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October 31, 2013

Jonathan Blum  
Deputy Administrator, Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**RE: FY2014 Medicare Inpatient Prospective Payment System (IPPS) Final Rule – Anticipated CMS Guidance on “Two Midnights”**

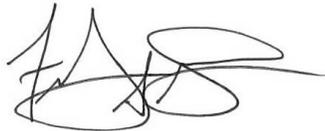
Dear Deputy Administrator Blum:

On September 26<sup>th</sup>, the Centers for Medicare & Medicaid Services (CMS) held a Special Open Door Forum during which CMS stated that the Agency was planning to issue detailed subregulatory guidance to clarify the FY2014 Medicare Inpatient Prospective Payment System (IPPS) Final Rule’s “Two Midnights” requirement. CMS specifically stated that such guidance would address that hospital utilization review programs and conditions of participation are not changing with implementation of the Final Rule. CMS also confirmed that the IPPS Final Rule, “should not be used as a reason for hospitals to abandon their use of critical medical necessity and coverage assessments,” in public statements made by the CMS Philadelphia Regional Office. We agree that the “Two Midnights” requirement should not be interpreted as a substitute for sound clinical judgment based on objective, evidence-based medicine.

To assist CMS in issuing needed clarifying language, attached please find proposed language for inclusion in the forthcoming subregulatory guidance that CMS is currently preparing. We appreciate your continued efforts to clarify these important details regarding “Two Midnights” in order to minimize confusion and ensure beneficiaries are receiving appropriate care at the appropriate time. Thank you.

Sincerely,

  
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John Rother  
President & CEO, National Coalition on Health Care

  
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Frederic S. Goldstein  
Executive Director, Care Continuum Alliance

## **CMS IPPS Final Rule – Proposed Subregulatory Guidance Language Regarding Medical Necessity**

The FY 2014 Inpatient Prospective Payment System (IPPS) Final Rule reaffirmed CMS’s longstanding policy that the admitting physician is in a unique position to weigh all of the relevant clinical information to critically assess the patient’s individual medical needs on a case-by-case basis. The two midnights benchmark is intended to assist physicians in making inpatient admission decisions that are appropriate for reimbursement under Medicare Part A; however, it is not a substitute for the application of sound clinical judgment based on objective, evidence-based medicine. As discussed during the CMS Special Open Door Forum on September 26, 2013, the FY1014 IPPS two midnights requirement serves as an overlay to the medical necessity determination made by the physician, and validated by the hospital through its Utilization Review process.

Pursuant to the Medicare Benefit Policy Manual (Chapter 1, Section 10), the decision to admit a patient to the hospital for inpatient treatment is a complex medical judgment that is made by the practitioner or practitioners responsible for the care of the patient and familiar with the patient’s medical needs and overall course of treatment. However, admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital.

In order to qualify for reimbursement under Medicare Part A, an inpatient hospital stay should be reasonably expected to span a time period that crosses at least two midnights (i.e., more than 1 Medicare utilization day), during which time the beneficiary must be receiving medically-necessary hospital (inpatient) care. In making the determination that the patient requires inpatient hospital care spanning two midnights or more, the admitting practitioner(s) shall take into consideration the objective medical information available prior to the second midnight of the patient’s hospital course. The following factors, enumerated in the Medicare Benefit Policy Manual (Chapter 1, Section 10) constitute the objective medical evidence utilized to support the appropriateness of an inpatient admission and the admitting practitioner(s)’ expectation regarding the length of the patient’s hospital stay:

- Medical history, comorbidities, and risk factors
- Signs, symptoms, and current medical condition
- The likelihood of an adverse event occurring while the beneficiary is in the hospital
- The need for acute therapeutic services or emergent procedures
- The immediate physical safety of the patient

Consistent with CMS policy and guidance, CMS and its contractors rely on the physician to use his or her clinical judgment and evaluation of the patient’s needs to make an admission determination. According to CMS Ruling 95-1, that judgment must be supported by “acceptable standards of practice.” Likewise, in reviewing inpatient admissions of less than two midnights for medical necessity on a retrospective basis, Medicare contractors should look to the objective medical evidence documented in the medical record from the start of services until the time that the admission decision was made by the treating practitioner and consider this information in the context of acceptable standards of medical practice. In December 1995 the Health Care Financing Administration issued HCFA Ruling 95-1 (now known as CMS Ruling 95-1), advised that:

*Medicare contractors, in determining what ‘acceptable standards of practice’ exist within the local medical community, rely on published medical literature, a consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts.*

Following evaluation of the patient’s clinical condition and medical needs, in consideration of accepted standards of medical practice and the two midnight benchmark, the treating physician formally admits the patient as a hospital inpatient pursuant to an admission order in accordance with the Medicare hospital Conditions of Participation. As a condition of Medicare payment under Part A for such an admission, the order must be documented in the medical record, and the physician must further certify the medical necessity of the inpatient admission. The physician’s order and certification serve as evidence of the physician’s medical opinion that the patient requires an inpatient hospitalization in accordance with Medicare regulation and policy; however, per the Final IPPS Rule we indicated that:

*No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order or certification will be evaluated in the context of the evidence in the medical record.*

Even though a physician's certification is required for payment, CMS Ruling 93-1 (previously known as HCFA Ruling 93-1, released May 1993) makes clear that coverage decisions are not made based solely on this certification; instead, "they are made based upon objective medical information about the patient's condition and the services received."

To ensure that hospitals are submitting a valid claim, hospitals have always been responsible for reviewing the physician's admission decision to ensure that the decision to admit is consistent with Medicare's rules, regulations and guidance as well as hospital admission guidelines. The Medicare hospital Conditions of Participation found in the Code of Federal Regulations (42 CFR Section 482.30) requires hospitals to have, "...[a] utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs."

The CMS State Operations Manual (CMS IOM 100-07), Appendix A—Survey Protocol, Regulations and Interpretative Guidelines for Hospitals, Interpretive Guidelines §482.30(d) further supports and defines the physician's and hospital's role in admission decisions, "[i]n no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate." The necessity for the physician to serve as the arbiter of medical necessity in the context of final utilization review determinations, and the requirement for the hospital's participation in that process, is reaffirmed by CMS Transmittal 1803, Change Request 6626, issued August 28, 2009, which states:

*The State Operations Manual states that in no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate (see Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals). However, CMS encourages and **expects hospitals to employ case management staff to facilitate the application of hospital admission protocols and criteria**, to facilitate communication between practitioners and the UR committee or Quality Improvement Organization (QIO), and to assist the UR committee in the decision-making process.*

Before submitting a claim for reimbursement under Medicare Part A, it is incumbent upon the hospital to validate that the physician's inpatient admission order conforms to Medicare regulation and payment policy and that the hospital stay is therefore appropriately billed on an inpatient claim. Involvement of the hospital's utilization review committee, in accordance with Medicare hospital Conditions of Participation, including the application of commercial screening tools in conjunction with physician review utilizing evidence-based peer reviewed guidelines, will help to ensure proper claim submission by the provider and timely Medicare reimbursement.