



American Hospital  
Association

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June 26, 2009

Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-1538-P, Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010; Proposed Rule (Vol. 74, No. 86), May 6, 2009.***

Dear Ms. Frizzera:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, including 1,200 inpatient rehabilitation hospitals and units, and our nearly 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2010 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule. While we support the standard annual payment updates in this regulation, we have a number of concerns about the proposed changes to the current IRF criteria in Section 110 of the *Medicare Benefits Policy Manual* (MBPM), and other proposed regulatory changes.

The proposed rule updates the FY 2010 IRF PPS relative weights and average length of stay values; facility-level adjustments; wage index and labor-related share values; outlier threshold; and, as required by statute, implements a market basket update. We encourage CMS to use the most recent available data for these changes and recommend that the outlier loss threshold for FY 2010 be recalculated using 2008 claims – as was done for the FY 2010 inpatient PPS proposed rule.

Our comments below focus on CMS' proposals to codify in federal regulation several new IRF facility and patient criteria and change Section 110 of the MBPM. CMS says the existing IRF regulations are out-of-date and inconsistent with the IRF PPS implemented in FY 2002. While we appreciate CMS' efforts to update and clarify the IRF regulations and MBPM provisions, we believe the current proposals need further consideration prior to implementation.



#### **PROPOSED CHANGES TO IRF FACILITY CRITERIA**

Currently, to be certified by the Medicare program as an IRF, an IRF hospital or unit must meet a number of facility criteria, including the acute-care hospital conditions of participation, the 60% Rule and other criteria. Generally, CMS contractors assess these criteria annually to determine whether to renew an IRF's facility certification for the coming year. If an IRF fails to meet the facility requirements, it may be decertified from the Medicare program. CMS then may require the decertified IRF to pay back the difference between payments the IRF received for claims paid during the prior year under the IRF PPS and the lower payments Medicare would have made under the inpatient PPS.

In the proposed rule, CMS recommends changing the IRF facility regulations by codifying several new IRF facility criteria currently in effect as patient criteria in the MBPM. However, CMS fails to articulate any inadequacies of the current facility criteria. Certain proposed criteria, such as the so-called "three-hour rule," are appropriate patient criteria but not effective facility criteria. Given that IRFs already must satisfy substantial facility criteria similar to those of other hospital settings, and may face a significant financial penalty if they fail to do so, we do not believe further IRF facility criteria are warranted at this time.

When considering modifications to the existing IRF facility criteria, CMS should not propose the use of IRF *patient* criteria, which are used to assess the medical necessity of individual patients, as *facility* criteria that establish whether an IRF's Medicare certification will continue. Patient and facility criteria serve two distinct purposes – medical assessment of a patient versus assessment of a facility's attributes and capacity.

CMS' proposal to add the three-hour rule to the codified facility criteria illustrates why a clinical guide for patients should not be used as a basis for facility certification. Though called a "rule," the three-hour rule actually is a clinical care *guideline* applied on a patient-by-patient and day-by-day basis. It reflects the expectation that most, but not all, IRF patients generally require three hours of therapy, five days per week. Exceptions may be made for patients unable to tolerate that level of therapy. Although IRF claims may not be denied solely on the basis of the rule, some CMS contractors have done so and these denials have been successfully overturned through the Medicare appeals process. Because the rule is a patient guideline that may be tailored to each particular case, rather than an unequivocal "rule of thumb," it is inappropriate for determining whether a facility's Medicare designation should continue to the next year.

#### **PROPOSED CHANGES TO IRF PATIENT CRITERIA: SECTION 110 OF MBPM**

CMS, through a concurrent process outside its IRF rulemaking for FY 2010, proposes significant changes to Section 110 of the MBPM, which provides the medical necessity guidelines for IRF patients. The proposed changes amount to a complete rewrite of the IRF patient criteria. **While we applaud CMS for attempting to bring greater clarity to the criteria used to determine which patients are appropriate for IRF care, we have several concerns that we urge the agency to consider and address before proceeding to change the IRF patient criteria in the MBPM or regulations. Given the complexity and scope of the proposed changes, we urge CMS to use a Technical Expert Panel comprised of**

**researchers, providers and other experts to supplement the efforts to date by a CMS internal work group.**

The AHA is concerned especially about language in the introduction of the proposed Section 110 revisions pertaining to the clinical status of patients transferred to an IRF from a general acute hospital. **The statements highlighted below could materially and inappropriately narrow the scope of IRF services.**

