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ASSOCIATE BUSINESS MEMBER
Medline Healthcare
Mundelein, IL

Mark Parkinson
PRESIDENT & CEO

June 25, 2013

Ann Marshall
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-05-17
7500 Security Boulevard
Baltimore, MD 21244

Re: AHCA Comments on CMS' *Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services Under Medicare Part A*, Proposed Rule, Hospital Inpatient Prospective Payment Systems, May 10, 2013, CMS-1599-P

Dear Ms. Marshall,

AHCA is the nation's leading long term care (LTC) organization representing more than 11,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than one million of our nation's frail, elderly and disabled citizens who are in nursing facilities, assisted living residences, subacute centers and homes for persons with intellectual and developmental disabilities.

Under the proposed rule, Medicare would presume that an individual is an inpatient if the physician documents that the patient requires more than two midnights in the hospital following an inpatient admission. The "starting point for this time-based instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided." 78 Federal Register at 27648. On the other hand, Medicare would presume that hospital services spanning fewer than two midnights should be considered outpatient observation. For patients whose inpatient stay was fewer than two midnights, CMS would pay for inpatient care only if the services were identified on Medicare's inpatient-only list or "in exceptional cases such as beneficiary death or transfer." Id. 27649.

This is the second proposed rule to have been issued by CMS in the last four months in an effort, in part, to minimize the increasing number of lengthy observation stays. The first, issued on March 18, 2013, proposed that hospitals in general be allowed to rebill denied inpatients stays as outpatient stays. 78 Federal Register 16632, March 18, 2013. AHCA commented on that proposed rule to the effect that CMS' proposal to allow expanded Part B rebilling would not do much for beneficiaries caught up in overly long observation stays, and in fact, would actually harm beneficiaries who would find themselves unexpectedly responsible for a host of Part B charges.

We conclude, yet again, that this second proposal addressing inpatient admission criteria does not help the observation stay patient access his or her skilled nursing facility (SNF) post-acute benefit. It is not sufficient in itself to affect a reform of lengthy observation stays and may even confuse matters further.

- **The Observation Problem**

CMS has now acknowledged in many forums that there is a problem. In this second proposed rule, CMS again states that, in recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours has increased from approximately 3 percent in 2006 to approximately 8 percent in 2011. This trend concerns CMS because of the potential financial impact on Medicare beneficiaries.

CMS explains that beneficiaries who are treated for extended periods of time as hospital outpatients receiving observation services may incur greater financial liability than they would if they were admitted as hospital inpatients. They may incur financial liability for Medicare Part B copayments; the cost of self-administered drugs that are not covered under Part B, and the cost of post-hospital SNF care because section 1861(i) of the Act requires a prior 3-day hospital inpatient stay for coverage of post-hospital SNF care under Medicare Part A.

In stark contrast to Part B, as a hospital inpatient under Medicare Part A, a beneficiary pays a one-time deductible for all hospital inpatient services provided during the first 60 days in the hospital of the benefit period. Therefore, an inpatient deductible does not necessarily apply to all hospitalizations. Medicare Part A coinsurance applies only after the 60th day in the hospital.

- **The Solution**

Administrator Marilyn Tavenner in response to a question posed by Senator Charles Schumer, D-NY, at a Senate Finance Committee hearing on April 9, 2013, expressed CMS' willingness to, "work with your [Senator Schumer's] team" to try to resolve the growing problem the Senator raised of extended observation stays impeding Medicare beneficiaries' appropriate and necessary access to post-acute care in SNFs.

However, in response to a question posed by Senator Sherrod Brown, D-OH, for the April 9 Senate Finance Committee hearing record, the Administrator asserted, in written remarks that CMS does not have the authority to change the CMS policy on whether time spent in observation status is considered with regard to determining eligibility for Medicare coverage of post-acute SNF care. **In contrast, it is our position that CMS has both the authority and the obligation to make this happen and that the only and best way to provide needed Medicare covered post-acute access to beneficiaries is for CMS to count all days in observation toward the 3-day requirement for Medicare covered post-acute skilled nursing care.¹**

Below, we discuss the inadequacies of this latest proposed rule modifying inpatient admission criteria, and, further, discuss the need to include observation days in the count of the 3-day hospital stay requirement for SNF post-acute care and CMS' authority to do so. AHCA is asking that CMS do this in an expeditious manner.

