Despite Efforts to Address Provider Concerns, Compliance with Two-Midnight Rule Remains Elusive

Executive Summary

CMS 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." It has become evident that the definition and hospitals’ application of observation rules are markedly different, resulting in less-than-intended Medicare coverage. Hospitals and Medicare beneficiaries alike are footing the bill for these differences in coverage.

In 2013, HHS implemented the Two-Midnight Rule to streamline the determination of whether a patient should be admitted as an inpatient or held in observation. Hospitalists, however, have found the Two-Midnight Rule to be confusing and disruptive to their workflows. Further, the Office of Inspector General (OIG) has found that the Recovery Audit Contractor (RAC) program, which is responsible for enforcing observation rules, encourages short inpatient stays, which were found to result in a large number of improper Medicare payments.

In its Calendar Year (CY) 2016 Outpatient Prospective Payment System (OPPS) Proposed rule, CMS detailed its plans to allow hospitalists more judgment in determining whether to admit patients for short hospital stays. The Proposed rule also shifted the responsibility of reviewing inpatient determinations from RACs to quality improvement organizations (QIOs). The main tenets of the Two-Midnight Rule remain, however.

Hospitalists thanked CMS for considering their concerns regarding the importance of professional judgment in making admissions determinations. However, they noted the lack of clarity in the proposal and that CMS has not responded to requests for additional guidance. A Final rule is expected in early November 2015. In the meantime, CMS extended the enforcement delay of the Two-Midnight Rule to January 1, 2016.

This White Paper details the billing differences between inpatient and observation status—as well as the impact it has on beneficiaries’ access to care—to explain why hospitalists need to have a better understanding of how to determine the proper level of care for a patient under CMS rules. This White Paper also discusses providers’ concerns regarding the Two-Midnight Rule and includes guidance for hospitalists who want to improve their application of observation rules to receive the full benefit of Medicare reimbursements.
A Problem of Distinction

Following an emergency double hernia surgery, 92-year-old Harold Engler experienced serious complications and spent a total of 10 days in the hospital on “medical observation” without being admitted as an inpatient. Subsequently, he was sent to a local nursing facility for six weeks of rehabilitation. In Admitted or Not? The Impact of Medicare Observation Status on Seniors, a hearing before the Senate Special Committee on Aging on July 30, 2014, Engler’s wife testified that upon her husband’s discharge from the nursing facility, the Englers learned that they would have to pay $7,859 in nursing home charges immediately, “or the bill would be put into collection for the full amount of $15,000 or my house would have been attached for the full amount. We paid the $7,859, but I had to cash a money market account to pay the bill.”

Engler’s wife further testified that her husband’s medical observation status “did not make sense” to her “because [Engler] was on a floor with other inpatients and received care just like an inpatient in a hospital. The hospital never told me that he was under ‘medical observation;’ they said nothing about it.” If Engler had been admitted as an inpatient instead of being placed in observation, Medicare would have covered much more of his hospital costs, as well as his nursing facility care. Unfortunately, what happened to the Englers is not an isolated incident. While a 10-day observation stay is not common, it is not unusual for patients to be kept in observation for more than two or three days before being admitted or discharged.

The issue of consistent application of CMS’ observation rules, whether by providers or by Medicare contractors, is problematic, and beneficiaries and hospitals alike are paying the price. CMS has tried to remedy the problem with the relatively recent (and much contested) implementation of the Two-Midnight Rule—or the “Cinderella Rule,” as Amy Deutschendorf of Johns Hopkins Hospital in Baltimore calls it. “If you cross two midnights, you’re an inpatient. If not, you’re a pumpkin,” she remarked. This sounds like a joke until you realize that these “pumpkins” are stuck with thousands of dollars in bills that Medicare would otherwise cover for inpatients. Inconsistent inpatient-outpatient designation can also lead to denied claims for reimbursement for providers.

Discrepancy between CMS definition and hospital application. In Chapter 6, sec. 20.6 of the Medicare Benefit Policy Manual (Pub. 100-02), “Hospital Services Covered Under Part B,” CMS 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.”