The proposed language states:

*The inpatient rehabilitation facility benefit is designed to provide intensive rehabilitation therapy ... A patient requiring acute inpatient care is expected to remain in the acute inpatient hospital setting, with appropriate rehabilitative treatment provided until such time as the patient no longer requires acute inpatient care.*

This statement overlooks IRFs' status as inpatient hospitals meeting Medicare's hospital conditions of participation that provide a specialized form of acute inpatient care. It also fails to recognize that IRFs treat medically complex patients requiring *both* medical and rehabilitative care. For IRF patients – such as stroke, brain injury, spinal cord and trauma patients – it is the very combination of their medical and rehabilitation needs that make them medically necessary candidates for IRF care. The current IRF patient criteria establish a high severity case-mix that is distinct from other settings providing therapy, including the need for close supervision by specialized physicians, 24-hour rehabilitation nursing and daily, intensive rehabilitation.

The proposed language also states:

*...patients must have completed medical management in the acute care setting prior to admission to an IRF... IRF admissions for patients who are still in the acute phase of their illness and still require acute inpatient care will not be considered reasonable and necessary.*

These guidelines would significantly diminish the scope of IRF services provided to Medicare beneficiaries. Today, patients who *lack* the need for medical management are generally considered too clinically stable for IRF care and, therefore, suitable for a less-intensive setting, such as a skilled nursing facility, that typically lacks close physician oversight, 24-hour specialized registered nurse care and other unique IRF attributes. **Removing the medical management component of the IRF medical necessity criteria restricts IRFs to treatment of a much narrower patient population – those who are medically stable and simply in need of intensive rehabilitation.** It is not clear that the remaining patients who need intensive rehabilitation, but no longer require medical management, would meet IRF patient requirements, such as close physician supervision and 24-hour rehabilitation nursing. **A change of this magnitude goes well beyond CMS' stated goal of clarifying the existing Section 110 guidelines.**

Currently, patients must demonstrate a need for medical management in addition to intensive therapy, as indicated by comorbidities and medical complications, to qualify for IRF care.

Otherwise, CMS contractors may deny Medicare coverage for not having an adequately high level of severity to warrant hospital-level rehabilitation. In fact, CMS contractors frequently find that a “less-intensive setting” is appropriate for these patients. Eliminating the medical management function from IRFs has the potential to disqualify many current patients from future IRF care, which is why CMS should propose this change through rulemaking to allow for full public engagement.

CMS also proposes new patient criteria pertaining to the clinical capacity and medical services provided by other non-IRF medical settings. Today, the determination of medical necessity for an IRF patient is based solely on the clinical characteristics of that patient relative to the criteria in Section 110. If a patient meets the eight IRF criteria in Section 110, that patient satisfies CMS’ medical necessity guidelines. These criteria take into account the diagnosis, functional level, comorbidities and other clinical characteristics of the patient relative to the IRF scope of services. Under the proposed changes, medical necessity determinations also would need to take into consideration care provided at other settings, such as inpatient hospitals and skilled nursing facilities, where care varies by community and provider. IRFs and CMS contractors do not have, and should not be expected to acquire and maintain, specific knowledge about the clinical capacity and quality of care provided by other non-IRF providers in a particular community. **It is unreasonable for CMS to expect IRFs to base medical necessity and admission determinations on external criteria not pertaining to patients’ clinical status and need.**

Proposed New Medical Necessity Concepts Requiring Clarification. There are several concepts in the proposed Section 110 changes that, without clarification, would create confusion and may lead to inconsistent interpretations by both IRFs trying to implement CMS’ expectations and CMS contractors using the new provisions to determine medical necessity. The list below is not exhaustive and should be expanded through a combined CMS-stakeholder effort.

Section 110 – Introduction:

- First paragraph:
  - ✓ Define and provide policy intent for “benefit significantly.”
- Second paragraph:
  - ✓ Define and provide policy intent for “medical management,” “appropriate response” and “acute phase of their illness.”

Section 110.1.1 – Preadmission Screen:

- Why does this section indicate that the need for medical treatment within 48 hours of IRF admission is a criterion for IRF medical necessity when the introductory section indicated that medical management is a function of the referring inpatient hospital?