¹ Representatives Joseph Courtney (D-CT) and Tom Latham (R-IA) and Senator Sherrod Brown (D-OH) share our concern and have introduced the *Improving Access to Medicare Coverage Act of 2013* (H.R. 1179/S. 569) to address these situations.

I. Discussion

A. CMS' Goal for the Proposed Rule

The genesis of CMS' first rule addressing observation stays, the Part B Inpatient Billing proposed rule, was a response to the assertion by various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for long periods of time, rather than admitting them as inpatients. The genesis of this second proposed rule is CMS' belief that it is important to consider whether it can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment.

The focus therefore of this latest proposed rule is to add another criterion to the determination of whether or not a beneficiary should be admitted to the hospital as an inpatient -- a length of stay criterion. Even though CMS does not state so, it is possible that it believes that if it clarifies inpatient versus observation stay criteria by this length of stay proposal, observation stays will either decrease or be very limited in duration.

AHCA does not believe that this is so. CMS does not make the connection, and does not even seem to try to, between addressing lengthy observation stays and its new length of stay proposal.

B. The Development of the Proposed Rule

CMS states in the proposed rule, "The majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis)." In 2012, the Comprehensive Error Rate Testing (CERT) Contractor found that Medicare Part A inpatient hospital admissions for 1-day stays or less had an improper payment rate of 36.1 percent. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. The improper payment rate further decreased to 8 percent for those beneficiaries who were treated as hospital inpatients for 4 days.

CMS goes on to explain that inpatient hospital short-stay claim errors are frequently related to minor surgical procedures or diagnostic tests. In such situations, the beneficiary is typically admitted as a hospital inpatient after the procedure is completed on an outpatient basis, monitored overnight as an inpatient, and discharged from the hospital in the morning. Medicare review contractors typically find that while the underlying services provided were reasonable and necessary, the inpatient hospitalization following the procedure was not (that is, the services following the procedure should have been provided on an outpatient basis).

CMS indicates that, through the proposed rule, it is seeking to clarify its longstanding policy on how Medicare review contractors review inpatient hospital admissions for payment under Medicare Part A. It is attempting to address the ongoing challenge in deciphering the blurred line between outpatient observation stays and inpatient short stay admissions and resolve ongoing confusion as to when a patient should be admitted to inpatient status. The goal would be that, if finalized, hospital inpatient admissions spanning two midnights in the hospital might generally qualify as appropriate for payment under Medicare Part A. Anything less would be considered observation and paid under Part B, unless the physician could prove otherwise.

Under the proposal, according to CMS, Medicare’s external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 “midnights”) in the hospital receiving medically necessary services. The proposed rule states that it would create a presumption that hospital admissions of less than two days would not be reasonable and necessary, and that the patient should have been treated on an outpatient basis, “unless there is clear documentation in the medical record supporting the physician’s order and expectation that the beneficiary would require care spanning more than 2 midnights or the beneficiary is receiving a service or procedure designated by CMS as inpatient-only.” (78 *Fed.Reg.* at 27646.)

CMS opines that if a hospital is found to be abusing this 2-midnight presumption for non-medically necessary inpatient hospital admissions hospital is systematically delaying the provision of care to surpass the 2- midnight timeframe, CMS review contractors would disregard the 2- midnight presumption when conducting review of that hospital. Similarly, CMS would presume that hospital services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear documentation in the medical record supporting the physician’s order and expectation that the beneficiary would require care spanning more than 2 midnights or the beneficiary is receiving a service or procedure designated by CMS as inpatient-only.²

C. The Implications of the Proposed Rule As Seen By Hospitals and Physicians

A critical factor and first step in trying to determine whether the new policy will ameliorate the current observation problems is understanding whether the front line decision makers -- the admitting physicians, the hospitalists, the utilization reviewers, etc. believe that the policy is a positive step. In short, will the clarification be enough to resolve the longstanding dilemma for providers, such hospitals and physicians, as to when it is appropriate to order an inpatient stay?