The Society of Hospital Medicine noted that there are 1,141 distinct ICD-9 condition codes associated with observation status billing claims. “The large number of diagnosis codes, combined with the fact that the top three codes accounted for less than one-fifth of all observation encounters, demonstrates
that observation status is not ‘well-defined’ and suggests that observation policy is markedly different from what is occurring in real clinical practice,” wrote the Society of Hospital Medicine in its report, *The Observation Status Problem: Impact and Recommendations for Change*.

Observation care data does not show a “well-defined set of specific, clinically appropriate services,” according to the testimony of Ann Sheehy, MD, Chief of the Division of Hospital Medicine at the University of Wisconsin. She testified that a report issued by the Medicare Payment Advisory Commission (MedPAC) indicated that between 2006 and 2012, the average length of observation stay increased from 26 hours to 29 hours.

Sheehy testified that ten percent of more than 43,000 patients in a University of Wisconsin Hospital study were hospitalized under observation. Most of those patients stayed an average of 33.3 hours, and one in six stayed longer than 38 hours, “indicating that stays longer than two days were not ‘rare and exceptional’ as CMS had intended.” The study also showed that 1,141 unique ICD-9 diagnosis codes were used, “indicating that observation was not ‘well defined.’”

**Financial impact on patients.** In an interview with *Health Law Daily*, Sheehy noted that “for patients, the financial liability is complicated, and there are many unknowns.” Observation care is considered an outpatient service and is billed as such under Medicare Part B, which covers physician visits, outpatient services, and home health services, but not pharmacy charges. Patients hospitalized under observation often receive the same services as patients hospitalized as inpatients, who are billed for those services under Medicare Part A.

While observation care is often indistinguishable from inpatient care, Part B billing may carry greater out-of-pocket costs than Part A, Sheehy said. Medicare Part B services are billed with deductibles, 80/20 cost sharing, and no cumulative limit, whereas Part A covers inpatient services with one-time deductibles per benefit period ($1,260 for 2015).

Despite the clear distinction in billing, Sheehy said, the OIG “issued a report in [July] 2013 stating that patients under observation paid less out-of-pocket than patients with similar diagnoses. Yet this report generated more questions than it answered because the Part B payments used were estimates, and self-administered drug charges were excluded from the out-of-pocket expenses that observation patients paid.” Sheehy stressed that the report grouped together and compared large categories of patients but did not provide any information on the services delivered.

Because “cost, charges, and reimbursement are directly related to the services delivered, one cannot know if the observation patients, on average, received fewer services than the inpatients they were compared to, which could explain why out-of-pocket expenses were less for observation patients,” Sheehy said. “To compare observation and inpatient financial out-of-pocket vulnerability, one must compare the patient payments for the exact same services when billed under Medicare Part B versus Medicare Part A.”

The issue of consistent application of CMS’ observation rules, whether by providers or by Medicare contractors, is problematic, and beneficiaries and hospitals alike are paying the price.

**Part D prescription drug claims.** Beneficiaries also find themselves subject to large hospital bills for drugs they received while they were receiving outpatient observation care. According to the Center for Medicare Advocacy (CMA), while a patient is in observation status, Part B is billed for 80 percent of the hospital services provided. Outpatient prescription drugs, however, are not billed to Part B but must be submitted by the beneficiary as a claim to Medicare Part D or another outpatient drug plan before the beneficiary can receive reimbursement for the drugs.

*Chapter 5, sec. 60.1* of the *Medicare Prescription Drug Benefit Manual* (Pub. 100-18) states that Part D plans are required to ensure access to drugs covered by the plan that are dispensed from “out-of-network pharmacies,” including institution-based pharmacies such as those in hospitals. “In essence, patients in observation status at a hospital cannot be expected to get their outpatient drugs from a pharmacy that contracts with their Part D plan (like a CVS or Walgreens). Rather, they must take the drugs given to them by the hospital, dispensed from the hospital’s out-of-network pharmacy,” the CMA explained. Ultimately, obtaining drugs from out-of-network pharmacies results in increased copays for beneficiaries.
Barriers to care. In addition to facing increased out-of-pocket costs, patients held in observation, unlike inpatients, do not receive credit for the three-day stay required for Medicare coverage for skilled nursing facility (SNF) care. According to the OIG report, beneficiaries in observation stays “incurred bills from SNFs for tens of thousands of dollars because they did not qualify for SNF services under Medicare.” In her testimony before the Senate Special Committee on Aging in the Admitted or Not? hearing, Sheehy stated that when patients discover they are in observation status—and how observation status affects their billing—anxiety about the cost of the services takes over.

