

February 26, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Re: Medicare Program: Appeal Rights for Certain Changes in Patient Status (CMS-4204-P)

Dear Administrator Brooks-LaSure:

The undersigned organizations joined together in coalition more than a decade ago to advocate for addressing the observation stays issue. Composed of an extraordinarily diverse group of well over 30 organizations representing Medicare beneficiaries, health care professionals, and health care facilities, the coalition has worked to ensure that all Medicare beneficiaries receive equal access to needed post-acute care in a skilled nursing facility (SNF). The coalition appreciates the opportunity to comment on this notice of proposed rulemaking (NPRM) implementing the court order to establish Appeal Rights for Certain Changes in Patient Status.

We support the general approach to the appeal processes that the Centers for Medicare and Medicaid Services (CMS) has outlined for Medicare beneficiaries who were admitted to hospitals as inpatients and subsequently reclassified as outpatients receiving observation services. **We strongly urge CMS to finalize and implement this rule as quickly as possible.** Some members of the class and their families who have suffered significant financial and health costs have waited 15 years for a remedy. CMS must not make them wait any longer and must make this rule a top priority.

In addition, the coalition urges CMS to address the issue of observation stays more broadly for all Medicare beneficiaries (including those whose entire stay is called observation) and to count all time in the hospital towards satisfying the three-day inpatient requirement. The Attachment to this comment letter sets out CMS's legal authority to make the broader change we propose and provides a history of both CMS's decades-long consideration of observation stays and research articles discussing the extent and effects of observation stays. The adverse impact of observation stays on minorities, documented in a 2020 study, makes this issue a matter of equity as well.

This NPRM stems from the nationwide class action, *Alexander v. Azar*, 613 F. Supp. 3d 339 (D. Conn. 2020), *aff'd sub nom. Barrows v. Becerra*, 24 F. 4th 116 (2d Cir. 2022). In their lawsuit, Medicare beneficiaries established the right to challenge changes in their patient status determinations from inpatient to outpatient receiving observation services. Such reclassifications constitute denials of Part A coverage.

Although the actual hospital services received are typically indistinguishable to beneficiaries under either classification, the distinction between designation as an inpatient (Part A coverage) versus outpatient (Part B coverage) can result in devastating financial consequences for Medicare beneficiaries. Namely, Medicare only covers subsequent care in a skilled nursing facility (SNF) for those who were hospitalized as inpatients under Part A for three or more consecutive days.

Any time in the hospital categorized as outpatient and covered under Part B does not count toward the three-day requirement. This has forced many Medicare beneficiaries to either pay thousands of dollars out of pocket for required SNF care or to forgo it altogether, even when they have spent more than three days in the hospital. In addition, individuals who are not enrolled in Part B when they are hospitalized and designated as outpatients can face enormous out-of-pocket costs because Part A does not cover observation services. These beneficiaries are responsible for the *full cost* of their hospitalization.

In March 2020, the U.S. District Court in Hartford, Connecticut issued a decision concluding that Medicare beneficiaries whose classification is changed from inpatient to outpatient receiving observation services have the right to appeal that decision to Medicare and a chance to receive certain types of coverage, or to receive reimbursement from Medicare for certain noncovered services resulting from that change. The U.S. Court of Appeals for the Second Circuit subsequently upheld the district court's decision. This NPRM implements the district court's order.

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 receiving observation services dating back to January 1, 2009. Several aspects of the proposed process will make it relatively easy for beneficiaries to navigate. For example, the proposed process will be familiar to Medicare beneficiaries and their advocates because it is largely similar to existing Medicare claims appeals processes. Also, CMS's proposals to create a model appeal form and establish a single point of contact to initiate retrospective appeals will minimize burden on beneficiaries and simplify the messaging around starting the process.

CMS is proposing to limit the time to file a request for a retrospective appeal to 365 calendar days following the implementation date of the final rule. **We recommend CMS extend this filing period to two years, in addition to allowing extensions for a showing of good cause.**

One year is too short. Certainly, some eligible beneficiaries who were aware of the court order and awaiting this rulemaking will be equipped to file their appeal requests quickly. However, not everyone who benefits from this rulemaking will be so well informed. Given that some of the changes in status underlying the 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. We believe that 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 impacted beneficiaries and their representatives are aware of the new retrospective appeal process.** We support CMS's plans to continue posting information on Medicare.gov and CMS.gov. However, impacted class members may not visit these websites. We recommend including information about the new 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, enrollment counselors, and advocates can provide to 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.