AHCA, in reaching out to hospital and physician representatives, has come to understand that generally they appear to think the clarification is not enough to resolve the longstanding dilemma for providers as to when it is appropriate to order an inpatient stay. In fact, there is a concern that it will do more harm than good. We understand that the hospital community fears that while the critical dilemma is essentially a clinical one, the proposed rule imposes a payment remedy that

² The proposed regulation, 42 CFR §412.3(c)(1) reads in relevant part as follows:

- When a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed.
- Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. The expectation of the physician should be based on such complex medical factors as
 - Patient history and comorbidities;
 - The severity of signs and symptoms;
 - Current medical needs; and
 - The risk of an adverse event.
- The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

likely could be applied aggressively by CMS's payment recovery contractors, reflecting a desire to reduce payments to hospitals in the process.

In particular, there is a fear that the practical impact of the proposal is to give unbridled discretion to Medicare Recovery Auditors and other review contractors to deny one-day inpatient stays and that the Medicare recovery auditors, while still having a financial interest in denying stays of more than one day, will in a sense see the opportunity to deny most, if not all, one-day stays, and force hospitals to take their chances on appeal.

The argument can be made that, although the proposal is framed as a presumption, at least as worded in the preamble, the proposed rule inappropriately would in effect establish a *per se* rule that inpatient admissions that are not expected to last at least two days are not medically reasonable and necessary (unless the beneficiary is receiving an inpatient-only service or procedure).

It is clear to all stakeholders, including SNF post-acute providers, that the proposed rule offers no legal or medical support for the idea that a one-day stay that is expected to be a one day stay is not medically reasonable and necessary.

The issue of short stay inpatient admissions has been identified as an area of concern by regulators and enforcement agencies. However, hospitals believe that the CERT contractor finding that 36.1 percent of inpatient stays of one day or less were inappropriate clearly indicates a need for clearer clinical guidelines for patient status determinations. This finding certainly does not support a drastic medical review policy that creates a presumption against medical necessity of inpatient stays of one day or less.

Lastly, in short, the "two midnight" would do very little for physicians who are trying to make appropriate, real time patient status decisions. It provides a clear avenue for medical reviewers to second guess physician decisions and deny hospital payment, while providing no additional guidance to help inform the up-front decision making process that is later picked apart by medical reviewers.

D. Counting Observation Days Toward the 3-day Stay Requirement for SNF Post-Acute Care

AHCA applauds CMS effort in trying to minimize the uncertainty in inpatient vs outpatient criteria. However, the proposal has created controversy among those who will have to execute it. Thus, its immediate effectiveness is at stake. And it does not appear at all useful in minimizing or ending lengthy observation stays. It does not come close to providing SNF post-acute benefit protection to long stay observation patients.

It is AHCA's position CMS must address observation stays head on and proceed to count observation days in the 3-day stay requirement. CMS has the authority to do this. In its prior incarnation as the Health Care Financing Administration (HCFA), the agency developed observation days as a Medicare covered benefit and provided a payment methodology, changed by the agency numerous times, to reimburse for observation. As discussed below, it is clear that the inherent authority to create coverage for observation days, to expand, contract, and regulate that coverage by guidance -- and to distinguish and delineate inpatient from outpatient encompasses the authority to count observation days toward the 3- day stay requirement.

Section 1861(i) of the Social Security Act requires that a beneficiary be an inpatient of a hospital for not less than 3 consecutive days before discharge from the hospital in order to be eligible for coverage of post-hospital extended care services.³ No one can argue with the fact that the word inpatient is imbedded in the authorizing legislation passed in 1965. However, the term “inpatient” at the time of passage of Section 1861(i) meant any patient in the hospital who was not receiving emergency care.

