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August 26, 2019

Seema Verma Administrator, Centers for Medicare & Medicaid Services U.S. Department of Health & Human Services Hubert H. Humphrey Building, Room 445-G 200 Independence Avenue SW Washington, DC 20201

Dear Administrator Verma:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) is the nation's largest association of long term and post-acute care providers. The Association advocates for quality care and services for frail, elderly, and disabled Americans. Our members provide essential care to approximately one million individuals in close to 14,000 not-for-profit and for-profit member facilities.

AHCA/NCAL was encouraged by your <u>recent comment on Twitter</u> about the three-day stay issue and government not always making sense. You also noted you were listening and taking feedback on this red tape issue. We wanted to be sure to share with you again our position on this issue, which we have been advocating for years. AHCA/NCAL is part of a <u>national coalition</u> of 33 provider and beneficiary organizations that are dedicated to preserving Medicare beneficiaries' access to necessary skilled nursing care following a hospital stay, regardless of whether that stay was classified as inpatient or outpatient observation.

As you know, under current law, a Medicare beneficiary must spend at least three days as a hospital *inpatient* for Medicare to cover a subsequent stay in a skilled nursing center (known as the "Skilled Nursing Facility 3-day rule"). Each year thousands of beneficiaries are unable to access their skilled nursing benefit because of the administrative classification of their hospital stay, even if the stay is deemed medically necessary, and even if the stay spans three days or more.

There has been significant media attention around this issue, and this matter certainly fits into the current conversation around surprise medical billing. Most recently, a section of the <u>Office of Inspector General (OIG) July 2019 report</u> called for CMS to analyze the potential impact of counting time spent as an outpatient toward the three-night requirement for skilled nursing facility (SNF) services so that beneficiaries receiving similar hospital care have access to these services. AHCA/NCAL believes that CMS already has the authority needed to implement the solution to this issue.

# Legal Argument: CMS Has Authority to Define Inpatient Care

Under a 2008 decision of the Second Circuit Court of Appeals, the Secretary of Health and Human Services (HHS) has authority under the Medicare statute to count the time a patient spends in the hospital, regardless of inpatient or outpatient classification, toward satisfying the SNF three-day rule for Medicare coverage of the SNF stay<sup>1</sup>. In its decision, 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, it acknowledged that the Secretary has the authority to change the interpretation of "inpatient" to include time spent in observation as an outpatient:

"[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." <sup>2</sup>

# CMS Already Has Set Precedence for Defining "Inpatient" for Purposes of Satisfying the SNF Three-day Rule

CMS already allows certain hospital stays to count in qualifying a patient for Part Acovered care in a SNF, even when the hospital stay itself is not a Part A-covered hospital stay. We provide two examples:

- 1. In the context of hospice services, CMS has recognized that "general inpatient care" in a hospital, 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<sup>3</sup>; and
- 2. 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."<sup>4</sup>

In fact, the argument for counting days spent as an outpatient under observation for purposes of satisfying the SNF three-day rule is far stronger than either of the above 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. Furthermore, CMS already has clarified that a beneficiary stay spanning at least three days does not actually need to be Medicare-covered for it to satisfy the SNF three-day rule. In describing why a

Guidance/Guidance/Manuals/downloads/bp102c09.pdf

<sup>&</sup>lt;sup>1</sup> Estate of Landers v. Leavitt, 545 F.3d 98 (2<sup>nd</sup> Cir. 2008).

 $<sup>^{2}</sup>$  Ibid.

<sup>&</sup>lt;sup>3</sup> Medicare Benefit Policy Manual, Chapter 9, §40.1.5, accessed at: <u>https://www.cms.gov/Regulations-and-</u>

<sup>&</sup>lt;sup>4</sup> Medicare Benefit Policy Manual, Chapter 8, §20.1.1, accessed at: <u>https://www.cms.gov/Regulations-and-</u> <u>Guidance/Guidance/Manuals/downloads/bp102c08.pdf</u>

beneficiary continues to be eligible for Part A SNF coverage after a hospital withdraws its Part A claim and resubmits it as a Part B claim instead, 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. 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 the 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 ruing the stay meets the broad definition of medical necessity."<sup>5</sup>

CMS concludes that a patient 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.

# Conclusion

Both the Court and CMS have recognized CMS's authority to define "inpatient" care for purposes of satisfying the SNF three-day rule. CMS has exercised this authority in certain areas of the Medicare program and could do so here as well. CMS could issue subregulatory guidance in the form of an update to the Medicare Benefit Policy Manual, clarifying that any time a patient spends in the hospital, regardless of whether the stay is administratively classified as inpatient or outpatient, may count toward satisfying the SNF three-day rule for purposes of ensuring Medicare coverage of a subsequent, medically necessary SNF stay. Finally, we have included an attachment from the Center for Medicare Advocacy noting CMS's legal authority to address this problem.

AHCA/NCAL urges CMS to take action and eliminate a confusing policy barrier that each year needlessly prevents thousands of Medicare beneficiaries from accessing their benefit to high quality, post-acute care. CMS can fix this problem immediately by recognizing observation stays as qualifying stays for the purposes of the three-day stay requirement. Thank you for your focus on this pressing issue. Please do not hesitate to contact AHCA's Senior Director of Not for Profit & Constituent Services, Dana Halvorson, at 202-898-2822 or dhalvorson@ahca.org if you have any questions.

Sincerely,

Mark Parkinson AHCA/NCAL President & CEO

Enclosure

Scott Tittle NCAL Executive Director

<sup>&</sup>lt;sup>5</sup> 78 Federal Register 50495, 50921 (August 19, 2013).



www.MedicareAdvocacy.org

#### CMS HAS AUTHORITY UNDER EXISTING LAW TO DEFINE INPATIENT CARE

Under a 2008 decision of the Second Circuit Court of Appeals, the Secretary of HHS 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 skilled nursing facility (SNF). *Estate of Landers v. Leavitt*, 545 F.3d 98 ( $2^{nd}$  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 authority to *change* his 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, the Centers for Medicare & Medicaid Services (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 suggestions 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.

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, 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, <u>http://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/bp102c09.pdf</u>.

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,

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/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.

Most recently, 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 writes, "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.

### Conclusion

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.

The **Background** statement attached to this memorandum shows CMS's ongoing consideration of this issue, CMS's repeated expressions of concern about the impact of extended observation stays on Medicare beneficiaries, and the findings of independent research on observation.

#### Background

#### CMS's concern about observation and outpatient status

In the nine 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/94244031HosptialObservationBedsListeningSessio n082410.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 spend 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.

#### **Research and studies**

In the nine years since CMS first asked for public comment on observation time, a considerable amount of research and analysis has 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.

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 new two-midnight rule has not changed the situation. 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).

### Conclusion

In the nine years since CMS first expressed concern about observation status, the use of outpatient status and observation status for hospitalized patients has dramatically increased. There is widespread support for counting all time in the hospital in determining Medicare patients' entitlement to Part A coverage of a SNF stay.

Toby S. Edelman Senior Policy Attorney July 16, 2014