We recommend that CMS provide more clarity and guidance to beneficiaries about submitting their medical records as part of the appeal request. The model appeal form and instructions should encourage beneficiaries to submit their medical records if possible, specify which records they should provide, and explain how to obtain assistance from the eligibility contractor in getting their records (and that such assistance is free of charge). The instructions should also make clear that Medicare beneficiaries can still submit 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.

Prospective Appeal Rights

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 strongly support CMS's proposal to extend eligibility for expedited appeals to individuals who lacked Medicare Part B coverage and did not stay in the hospital for three or more consecutive days.** We believe that this 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.

We support CMS's proposal to require hospitals to deliver a timely Medicare Change of Status Notice (MCSN) to individuals who are eligible to appeal their change from inpatient to outpatient. We recommend CMS revise the current draft MCSN to ensure its purpose is clear and that it accurately describes the benefits as well as the risks of appeal. We are concerned that the current draft may discourage appeals by warning of potentially higher hospital costs if the appeal is won without explaining that the ultimate cost varies depending on a beneficiary's particular situation. We appreciate that the notice includes instructions on how to get the MCSN 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.

Conclusion

We urge CMS to finalize this rule as soon as possible and to implement it immediately. People with Medicare who are switched 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.

In addition, the ad hoc coalition urges CMS to address the issue of observation status more broadly and to promulgate a final rule that counts all time in the hospital for purposes of satisfying the three-day inpatient hospital requirement for traditional Medicare's Part A SNF coverage. CMS has the legal authority to make this change, as confirmed by the Second Circuit Court of Appeals in *Estate of Landers v. Leavitt*, 545 F.3d 98 (2nd Cir. 2008) (discussed in the Attachment to this comment letter). In 2013, the HHS Office of Inspector General recommended that CMS "consider how to ensure that beneficiaries with similar post-hospital care needs have the same access to and cost-sharing for SNF services." HHS Office of Inspector General, *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries*, OEI-02-00040, p. 15 (Jul. 29, 2013), <https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf>.

Nearly 20 years ago, CMS asked whether it should count all the time in the hospital. While the idea received widespread support from the public, CMS said it wanted to review the issue further. It is simply time to correct this unfair, unreasonable, and unnecessary barrier to Medicare-covered SNF care.

If you have any questions concerning our comments, please contact Toby Edelman at tedelman@MedicareAdvocacy.org and Dana Ritchie at dritchie@ahca.org.

Sincerely,

Advancing Excellence in Long-Term Care Collaborative
ADVION (formerly National Association for the Support of Long Term Care)
Aging Life Care Association®
AMDA - The Society for Post-Acute and Long-Term Care Medicine
American Association of Healthcare Administrative Management (AAHAM)
American Association of Post-Acute Care Nursing (AAPACN)
American College of Emergency Physicians (ACEP)
American Geriatrics Society (AGS)
American Health Care Association (AHCA)
American Medical Association
American Society of Consultant Pharmacists
Association of Jewish Aging Services (AJAS)
Catholic Health Association of the United States (CHA)
Center for Medicare Advocacy

CIMPAR, SC

The Hartford Institute for Geriatric Nursing

IDEAS Institute

Justice in Aging

LeadingAge

Lutheran Services in America

Medicare Rights Center

National Association of Benefits and Insurance Professionals (NABIP)

National Center for Assisted Living (NCAL)

The National Consumer Voice for Quality Long- Term Care

Quantum Age Collaborative

Society of Hospital Medicine (SHM)

Special Needs Alliance

Vision Centre: Leadership Development for Aging Services

ATTACHMENT

I. The Second Circuit Court of Appeals recognized the Secretary’s authority to count time in observation status towards meeting the three-day inpatient requirement.