“Some patients ask me to change them to inpatient, which I cannot do under current payment policies,” she said. “At a time when they should rightfully be focused on their health and getting well, seniors are facing the stress of incomprehensible status determinations and the associated consequences.” Some patients then refuse to be admitted for necessary care out of concern for the cost, she added.

Bagnall v Sebelius. In November 2011, the CMA filed suit in the United States District Court for the District of Connecticut, seeking to certify a nationwide class of “Medicare beneficiaries who, on or after January 1, 2009, have had or will have had any portion of a stay in a hospital treated as observation status and, therefore, not covered under Medicare Part A.” The lawsuit sought declaratory, injunctive, and mandamus relief against HHS for beneficiaries who were allegedly deprived of Part A coverage “by being improperly classified as outpatients.”

The beneficiaries alleged that, despite the lack of the term “observation status” or any other similar term in Medicare statute or regulations, HHS “has long had a policy under which Medicare beneficiaries in hospitals, instead of being formally admitted, are placed on what is commonly referred to as ‘observation status[,]’” The beneficiaries further alleged that some beneficiaries had their statuses retroactively changed to observation after they were formally admitted. In addition, “Beneficiaries placed on observation status do not receive written notification of their status and have no appeal rights to challenge that status.”

On September 23, 2013, the district judge dismissed the suit for failure to state a claim, finding that a prior decision “effectively undercut plaintiffs’ contentions,” according to the CMA. The court also rejected technical challenges to the policy and rejected the beneficiaries’ challenges of the lack of notice and hearing rights for beneficiaries. Additionally, the court concluded that the beneficiaries lacked standing to challenge the content of the notices, finding that the hospitals would be responsible (rather than HHS) if notices were not provided and that the beneficiaries lacked the property interest necessary to raise due process concerns.

The beneficiaries appealed in February 2014, limiting the case to the right to receive effective notice, as well as the review procedure for beneficiaries who are receiving observation care. The American Hospital Association (AHA), in addition to other professional organizations, submitted an amicus brief in the appeal. The brief was neutral as to the parties but noted that the litigation “highlights an important gap in the Medicare reimbursement rules.” The brief provided support for the argument that inpatient admissions decisions are best left to the judgment of the treating physician but highlighted barriers posed by Recovery Audit Contractors (RACs) (more recently referred to as Recovery Auditors) and similar entities charged with preventing Medicare fraud. These arguments are discussed later in this White Paper.

Attempts for Clarity in Federal and State Legislation

In recent years, lawmakers have attempted to resolve the problem of observation care through federal legislation. The Improving Access to Medicare Coverage Act of 2013 (H.R. 1179), sponsored by Rep. Joe Courtney (D-Conn), was introduced on March 14, 2013. The bill proposed to count all of the time a patient spent in the hospital toward the three-day inpatient requirement. Though CMA noted that there was no organized opposition to the legislation, which “offers a simple and straightforward solution to the problem of observation status for patients,” the bill never progressed further.

The Fairness for Beneficiaries Act of 2013 (H.R. 3144), which was sponsored by Rep. Joe Courtney (D-Conn) and introduced on April 19, 2013, sought to eliminate completely the three-day inpatient requirement for coverage of an SNF stay. According to the CMA’s analysis, H.R. 3144 was “an appropriate long-term goal.” The CMA stated, however, that the bill had the potential to prove even more costly to the Medicare program than the current system. H.R. 3144 did not progress further than the House.

