Since the introduction of the Two Midnight Rule in 2014, observation status and short inpatient stays have been the subject of much contention among health care providers. CMS has made efforts to bring the requirements of the Two Midnight Rule more in-line with the wishes of providers by incorporating physicians’ judgment into the decision whether to admit a patient or keep him or her in outpatient observation status. Confusion over the distinction between inpatient admission and outpatient observation services, as well as the notice requirements for such services, still exists. This confusion is preventing the Two Midnight Rule and the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) (P.L. 114-42) from being applied as intended.

This Strategic Perspective provides an overview of the Two Midnight Rule and discusses:

- amendments made to the original Two Midnight requirements to incorporate physician judgment;
- the elimination of a -0.2 percent payment adjustment under Two Midnight following several years of implementation;
- requirements under the NOTICE Act and the progress of implementing the Medicare Outpatient Observation Notice (MOON) document; and
- how ambiguity surrounding observation status affects the implementation of the NOTICE Act.

Discrepancy between CMS Definition and Hospital Application

The Medicare Benefit Policy Manual (Pub. 100-02, Ch. 6, sec. 20.6) defines observation care as "a well-defined set of specific, clinically appropriate services, which include treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital . . . and in the majority of cases, the decision . . . can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do outpatient observation services span more than 48 hours."

Observation care data does not show a "well-defined set of specific, clinically appropriate services," Ann Sheehy, MD, chief of the Division of Hospital Medicine at the University of Wisconsin, testified before the Senate Special Committee on Aging in 2014. Sheedy addressed long-standing difficulties in the distinction between observation and inpatient care. In her testimony, she referenced a Medicare Payment Advisory Commission (MedPAC) report stating that the average length of observation stays increased from 26 hours to 29 hours between 2006 and 2012. Additionally, a study conducted at the University of Wisconsin Hospital showed that ten percent of patients hospitalized were kept under observation for an average of 33.3 hours, indicating that stays exceeding 28 hours were not "rare and exceptional." The same study showed that 1,141 unique ICD-9 diagnosis codes were used in the hospital’s observation cases, demonstrating that observation care is not limited to "a well-defined set of specific, clinically appropriate services."

In an interview with Wolters Kluwer, Sheehy said that, "for patients, the financial liability is complicated and there are many unknowns." Observation services, which fall under outpatient care and are billed under Medicare Part B, are often indistinguishable from inpatient services. Patients hospitalized under observation often receive the same services as patients hospitalized as inpatients, who are billed for services under Medicare Part A. Despite the similarities, Part B billing may carry greater out-of-pocket costs than Part A, Sheehy said.
Two Midnight: Creating Distinctions for Providers

To address the ambiguity surrounding observation services, CMS set forth the Two-Midnight Rule in the fiscal year (FY) 2014 Inpatient Prospective Payment System (IPPS) Final rule (78 FR 50496). Under the rule, inpatient admission is reasonable and necessary if either of the following are met:

- a two-midnight presumption: an inpatient stay spans two midnights from the time of admission, absent evidence of gaming or abuse; or
- a two-midnight benchmark: the admitting practitioner has a reasonable and supportable expectation, documented in the medical record, that the patient would need to receive care at the hospital over a period spanning two midnights.

CMS intended the rule to simplify the way Medicare contractors determine whether services rendered during a hospital stay should be billed as inpatient or outpatient, according to a 2013 Office of Inspector General Memorandum Report.

Physicians may use judgment to make exceptions. Previously, a "rare and unusual" policy created only one exception to the Two-Midnight Rule. In the FY 2016 Outpatient Prospective Payment System (OPPS) Final rule, CMS took stakeholder feedback into account and acknowledged that there are other patient-specific circumstances under which certain cases may be appropriate for Part A payment absent a stay spanning two midnights. Under a new policy, physicians may make case-by-case exceptions to the rule to allow inpatient classification for short stays. To qualify for the exception, the physician must determine that a hospital patient will require hospital care for only a limited period of time (not crossing two midnights), and the physician must document in the patient's medical record that the inpatient stay is reasonable and necessary (see OPPS payment update a net cut for many, November 13, 2015). Quality Improvement Organizations (QIOs) are in charge of reviewing these short inpatient stays. While CMS put reviews by QIOs on hold beginning May 2016 "to promote consistent application of the medical review policies" concerning short stays and standardize the review process, QIOs returned to performing initial patient status reviews as of September 12, 2016 (see QIOs back to reviewing Two-Midnight rule claims, September 13, 2016).

Two-midnight payment adjustment. In the 2014 IPPS Final rule, CMS estimated that the Two-Midnight Rule would increase expenditures by Medicare. As a result, CMS made a -0.2 percent adjustment to hospital payment rates. In the FY 2017 IPPS Final rule (81 FR 56761), however, CMS stated that, while the assumptions underlying the adjustment were reasonable at the time they were made, it would be permanently removing the adjustments for FY 2017 and, retroactively, its effects for FYs 2014, 2015, and 2016 by adjusting the FY 2017 payment rates with an increase of 0.8 percent (see 1.5 percent payment cut overshadows end of Two-Midnight adjustment, August 3, 2016). In the Final rule, CMS wrote, "While we generally do not believe it is appropriate in a prospective system to retrospectively adjust rates, we take this action in the specific context of this unique situation."

NOTICE Act: Informing Patients of their Outpatient Status

To address Medicare beneficiaries' lack of knowledge regarding their own inpatient or outpatient status, President Barack Obama signed the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) (P.L. 114-42) into law on August 6, 2015. Effective March 16, 2016, the NOTICE Act requires hospitals to explain to patients in observation status for more than 24 hours the financial consequences of the status, including possible effects on coverage, and the reason the hospital decided not to admit them. The notification is required to be in writing and must be given to the patient or the patient's representative within 26 hours of the beginning of the outpatient status or at discharge—whichever occurs earlier.

