It is also important that CMS provide guidance and clarity on how to handle situations when beneficiaries try to appeal the patient status issue from a Medicare Summary Notice, as they are used to doing for other issues. For instance, an eligible beneficiary may not appeal using the Medicare Change of Status Notice, and then pay out of pocket for SNF services. If the beneficiary does not understand that she can submit an appeal of the Change of Status Notice at any time (perhaps because she lost that notice after discharge from the hospital) she may try to appeal the Medicare Summary Notice showing hospital observation services covered by Part B. Medicare Administrative Contractors (and other contractors, adjudicators, and Medicare representatives) should no longer state in responses to beneficiaries that whether a hospital stay is classified as inpatient or outpatient receiving observation services is “not appealable by the beneficiary,” or “can only be decided by the doctor,” as we have seen in the past. Instead, contractors should provide appropriate guidance and instructions to beneficiaries on which beneficiaries can appeal this issue and how to do so.

e) Standard of Review

We reinforce that the regulations and instructions to beneficiaries, providers, and to entities that will review these appeals must provide the correct standard of review. We are concerned about the wording that is repeated throughout the proposed rule, specifically directing review of the information in the record to determine if the hospital admission “satisfied the relevant criteria for Part A coverage *at the time the services were furnished.*” We believe that CMS may have meant this language to distinguish between the time periods before and after the Two Midnight Rule came into effect. The court’s decision makes this distinction, and the proposed rule appropriately uses some of the language from the decision that would be applicable to a post-Two Midnight Rule stay. *See* 88 Fed. Reg. at 89507 (“Class members shall be permitted to argue that their inpatient admission satisfied the relevant criteria for Part A coverage—for example, that the

medical record supported a reasonable expectation of a medically necessary two-midnight stay at the time of the physician's initial inpatient order, in the case of a post-Two Midnight Rule hospital stay—and that the hospital utilization review committee's (URC) determination to the contrary was therefore erroneous").

However, the use of the phrase "at the time the services were furnished" throughout the NPRM may confuse and mislead reviewers to improperly base their Part A coverage determination on a *hindsight* review of all the "services that were furnished" over the course of the beneficiary's hospital stay, rather than correctly evaluating whether the relevant criteria for Part A coverage were met when the status order was issued, based on the patient's clinical information available at that time.

A hindsight review of furnished services may be appropriate in determining whether a beneficiary's SNF stay "satisfied the relevant criteria for Part A coverage," because the reviewer must assess whether the beneficiary required and received skilled services on a daily basis at the SNF. But a retrospective evaluation of the individual services that the beneficiary received in the hospital is not the standard of review for hospital admission decisions. We believe that CMS's existing manual guidance provides the correct standard for reviewing these appeals. It directs that "In making these judgments...QIOs consider only the medical evidence which was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary." Medicare Benefits Policy Manual, Ch. 1, § 10. We believe that other existing CMS training materials for QIOs also contains appropriate emphasis on the prospective nature of the standard of review.

We urge CMS to clarify the standard of review language in the regulations and instructions to align with the guidance set forth in the manual.

III. CONCLUSION

We reiterate that CMS should finalize this rule as soon as possible and implement it immediately. People with Medicare who are reclassified from inpatient to outpatient receiving observation services while hospitalized have been without recourse for too long. They deserve their appeal rights, and in many cases reimbursement for out-of-pocket costs that Medicare should have covered, right away.

Thank you for the opportunity to submit these comments. For additional information, please contact Alice Bers at ABers@medicareadvocacy.org or Wey-Wey Kwok at WKwok@medicareadvocacy.org, both at (860) 456-7790.

Sincerely,

/s/ Alice Bers

Alice Bers
Litigation Director

/s/ Wey-Wey Kwok

Wey-Wey Kwok
Senior Attorney

/s/ Carol A. Wong

Carol A. Wong
Associate Litigation Director
Justice in Aging

/s/ Natalie Kean

Natalie Kean
Director of Federal Health Advocacy
Justice in Aging

/s/ Luke Liss

Luke Liss
Pro Bono Partner
Wilson Sonsini Goodrich & Rosati