Finally, the Creating Access to Rehabilitation for Every Senior (CARES) Act of 2013 (H.R. 3531), sponsored by Rep. Jim Renacci (R-Ohio) and introduced November 19, 2013, proposed the elimination of the three-day inpatient requirement as long as the patient goes to an SNF with an overall rating of three or a rating of four stars.
The Two-Midnight Rule is intended to simplify the way CMS Medicare contractors determined whether services rendered during a hospital stay should be billed as inpatient or outpatient.

HHS sought to remedy the discrepancy in determining whether inpatient or outpatient care was more appropriate with the implementation of the Two-Midnight Rule, set forth in the August 19, 2013, Inpatient Prospective Payment System (IPPS) Final rule (78 FR 50496). Under the Two-Midnight 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.

The Two-Midnight Rule is intended to simplify the way CMS Medicare contractors determined whether services rendered during a hospital stay should be billed as inpatient or outpatient, according to the July 2013 OIG report. The rule is also intended to reduce observation stays lasting two nights or longer and the number of short inpatient stays.

Interfering with the physician’s professional judgment. Hospitals rallied against the Two-Midnight Rule, arguing that it impinges upon a physician’s professional judgment. In a lawsuit against HHS, the AHA, several hospitals, and other hospital organizations sought to have the Two-Midnight Rule invalidated. The AHA argued
Despite efforts to address provider concerns, compliance with Two-Midnight Rule remains elusive.

That under the prior policy a physician could admit a patient if his or her medical condition and the anticipated services would result in a stay 24 hours or longer. Under Two-Midnight, a patient admitted in the early hours of the morning may not qualify as an inpatient until almost 48 hours had passed. Other medical factors used by physicians are overshadowed by the time requirement, such that a patient may not qualify for inpatient reimbursement even if intensive care unit (ICU) services are medically necessary.

“The [Two-Midnight Rule] determines insurance coverage based on an arbitrary cut point, which hurts patients who might present for care just after midnight, or patients who might need a short period of intensive care,” Sheehy testified. “Such a rule based not on clinical need, but on time of day a patient becomes ill, is not the right solution for the observation problem.”

**Issues for hospitalists.** In a report titled, *The Observation Status Problem: Impact and Recommendations for Change*, the Society of Hospital Medicine (SHM) highlighted a lack of understanding among hospitalists regarding the requirements of the Two-Midnight Rule. While, “[c]ompared to prior observation policy, hospitalists report equivalent levels of understanding of the Two-Midnight Rule and the longstanding prior policy, 68.5 percent and 65.6 percent, respectively.” While at first glance the understanding of the Two-Midnight Rule seems to have slightly improved, taking into consideration the “aggressive attempts to provide educational opportunities to the physician community, CMS has not been able to connect meaningfully with more than half of hospitalists on the Two-Midnight Rule.”

The SHM noticed that these numbers conflict with CMS’s intention to use the Two-Midnight Rule to create a simpler decision making system for physicians. “A simpler system should achieve significant gains in understanding—a goal that remains unrealized in light of the Two-Midnight Rule in its current form,” the report stated.

A survey, conducted by the SHM, showed that more than half of respondents (55 percent) disagreed or strongly disagreed that the Two-Midnight Rule improved the workflow of hospitalists compared to the previous policy on observation care. Additionally, even when slightly more than half of survey respondents in the SHM’s report acknowledged they had a general knowledge of the application, the survey found that less than half (40.4 percent) were confident in determining their patients’ statuses on their own, and only slightly more (46.3 percent) were confident in making such decisions with help from other players or systems in their hospitals. The report quoted one respondent as saying, “I am part of the utilization committee and serve as a physician advisor to help determine inpatient vs. observation level of care. I have received special training and still don’t feel I have a good grasp on how to assign level of care for all patients.”

**Significant Reimbursement Consequences Under the Two-Midnight Rule**

In addition to physicians’ lack of confidence in applying the Two-Midnight Rule, efforts to comply with Two-Midnight can lead to denied Medicare claims. As a condition to payment under Medicare Part A, the
Two-Midnight Rule requires that hospitals have written admission orders in each patient’s medical record, conforming to the two-midnight benchmark and authenticated before the patient is discharged.