The intent of the 1965 legislation appears to have been twofold: The post-acute benefit was intended to provide rehabilitation and nursing care for the elderly after a hospital stay, and the 3-day requirement was a crude gatekeeper tool. In short, there were no formal observation stays in 1965 and would not be recognized by HCFA until 24 years later in 1989. Observation status was not prescribed in legislation and, in fact, cannot be found in regulation.

In sum, Medicare observation reimbursed status was created by HCFA. HCFA developed observation days as a Medicare covered benefit and provided a payment methodology, changed by the agency numerous times, to reimburse for observation. It did this in an era in which hospitals and HCFA were dealing with the impact of the DRG system and hospital efforts to minimize the financial implications of a bundled DRG payment.

In HCFA’s view, the number of patient days within the DRGs was being whittled away by short-stay inpatient stays and the diversion of diagnostic and non-diagnostic services to pre-admission outpatient status. HCFA responded with hospital post-acute transfer rules,⁴ and the three-day DRG-payment-window.⁵ It also over time increased stringency in observation guidance.

It is clear that the inherent authority to create coverage for observation days, to expand, contract, and regulate – by guidance -- that coverage, and to distinguish and delineate inpatient from outpatient encompasses the authority to count observation days toward the 3- day stay requirement. Technically speaking, CMS could totally undo what it has done and eliminate observation coverage and payment altogether.

Patients who then might be candidates for observation would have to be treated within the remaining construct -- which would be the ER or admission as an inpatient. Since observation medicine, when practiced correctly and appropriately, is now an accepted and integral category of medical practice, it is, of course, inconceivable that any such thing would happen. But something negative has happened – the beneficiary was lost track of and is paying the price of this medical evolution.

³ “The term “post-hospital extended care services” means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer...” SSA Section 1861(i).

⁴ Under the Medicare post-acute-care (PAC) transfer policy, acute-care hospitals are reimbursed under a per-diem formula whenever beneficiaries are discharged from selected diagnosis-related groups (DRGs) to a skilled nursing facility, home health care, or a prospective payment system (PPS)-excluded facility. Total per-diem payments are below the full DRG payment only when the patient's length of stay (LOS) is short relative to the geometric mean LOS for the DRG; otherwise, the full DRG payment is received. This policy originally applied to 10 DRGs beginning in fiscal year 1999. Currently, more than one-third of the 749 Medicare severity diagnosis-related groups (MS-DRGs) for fiscal year (FY) 2012 are subject to the PACT policy.

⁵ See <http://www.cms.gov/Medicare/Medicare-Fee-for-Servicepayment/AcuteInpatientPPS/ThreeDayPaymentWindow.html>

CMS' current stance that it does not have the authority to count observation days in the 3-day requirement is puzzling since it has indicated in the past that it did have such authority. In the FY 2006 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) proposed rule, May 19, 2005, 70 Federal Register 29070, CMS invited comments on the hospital practice of having patients spend time in observation status prior to a formal inpatient admission, and on the potential implications of this practice for the SNF benefit's qualifying 3-day hospital stay requirement.

In effect, CMS acknowledged that counting observation days toward the 3-day qualifying stay was within CMS' authority. As explained here, this is indeed the case since observation days are a construct stemming from past hospital practice and CMS' acceptance of the practice. AHCA commented on the proposal as requested along with other provider and beneficiary groups. Unfortunately, CMS pulled back in the final rule, but expressed the intention to continue to review the issue.

It is clear that HCFA, now CMS, and the hospitals in concert moved services outside of the DRG payment system, but they have not and could not remove patient need for post-acute care. The recognition in 1965 of the need for nursing and rehabilitative care after a hospital stay was prescient and has not vanished. The elderly do not benefit from lengthy stays in a hospital no matter where the bed. Ambulation and restoration is minimal. In addition, the need for SNF post-acute care has increased due to the shortened length of hospitals stays.