Section 101.1.2 – Post-Admission Physician Evaluation; Section 101-1.3 – Individualized Plan of Care:

- To minimize provider burden and allow for some flexibility, CMS should reconsider as a whole and reconcile the numerous proposed new timeframes related to patient assessment and patient plans of care, including the pre-admission patient evaluation, plan of care requirements for the IRF-Patient

Assessment Instrument, the physician evaluation required within 24-hours and the plan of care required within 72-hours of admission.

Section 110.2.2 – Interdisciplinary Team:

- Why does this section indicate that medical management is a criterion justifying an IRF stay when the introductory section indicates that medical management is a function of the referring inpatient hospital?

Rehabilitation Nursing:

- The proposed new Section 110 lacks a section on 24-hour rehabilitation nursing. The current criteria in Section 110.4.2 establish that IRF patients must require round-the-clock availability of a registered nurse with specialized training or experience in rehabilitation. This requirement sets IRFs apart from every other Medicare setting. CMS should retain a specific requirement for rehabilitation nursing in any future version of Section 110 to preserve this core component of IRF care.

Since a CMS internal workgroup developed the proposed Section 110 changes, CMS should provide stakeholders with citations for the evidence it used as a foundation for both these proposed manual changes and the related regulatory proposals. To expand upon the work by the internal workgroup, CMS should utilize a collaborative process involving stakeholders and other experts to prepare the next iteration. Moving forward, CMS also should explain in detail the process it uses to refine the current language, which it did not do in the proposed rule. **The resulting clarifications, supporting documentation and updated version of CMS' proposal for revising Section 110 should then be issued for public comment through formal rulemaking.**

**It is wholly inappropriate to propose narrowing the scope of services for IRFs through a Manual change.** We believe that a change of this magnitude constitutes new policy – rather than simply a clarification of existing guidelines – that must be proposed through formal rulemaking. In fact, the potential for these changes to fundamentally alter the role of IRFs within the continuum of care may be significant enough to warrant congressional oversight and input. **Therefore, we urge CMS to withdraw its proposed changes to Section 110 and the related proposed rule provisions to codify portions of Section 110.** Instead, CMS should revisit the proposed patient criteria clarifications in collaboration with the IRF field and other experts. This will provide CMS with a basis for re-proposing through formal rulemaking a clear update to Section 110, with perhaps selected portions being recommended for codification.

#### **OTHER PROPOSED IRF PPS CHANGES**

Group Therapy. We appreciate CMS' recognition that group therapy brings value to IRF patients. While we agree that IRF patients' treatment should consist primarily of individual therapy, group therapy remains an important treatment approach for many IRF patients. CMS should maintain this beneficial option for IRF patients who have the ability to learn and can be motivated by a group environment. For example, certain group therapy activities related to daily living can be very instructive. As CMS moves forward, it is essential that such changes be evidence-based, and that the agency use a transparent, collaborative process. To the extent possible, as its contractors are required to do when issuing local coverage

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determinations, CMS should provide citations for the resources it uses to develop such proposals.

Memorandum HCFAR 85-2. CMS proposes rescinding memorandum HCFAR 85-2, issued by its predecessor in 1985, which clarified the policies the agency used to determine whether an IRF admission was medically necessary, and to instead use the proposed new version of Section 110 as the sole criterion for establishing IRF medical necessity. HCFAR 85-2 is a resource commonly cited by providers during Medicare administrative appeals involving denials of IRF claims for lack of medical necessity. While we agree that Section 110 needs updating, and that it is possible that this work may eventually lead to the appropriate rescinding of HCFAR 85-2, no changes should be made until a thorough examination of the proposed Section 110 changes is conducted through formal rulemaking. Such a future evaluation of HCFAR 85-2, in light of the final outcome of the proposed Section 110 changes, also should involve stakeholder input through a Technical Expert Panel.

Medicare Advantage. We support CMS' proposal to require IRFs to conduct patient assessments for Medicare Advantage patients and include them in the 60% Rule compliance assessments used to help establish IRF designation under the Medicare program. This change recognizes that IRFs, like other post-acute providers, treat increasing numbers of Medicare Advantage patients.

If you have any questions, please feel free to contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320 or [rarchuleta@aha.org](mailto:rarchuleta@aha.org).

Sincerely,

Rick Pollack  
Executive Vice President