Chapter 4, sec. 290.2 of the Medicare Claims Processing Manual (Pub. 100-04) sets forth the requirements for reporting observation services. In an article published in Reimbursement Advisor (Vol. 30, No. 1, September 2014) titled “Does Medicare Still Care about Observation Orders?” Mark Polston, a partner in the health care practice group at King & Spalding, LLP, in Washington, D.C., wrote, “Like an inpatient order, an order for observation services must be specific, that is, it should read that it is ordering ‘observation.’ Contractors are directed not to interpret an inpatient order as an order for observation services because, in CMS’s view, they are two different sets of services.”

According to Polston, “The challenge in getting a written order signed and authenticated by the ordering physician prior to discharge, particularly in short-duration stays, has proved to be significant. But with all of the attention paid to making sure that inpatient orders are signed on time, hospitals should not overlook the importance of their orders for observation services.” There may be consequences to a hospital’s reimbursement if admission orders are not provided or are not signed.

Both inpatient and observation claims denied. Polston points to the example of a hospital using electronic health records (EHRs) to prompt physicians to sign bed orders. Hospital personnel may be so focused on making sure inpatient admission orders are signed that they will be tempted to disable the prompt for all orders other than admission orders, making it more likely that an observation order will be left without a signature. An observation order without a signature is an easy audit flag and makes it possible for the contractor to deny payment despite any arguments as to why a signature does not appear on the order.

Under the two-midnight benchmark, described above, an unsigned observation order can also lead to the denial of a valid inpatient claim, Polston said. The benchmark can help overcome a presumption that a hospital stay less than two midnights is not medically necessary when the total amount of time the patient spent receiving hospital services (including outpatient observation care), spans two midnights or more. In determining if the benchmark is met, the start time of the outpatient services is an important consideration.

“If a hospital were to rely on time spent in observation to satisfy the two-midnight benchmark, then the physician’s observation becomes important as well,” Polston said. If the observation order is not signed by a physician, the contractor reviewing the claim may be uncertain about when observation services are ordered and can ultimately decide that observation services were never ordered. “In either case,” Polston said, “the contractor could deny the claim in a case in which the inpatient claim would otherwise have clearly been payable but for the unsigned order.” While Polston notes that in such cases, on appeal, a hospital could show when observation started based on a patient’s medical record, the appeals process also has its flaws.

Impact of the RAC Program on Hospitals and Beneficiaries

The RAC program is responsible for enforcing the rules on observation status but does not provide adequate protection for beneficiaries, according to Sheehy’s testimony. She called attention to an August 2013 OIG report that found the audit and appeals process to be lengthy and of unclear benefit. Sheehy testified that the University of Wisconsin Hospital typically has been made to wait more than 500 days for its appeals of RAC overpayment determinations to be adjudicated. The wait, she said, “is a clear denial of due process. The extensive wait time prior to adjudication impacts a hospital’s decision to file an appeal. These decisions may hurt Medicare patients as hospitals that are unable to have payments held in limbo for years or cannot afford a robust RAC audit and the appeals preparation team may end up having to rebill...
Despite efforts to address provider concerns, compliance with Two-Midnight Rule remains elusive

Medicare Part B instead of entering the appeals process, therefore declaring observation on patients that might otherwise qualify as inpatient.”

In 2012, only 7 percent of RAC determinations were challenged and overturned on appeal. The July 2013 OIG report also states that short inpatient stays (lasting fewer than two nights) resulted in “a significant portion of payments [that were] improper because the services should have been provided in the outpatient setting. Recoupment efforts by RACs have “contributed to a shift from short inpatient stays to extended observation stays, which are increasing.”

Sheehy further noted in her testimony that, while “the goal of the RAC program is to reduce improper payments, RACs are the only Medicare auditors paid on a contingency fee system. But instead incentivizes the creation of more audits by questioning physicians’ judgment.”

RACs discouraging short inpatient stays. In its Bagnall v. Sebelius amicus brief, the AHA also voiced its objections to the RAC program, noting that the contingency payments for RACs are between 9 and 12.5 percent of the overpayment amount, “creat[ing] a strong incentive for RACs to deny claims. The more claims they deny, the more they are paid.” Citing data collected by the organization showing that 74 percent of appealed RAC decisions are reversed, the brief states, “Unsurprisingly, the evidence suggests that these incentives encourage the improper denial of large numbers of claims.”