Under a 2008 decision of the Second Circuit Court of Appeals, the Secretary of HHS clearly has authority under the Medicare statute to include a hospital patient’s time in observation as part of inpatient time in the hospital for purposes of determining whether the patient qualifies for Part A coverage of a subsequent stay in a SNF. *Estate of Landers v. Leavitt*, 545 F.3d 98 (2nd Cir. 2008). The Court recognized that neither the statute nor regulations define the word “inpatient” and that the Secretary defined inpatient in the Medicare Benefit Policy Manual as occurring after a formal physician order for admission. Although the Court upheld the Secretary’s position in litigation – that only time in formal inpatient status may be counted toward satisfying the qualifying three-day inpatient requirement – it acknowledged that the Secretary had the legal authority to *change* this interpretation of inpatient to include time spent in observation. The Court wrote:

[W]e note that the Medicare statute does not unambiguously require the construction we have adopted. If CMS were to promulgate a different definition of inpatient in the exercise of its authority to make rules carrying the force of law, that definition would be eligible for *Chevron* deference notwithstanding our holding today.

545 F.3d at 112.

In fact, CMS has recognized its authority to change the definition of inpatient. In May 2005, CMS asked for public comment on whether time in observation should be counted towards satisfying the three-day inpatient requirement for Medicare Part A SNF coverage. 70 Fed. Reg. 29069, 29098-29100 (May 19, 2005). In August 2005, CMS acknowledged that most commenters “expressed support for the idea that hospital time spent in observation status immediately preceding a formal inpatient admission should count toward satisfying the SNF benefit’s statutory qualifying three-day hospital stay requirement.” 70 Fed. Reg. 45025, 45050 (Aug. 4, 2005). CMS reported that “some advocated eliminating the statutory requirement altogether.” *Id.*

CMS analyzed the two public recommendations separately. With respect to repealing the three-day requirement entirely, CMS wrote, “we note that such an action would require legislation by the Congress to amend the law itself and, thus, is beyond the scope of this final rule.” *Id.* With respect to *counting* time in observation towards the qualifying inpatient stay, CMS wrote, “we note that we are continuing to review this issue, but are not yet ready to make a final determination at this time.” *Id.*

CMS correctly understood that it could not repeal the three-day statutory requirement by regulation but that it *could* count the time in outpatient status, if it chose. Its only stated reason for not counting observation time, despite widespread support of such a change from commenters, was that it wanted to continue reviewing the issue. The current rulemaking process presents the opportunity to make this policy change long sought by beneficiaries, their advocates, health care professionals, and health care providers.

Finally, CMS allows certain hospital stays to count in qualifying a patient for Part A-covered SNF care even when the hospital care is different from Part A-covered hospital care.

In the context of hospice services, CMS has recognized that “general inpatient care” in a hospital under the hospice benefit, although “not equivalent to a hospital level of care under the Medicare hospital benefit,” nevertheless qualifies a hospice beneficiary for Part A-covered SNF services. Medicare Benefit Policy Manual, Chapter 9, §40.1.5, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c09.pdf>.

Similarly, a three-day stay in a foreign hospital may qualify a beneficiary for Part A SNF coverage if the foreign hospital is qualified as an “emergency hospital.” Medicare Benefit Policy Manual, Chapter 8, §20.1.1, <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/bp102c08.pdf>.

The argument for counting observation or outpatient time for purposes of calculating eligibility for the Part A SNF benefit is, of course, far stronger than either of the prior examples since the consensus is that care in the hospital is indistinguishable whether the patient is formally admitted as an inpatient or called an outpatient.

More than a decade ago, in describing why a beneficiary continues to be eligible for Part A SNF coverage after the hospital withdraws its Part A claim and submits Part B claims for the patient’s care instead (the hospital rebilling option), CMS wrote: “the 3-day inpatient hospital stay which qualifies a beneficiary for ‘posthospital’ SNF benefits need not actually be Medicare-covered, as long as it is medically necessary.” 78 Fed. Reg. 50495, 50921 (Aug. 19, 2013). CMS confirms that a hospital’s decision to withdraw its claim for Part A reimbursement and to seek Part B reimbursement instead does not negate the fact that the patient received medically necessary inpatient care, for purposes of Part A SNF coverage. CMS continues:

In addition, the status of the beneficiaries themselves does not change from inpatient to outpatient under the Part B inpatient billing policy. Therefore, even if the admission itself is determined to be not medically necessary under this policy, the beneficiary would still be considered a hospital inpatient for the duration of the stay – which, if it occurs for the appropriate duration, would comprise a “qualifying” hospital stay for SNF benefit purposes so long as the care provided during the stay meets the broad definition of medical necessity described above.