Indeed, even CMS became concerned about certain procedures being performed outside of the DRG context. In developing "inpatient only" rules CMS itself, as early as 2000, acknowledged the blurring of lines between outpatient and inpatient. It stated:

We believe that certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, indisputably require inpatient care, and therefore are outside the scope of outpatient services. Certain other procedures that we proposed as "inpatient only" may not be so clearly classified as such, but they are performed virtually always on an inpatient basis for the Medicare population. **We acknowledge that emerging new technologies and innovative medical practice are blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many procedures, although we are concerned that some of the procedures that commenters claim to be performing on an outpatient basis may actually have been performed with overnight postoperative care furnished in observation units.** And, regardless of how a procedure is classified for purposes of payment, we expect, as we stated in our proposed rule, that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests."⁶

The necessity to choose between observation stays status and inpatient status has become a major bane of physician existence. Medicare observation stay criteria are generally considered by physicians to be poor, and guidelines used by Recovery Contractors with respect to the medical

⁶ See 65 Federal Register 18434, 18455-56, April 7, 2000 "Under section 1833(t)(1)(B)(i) of the Act, the Secretary has broad authority to designate which services fall within the definition of "covered OPD [outpatient department] services" that will be subject to payment under the prospective payment system."

necessity of inpatient care be nothing more than proprietary black boxes that make no sense.⁷ It is clear that there is no bright dividing line between an observation stay and an inpatient stay.

In short, CMS has the authority to determine and regulate what is an outpatient, an observation stay patient, and an inpatient, and to develop clinical and payment rules for all three categories. It is also clear that CMS has the authority to deem observation stays as inpatient stays for the purpose of access to Medicare covered post-acute care. There is no legislation that either prohibits or that can be construed to prohibit such decision making.

Perhaps what is needed is for CMS to examine closely the state of observation care in American hospitals. The only Medicare definition of observation stays appears in various CMS manuals, where observation services are defined as:

a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.⁸

Further, extensive literature indicates that observation medicine properly and appropriately practiced has duration of no more than 24 hours and is provided in a dedicated observation unit.

In the article published in 2001, *Principles of Observation Medicine*, Dr. Michael A. Ross and Dr. Louis G. Graff explain the following: that the average length of stay in the emergency department [in 2001] was in the range of 2 to 6 hours.⁹ At the same time, the national average hospital inpatient length of stay was roughly 5 days, with admissions of less than 1 day often being denied payment on the premise that it was unnecessary. Fundamentally, this design created a void for patients whose health care needs were **greater than 6 hours but less than 24 hours**. To meet their need, Emergency Department Observation Units (EDOUs) were developed. Over time, the provision of services in these EDOUs became more standardized and organized.

According to Drs. Ross and Graff, good observation medicine is practiced predominantly in dedicated units rather than on a patient floor. Moreover, the patients who are placed in observation on inpatient floors have the greatest chance of languishing in these beds and not receiving observation care as it should have been provided. Obviously, CMS could never have intended this outcome just as the agency could never have intended beneficiaries to be deprived of necessary post-acute care by lengthy observation stays.

II. Conclusion

It is AHCA's position that CMS should move rapidly to include observation days in the count of the required 3-day stay. CMS has the authority to count all days in observation status toward the 3-day requirement for Medicare covered post-acute SNF care. Lengthy observation stays are an aberration of good observation medicine. CMS should not let such an aberration drive beneficiary access to needed care. We appreciate this opportunity to share our thoughts with

⁷ See Transcript of the CMS Observation Open Door Call, 2011.

⁸ Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 6, §20.6; same language in Medicare Claims Processing Manual, CMS Pub. 100-04, Chapter 4, §290.1.

⁹ *Principles of Observation Medicine*, Dr. Michael A. Ross and Dr. Louis G. Graff, Emergency Observation Medicine, Volume 19, Number 1, February 2001. See also *State of the Art: Emergency Department Observation Units*, Michael A. Ross et al. Critical Pathways in Cardiology, Volume 11, Number 3, September 2012.

CMS. We have offered in the past, and re-affirm our offer, to work with CMS on this critical issue.

Sincerely,

A handwritten signature in black ink that reads "Elise Smith". The signature is written in a cursive, flowing style.

Elise Smith
Senior Vice-President Finance Policy and Legal Affairs

CC: Jonathan Blum
Laurence Wilson
Becky Kurtz
Maija Welton
Valarie Molaison
Jacob Parker