The AHA also found in its analysis of data that RACs have focused their attention on hospital claims for short inpatient stays. “The majority of medical necessity denials reported were for 1-day stays, where the care was found to have been provided in the wrong setting, not because the care was not medically necessary,” the AHA noted in its report, Exploring the Impact of the RAC program on Hospital’s Nationwide. The AHA posited that focusing on short inpatient stays is likely done with a financial motive, as “[d]enying payment for an entire inpatient stay is far more lucrative for the contractors than identifying an incorrect payment amount or an unnecessary medical service.” Through 2011, according to the report, RACs recovered $120 million for care they said was provided in the wrong setting. This amount accounts for more than 25 percent of the total recovered by the RACs.

The spotlight that RACs place on short inpatient stays has created a disincentive for hospitals to admit patients for short stays. In addition to the financial consequences, the administrative burden resulting when a RAC questions a claim—including submitting medical records and documentation, challenging and appealing the denial, and repaying the funds questioned—are substantial. The AHA noted, “Where physicians and hospitals previously may have erred on the side of more care for vulnerable Medicare patients, who are often quite elderly and have multiple chronic illnesses, the added enforcement risks appear to be forcing health care providers to place beneficiaries in observation status and see if it suffices.”

The AHA stressed that observation status cannot be used as a substitute for inpatient admission. “Outpatient observation is a distinct level of hospital care, which involves ongoing monitoring, testing, assessment, and reassessment solely for the purpose of determining the need to admit a patient. . . . It is different from inpatient, emergency, clinic, and recovery services and does not substitute for or duplicate the services delivered in another setting.” CMS agrees and stated in a Final rule

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*Because the outcomes could not be linked to specific RAC regions, these numbers exclude 3,968 unspecified appeals that were adjudicated by Administrative Law Judges.
(72 FR 66814) that it does “not consider observation services and inpatient care to be the same level of care and, therefore, they would not be interchangeable and appropriate for the same clinical scenario. The AHA’s brief further provided evidence of CMS’s position, quoting a letter in which CMS Administrator Marilyn Tavenner said that it is “not in the hospital’s or the beneficiary’s interest to extend observation care rather than either releasing the patient from the hospital or admitting the patient as an inpatient.”

**FY 2013 Recovery Audit Program appeals.** In FY 2013, the majority of appeals of RAC determinations at the administrative law judge (ALJ) level focused on short-stay inpatient hospital claims that were determined from medical documentation not to be medically necessary—i.e. that the patient could have been safely and effectively treated as an outpatient. There were more than 500,000 appeals to RAC decisions (including appeals focused on short-stay inpatient hospital claims) in FY 2013, and 18.1 percent were overturned in the provider’s favor.

**CY 2016 OPPS Proposed Rule**

In response to input from stakeholders including hospitals, physicians, the Medicare Payment Advisory Commission (MedPAC), beneficiary advocates, and Congress, CMS addressed certain concerns in the Calendar Year (CY) 2016 Outpatient Prospective Payment System (OPPS) Proposed rule (80 FR 39200, July 8, 2015). While CMS did attempt to clear up issues regarding physicians’ professional judgment and RAC review, the basics of the Two-Midnight Rule remain (see Two-Midnight Rule, policy changes in OPPS and ASC CY 2016 proposal, July 8, 2015).

**Case-by-case exceptions.** Previously, CMS created a “rare and unusual” policy, under which one exception to the Two-Midnight Rule was identified—prolonged mechanical ventilation. Based on feedback from stakeholders, CMS acknowledged that there are other patient-specific circumstances under which certain cases may be appropriate for Part A payment absent a two-midnight stay. The Proposed rule would allow physicians to make case-by-case exceptions to the Two-Midnight Rule, permitting inpatient classification of short stays. To qualify for this 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 patient requires a reasonable and necessary admission to the hospital as an inpatient.