Medicare Outpatient Observation Notice (MOON) proposed and delayed. In the 2017 IPPS Proposed rule (81 FR 24946), CMS proposed implementing section 1886(a)(1)(Y) of the Social Security Act requiring hospitals and critical access hospitals (CAHs) to notify an individual, orally or in writing, regarding the individual's receipt of observation services as an outpatient and the implications of receiving those services. Under the proposed process, hospitals and CAHs would be required to furnish notice to individuals entitled to Medicare benefits if the
individual has received observation services as an outpatient for more than 24 hours. This Medicare Outpatient Observation Notice (MOON) would be standardized for use by all applicable hospitals and CAHs. The MOON would include all of the information elements required to fulfill the written notice requirement of the NOTICE Act.

Section 2 of the NOTICE Act provides that the notification requirement becomes effective 12 months after the date of enactment of the NOTICE Act, August 6, 2016. The IPPS Final rule (81 FR 56762), however, stated that the required written notice to patients will not become effective until 90 days following the approval of the MOON by the Office of Management and Budget (OMB). According to the Center for Medicare Advocacy, what the Final rules mean is that the NOTICE Act will not be implemented until late fall of 2016 at the earliest.

**Implementing MOON requirements.** At the University of Wisconsin Hospital (UW), a multidisciplinary team of case managers, nursing leadership, and physician leadership is in charge of MOON implementation, said Sheehy. "At UW, our case managers are going to deliver the MOON. We are still figuring out how this will work, what the messaging will be, and who will deliver the MOON on weekends and holidays when the case management staffing is different."

Despite what seems like a relatively simple form, there are many issues to address. "For example," she said, "we have debated electronic versus paper—there is cost involved in getting this done electronically with an electronic signature, but with the rest of our medical record being electronic, generating a paper form and having to file and scan that on every patient is also not desirable. There is also the issue of who can and will answer any questions that the patient will have on MOON delivery."

**Concerns regarding MOON form.** With regards to the initial MOON, UW had concerns about confusing patients regarding the medical care that would be delivered based on an administrative billing status. "Directing patients to QIOs if they had quality concerns did not seem appropriate for the MOON, which was intended to notify patients of their billing status," Sheehy said. "This is important because we have worked hard to clarify with patients that observation is a Medicare billing status and has nothing to do with the necessary medical care they would receive."

CMS’s own rules also are causing concern in implementing the MOON. On the most recent iteration, UW had concerns about the statement "Fill in the specific reason the patient is in an outpatient, rather than an inpatient stay." Sheehy said, "This suggested that CMS wanted us to put clinical information there, when really, the most appropriate answer is that we believe the patient will stay less than two midnights, and [the stay] should be considered outpatient observation due to Medicare’s own rules. This field could create a lot of additional work for hospital staff [but is] unlikely to help patients understand the decision."

**Continued Ambiguity Surrounding Observation**

Despite statutory and regulatory changes to address the distinction between observation and inpatient care, clarity is still needed to help providers determine whether outpatient observation is appropriate. Specifically, industry stakeholders argue that the NOTICE Act requirements do not make meaningful distinctions among patients by limiting notice to patients who have received observation services for 24 hours. Furthermore, there is no definition for the set of services hospitals should use to bill Medicare for observation.

**Language does not match intent.** The NOTICE Act requires that notice must be provided to "each individual who receives observation services as an outpatient" for more than 24 hours. The Congressional Report for the NOTICE Act, however, states that the intention of the legislation is to give notice of status to all patients who are outpatients and not inpatients. According to the report, "The bill, H.R. 876, reported by the Committee on Ways and Means on February 26, 2015, is legislation to provide certainty to beneficiaries regarding their status as an outpatient under observation (or any similar status) and not as an inpatient."

The Center for Medicare Advocacy argues that limiting notice to patients who receive observation services for more than 24 hours misinterprets the clear intent of the NOTICE Act and makes no sense as a way of making meaningful distinctions among patients. The language of the NOTICE Act may exclude up to half of patients in the U.S. who are classified as outpatients by their hospitals but who do not receive observation services.
Still no definition for observation. There continues to be no definition for the set of services hospitals should use to bill Medicare for observation. Under CMS’s direction, physicians may order any medical services and tests they deem necessary, regardless of whether the patient is classified as an inpatient or outpatient. Thus, the "observation services" referenced in the NOTICE Act do not reflect distinctions in care, the Center for Medicare Advocacy noted. The inclusion of a physician’s judgment exception to the Two-Midnight Rule, while removing the much-objected-to bright line rule dividing inpatient and outpatient treatment, further muddies the water concerning the "well-defined set of specific, clinically appropriate services" described in the CMS manual.

"I think it will always be hard to understand how one can stay overnight in a hospital bed and still be an outpatient," Sheehy said. "I am certainly not alone in stating that I think this distinction should go away. Observation should return to what it was initially intended for, and that is for patients who need a few additional hours of care following in ED visit, ideally in an ED observation unit, to determine whether they can discharge home or if they need to be admitted to the hospital as an inpatient."

Conclusion

Despite issues with the current MOON form, Sheehy said, "It is hard to argue against transparency, and we do believe that patients have a right to be informed about their outpatient observation versus inpatient status." If CMS’s distinction between overnight observation stays and short inpatient stays must remain, it is clear that consistent definitions should be applied in the implementation of Two Midnight and NOTICE Act requirements.

Companies: Society of Hospital Medicine; Center for Medicare Advocacy; University of Wisconsin Hospital; University of Wisconsin

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