Id. A patient’s receiving “medically necessary” care in the hospital, not the classification of the care as “inpatient,” is the key factor for determining the patient’s eligibility for Part A SNF coverage.

As the Court in *Landers* held and CMS itself recognized in 2005, CMS has authority under the Medicare statute to redefine inpatient status to count all time in the hospital. In Manual provisions, CMS recognizes that time in a hospital that is different from Medicare-covered hospital time can count for purposes of Part A SNF coverage. In the hospital rebilling option, CMS recognizes that receiving medically necessary care in the hospital is the key factor in determining Part A SNF

coverage. CMS should confirm that time spent in observation or outpatient status qualifies a patient for Medicare Part A SNF coverage so long as the time in the hospital was medically necessary.

II. CMS has repeatedly expressed concern about observation and outpatient status

In the years since it declined commenters' recommendations to include observation time as inpatient time, CMS has received considerable input from the public and repeatedly expressed its own concern about the significant impact of observation on Medicare beneficiaries.

In July 2010, CMS sent letters to the national hospital associations asking why they used observation status for extended periods.

In August 2010, CMS held a Listening Session about observation status. <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/94244031HospitalObservationBedsListeningSession082410.pdf>. Commenters opposed use of observation status to deprive beneficiaries of Part A coverage of their subsequent medically necessary SNF stay.

In 2012, in proposed and final rules for the outpatient prospective payment system, CMS expressed concern about the increasing amount of time that patients spent in the hospital under observation. 77 Fed. Reg. 45155-157 (July 30, 2012) (proposed rules); 77 Fed. Reg. 68426-433 (Nov. 15, 2012) (final rules).

In 2012, CMS asked for public comment on possible changes to observation status, 77 Fed. Reg. 45061, 45155 (July 30, 2012), but again declined to make any changes, 77 Fed. Reg. 68209, 68433 (Nov. 15, 2012) ("[w]e will take all of the public comments that we received into consideration as we consider future actions that we could potentially undertake to provide more clarity and consensus regarding patient status for purposes of Medicare payment.")

In proposed rules on the Part A-B hospital rebilling option, CMS repeated its concerns. 78 Fed. Reg. 16632, 16634 (March 18, 2013).

In proposed rules on the inpatient prospective payment system, published May 10, 2013, 78 Fed. Reg. 27486, 27644-649, CMS once again commented on the increased use of observation status by hospitals and the consequences for Medicare beneficiaries.

In 2013, CMS established a hospital rebilling program and time-based definitions of inpatient care (the two-midnight rule), 78 Fed. Reg. 50495, 50906-931, 50938-954, respectively (Aug. 19, 2013). CMS expressed the hope and expectation that these changes would address concerns about extended observation and outpatient stays. 78 Fed. Reg. at 50922.

III. Research and studies document the increased prevalence and effects of observation stays

In the years since CMS first asked for public comment on observation time, research and analysis have also shown the increasing use of observation and outpatient status, the declining use of

inpatient status, and the financial consequences for beneficiaries of the changed descriptions of their status in the hospital. The HHS Office of Inspector General has documented how observation stays limit Medicare beneficiaries' access to post-hospital care and called on CMS to take action to ensure that all beneficiaries get equal treatment. The impact of observation stays on members of minority groups also shows the need to address the issue in interests of equity.

In 2012, Brown University reviewed 100% of Medicare claims data for 2007-2009. Researchers found that the number of observation stays increased 34% and inpatient admissions decreased, suggesting "a substitution of outpatient observation services for inpatient admissions." Zhanlian Feng, et al, "Sharp Rise In Medicare Enrollees Being Held In Hospitals For Observation Raises Concerns About Causes And Consequences," *Health Affairs* 31, No. 6 (2012). They also found that the average length of stay in observation increased by more than 7% and that more than 10% of patients were on observation for more than 48 hours. The Brown researchers identified the Recovery Audit Contractor program (as the Recovery Audit program was then known) and Condition Code 44 as the primary causes of hospitals' increased use of observation status.