CMS expects that in short inpatient stays, the patient will remain in the hospital at least overnight, but it also acknowledges that the patient may be unexpectedly discharged or transferred to another hospital and may not actually use a hospital bed overnight. Cases not spanning at least one midnight, however, will be prioritized for medical review. CMS did not propose any changes for hospital stays expected to be longer than two midnights. CMS further stated that it expects it to be rare and unusual for a beneficiary to require inpatient hospital admission following a minor surgical procedure or other treatment that would keep the patient in the hospital for only a few hours and not at least overnight.

**Review by quality improvement organizations.** Under the Proposed rule, CMS seeks to change the medical review strategy under the Two-Midnight Rule and have Quality Improvement Organizations (QIOs) conduct the “probe and educate” audits originally performed by MACs. The statutory duties of QIOs include review of some or all of the professional activities of providers and practitioners in the QIO’s service area in the provision of health care items or services to Medicare beneficiaries. Such reviews are meant to determine whether providers and practitioners are delivering reasonable and medically necessary services and, for inpatient services, whether the services could be effectively furnished on an outpatient basis. QIOs are well-suited to perform short-stay inpatient reviews, as the review fit within the scope of the QIOs CMS will continuously monitor and evaluate the proposed changes to the Two-Midnight Rule, specifically examining and evaluating applicable claims data to determine whether any patterns of case-by-case exceptions exist that might be appropriately announced as uniform, national exceptions.
Despite efforts to address provider concerns, compliance with Two-Midnight Rule remains elusive

statutory functions. The Proposed rule states, “QIOs manage a variety of beneficiary complaints and quality of care case reviews to ensure consistency in health care delivery and practice in the inpatient and outpatient setting while taking into consideration clinical practice guidelines and other local factors important to beneficiaries, providers, and practitioners, and the Department. These capabilities will be useful in making case-by-case review determinations.”

To complement the formal medical review process, CMS will continuously monitor and evaluate the proposed changes to the Two-Midnight Rule, specifically examining and evaluating applicable claims data to determine whether any patterns of case-by-case exceptions exist that might be appropriately announced as uniform, national exceptions. It will also examine the effect of the changes on short-stay inpatient claims and long outpatient observation stays and assess the payment policy in future years, making modifications based on the trends observed.

Responses from hospitalists. While most recognize the efforts taken by CMS to lend clarity to the Two-Midnight Rule, largely, hospitalists have responded with requests for further clarification on the rule. While the California Hospital Association (CHA) is “pleased that CMS shares [its] concerns and has proposed to change its medical review policy for short hospital stays [and believes] this is a critical first step in improving this policy,” the CHA asked CMS to “further qualify this language in the Final rule so that it is clear to all parties that CMS intends to return to its policy position prior to the implementation of the Two-Midnight Rule.” In doing so, CMS should engage physicians directly to educate them on the specifics of certain medical procedures that should remain outpatient procedures.

Johns Hopkins Hospital (JHH) wrote in its comment letter that, while it appreciates the willingness of CMS to address hospitals’ concerns that the Two-Midnight Rule removes physician judgment from the admission decision, it is dissatisfied with the implications to the modifications to the “rare and unusual” exceptions policy. The modification is likely to cause increased provider confusion because (1) CMS fails to define “inpatient hospital care” or identify specific examples of situations in which a patient may require such care, despite an expected length of care that is less than two midnights; (2) CMS does not outline specific medical review criteria for inpatient hospital admissions that are not expected to span two midnights; and (3) it remains unclear, without further guidance from CMS, whether CMS intended the case-by-case exception to be used only in rare and unusual circumstances or, conversely, a more broadly used exception to the two-midnight benchmark. “Without clarification by CMS of the proposed ‘rare and unusual exceptions’ policy, JHH believes that it will likely be used by the QIOs and RACs as a way to deny appropriate inpatient claims, thus increasing the administrative burden on providers and worsening the appeals backlog,” JHH wrote.

The American Association of Medical Colleges (AAMC), conversely, welcomed CMS’ recognition of stakeholder concerns regarding physicians’ clinical judgment. “The current proposal is closely aligned with AAMC’s consistent position: individual patient characteristics, comorbidities, and complications may necessitate an inpatient stay lasting fewer than two midnights, and CMS should defer to physicians to identify and document those cases for inpatient payments,” the AAMC wrote. Further, it stated that “CMS has struck a reasonable balance in its expectation that hospital stays lasting only a few hours, and not overnight, can reasonably be presumed to be appropriate for outpatient care. The AAMC appreciates that even alongside this revised guidance, CMS acknowledges that there still may be rare circumstances in which a hospital stay shorter than one midnight is appropriately designated as inpatient and billed under Medicare Part A. The Association understands the rationale for targeting short inpatient stays lasting less than one midnight for additional review and expects that the medical reviews of those cases will still consider the three clinical judgment factors listed above.” The AAMC also added that CMS should ensure that QIOs have adequate resources to assume their new medical review responsibilities under the Two Midnight Rule.

“The inpatient versus outpatient (observation) status designation remains an area of frustrations for hospitalists,” Sheehy told Health Law Daily. “It is purely a billing distinction, often disconnected from actual clinical care. Everybody understands that intensive care unit (ICU) care cannot safely be conducted in an outpatient clinic setting, but under current rules, it can be billed as outpatient. Although CMS has included the “case-by-case” language as above, they still have not added ICU care as an inpatient exception like they did for acute ventilator care. This means CMS still regards ICU care as something that may be billed as outpatient. I believe observation policy is going to remain frustrating for hospitalists until this billing status can be more consistently aligned with actual clinical care.”

She also noted that the lack of clarity regarding how to operationalize the “case-by-case” option, particularly
with regard to how it will be audited and enforced. “The main reason there is a large appeals backlog is that, historically, Recovery Auditors have not consistently respected physician judgment in making status determinations, even though this has been CMS’s intent. QIOs will now be the first line of audits under the Proposed rule, and Recovery Auditors will only be involved if a QIO determines there is a systematic problem. Although it is hoped that this will be an improvement over the prior auditing process, this is yet to be seen. Until this is known, it is hard to predict if hospitalists will really feel that the OPPS Proposed rule brings about meaningful changes in the Two-Midnight Rule.” A Final rule is expected in early November 2015. In the meantime, CMS extended the enforcement delay of Two-Midnight to January 1, 2016.

**Conclusion**

Until observation care reform is adopted, “[h]ospitals and physicians must follow current observation and inpatient policy,” Sheehy told *Health Law Daily*. “The Two-Midnight Rule is still new . . . and multiple clarifications have been issued since that time. Because of these factors, most hospitals require a workforce of case management, legal staff, physician advisors, data analysis, and others to advise physicians on status determinations and navigate the audits and appeals processes.” Hospitals that do not have such “on-site experience” should look to outside sources for guidance, and physicians and other providers should do their best to familiarize themselves with the rule and use the advice of outside sources to complement their own knowledge of the Two-Midnight Rule. Additionally, while the Two-Midnight Rule is the standard, physicians and hospital personnel alike should be aware of the requirement of a signed admission or observation order, respectively.

Patients can also take steps to educate and protect themselves with the help of the hospitals treating them. The Illinois Hospital Association (IHA), for instance, has created *A Patient’s Guide to Observation Care* as a template for hospitals to use. The guide sets forth Medicare’s intentions for observation care and rules related to billing. The guide also informs patients of their physicians’ and hospitals’ responsibilities in determining proper admission status. Finally, a signature sheet is provided that is given to patients to ensure that they have been informed of their placement in observation status. Additionally, a physician guide titled *Help Your Patients Understand Observation Care* and a fact sheet titled *Facts Nurses Should Know about Patients in Observation Care* are included with the patient’s guide. These documents are all editable to include each hospital’s name and logo. CMS has made a similar guide available for Medicare beneficiaries titled, *Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask.*

Among patient education guides, one piece of advice prevails—patients who are uncertain of their admission status should seek information from their physicians or case management representative.

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– Ann Sheehy, MD, Chief, Division of Hospital Medicine, University of Wisconsin