In 2013, the HHS Office of Inspector General described observation stays, long outpatient stays, and short inpatient stays. The Inspector General found that in 2012, 1.5 million hospital stays were classified as observation and 1.4 million hospital stays were classified as long outpatient stays (that is, the hospital described the patient as an outpatient but did not bill for observation hours). Moreover, more than 600,000 hospital stays were for three or more midnights, but did not include three *inpatient* midnights. The Inspector General recommended that CMS consider how to ensure that Medicare beneficiaries with similar post-acute care needs have the same access to, and cost-sharing requirements for, SNF care. *Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries*, OEI-02—12-00040 (July 29, 2013), <http://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf>.

Research at the University of Wisconsin Hospital and Clinics between July 1, 2010 and December 31, 2011 found

- 4,578 of the total 43,853 hospital stays (10.4%) were observation stays; and
- 756 observation stays (16.5%) exceeded 48 hours; 1,791 observation stays (39.1%) were 24-48 hours; 2,031 observation stays (44.4%) were less than 24 hours.

More than one quarter of patients in observation had longer lengths of stay and were more likely than inpatients to be discharged to a SNF, to have more acute/unscheduled admissions, to have more "avoidable days" (days not accounted for by medical need), and to have more "repeat encounters." The researchers concluded, "observation care in clinical practice is very different than what CMS initially envisioned and creates insurance loopholes that adversely affect patients, health care providers, and hospitals." Ann M. Sheehy, MD, MS, et al., "Hospitalized but Not Admitted: Characteristics of Patients With 'Observation Status' at an Academic Medical Center," *JAMA Intern Med.* 2013; ():-. doi:10.1001/jamainternmed.2013.7306. (abstract published online July 8, 2013), <http://archinte.jamanetwork.com/article.aspx?articleid=1710122>.

In an invited commentary on the Wisconsin study, Robert M. Wachter, MD, Department of Medicine University of California, San Francisco, described "Observation Status" as having "morphed into madness" and wrote, "[I]n fact, if one was charged with coming up with a policy whose purpose was to confuse and enrage physicians and nearly everyone else, one could hardly have done better than Observation Status." "Observation Status for Hospitalized Patients," *JAMA Intern Med* (published online July 8, 2013), <http://archinte.jamanetwork.com/article.aspx?articleid=1710118>.

CMS's two-midnight rule did not change the problems with observation stays. A retrospective application of the two-midnight rule at the University of Wisconsin Hospital and Clinics for the period January 1, 2012 – February 23, 2013 found

- Patients arriving at the hospital after 4:00 p.m. were admitted to inpatient status 31.2% of the time; if they arrived at the hospital before 8:00 a.m., they were admitted to inpatient status 13.6% of the time.
- There was little overlap in diagnosis codes for short-stay inpatients and observation patients.
- Most diagnosis codes in observation were the same, regardless of the patient's length of stay in the hospital.

Ann Sheehy, M.D., et al, University of Wisconsin, "Observation and Inpatient Status: Clinical Impact of the 2-Midnight Rule," *Journal of Hospital Medicine* (2014).

In 2016, the HHS Office of Inspector General identified the unfair and uneven impact of observation status on beneficiaries across the country and called for ensuring that all Medicare beneficiaries have the same access to post-hospital care in a SNF, regardless of how their hospital stays are classified. Office of Inspector General, Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy, OEI-02-15-00020 (Dec. 2016), <https://oig.hhs.gov/oei/reports/oei-02-15-00020.pdf>

Observation stays have an adverse impact on minority groups. A 2020 study found that observation status may disproportionately affect the poorest beneficiaries, who are both most likely to be readmitted for a subsequent observation stay within 30 days and less likely to be discharged to a skilled nursing facility. Ann M. Sheehy, MD, MS, et al, "Thirty-Day Re-observation, Chronic Re-observation, and Neighborhood Disadvantage, *Mayo Clinic Proceedings*, Vol. 95, Issue 12, pp. 2644-2654 (Dec. 1, 2020), [https://www.mayoclinicproceedings.org/article/S0025-6196\(20\)30858-2/pdf](https://www.mayoclinicproceedings.org/article/S0025-6196(20)30858-2/pdf), DOI: <https://doi.org/10.1016/j.mayocp.2020.06.059>