June 13, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1608-P  
Box 8016  
Baltimore, MD 21244-8016  

Re: FY 2015 Proposed Rule  

Dear Ms. Tavenner,

Uniform Data System for Medical Rehabilitation (UDSMR) represents more than 815 acute units and freestanding inpatient rehabilitation hospitals and is the world’s largest government-independent repository of rehabilitation outcomes and IRF-PAI data. We appreciate the opportunity to provide written comment on 42 CFR Part 412 Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015; Proposed Final Rule (CMS-1608-P), published in the Federal Register on May 7, 2014.

Comments on Specific Proposed Changes to the IRF PPS FY 2015 Final Rule:

VII. Proposed Refinements to the Presumptive Compliance Methodology

UDSMR is very concerned by the proposed refinements to the presumptive compliance methodology, especially section VII.C.2, “Other Proposed Changes to Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria.” We believe that the refinements to Appendix B are inconsistent with §412.29, “Classification criteria for payment under the inpatient rehabilitation facility prospective payment system,” specifically 42 CFR 412.29(b)(2). We also believe that these refinements will cause a significant number of IRFs to decline admission to patients that are currently eligible for IRF care, this raises a significant concern regarding decreased access to needed rehabilitation care.

There are four main areas of concern related to the proposed refinements to the presumptive compliance methodology:

1. **UDSMR believes that proposed refinements to Appendix B are inconsistent with 42 CFR 412.29(b)(2).**

   A review of the proposed refinements to Appendix B has identified numerous instances in which the addition of “excluded” etiologic diagnoses (EDs) for certain presumptively qualifying impairment group codes (IGCs) appears to potentially exclude populations of patients that would be clinically identified with a condition identified in 42 CFR 412.29(b)(2).
The following are examples of potential inconsistencies:

a. IGCs 08.11, Unilateral Hip Fracture, and 08.12, Bilateral Hip Fracture, with an ED of code 820.8, Closed fracture of unspecified part of neck of femur. While we recognize that CMS wants to exclude nonspecific codes from presumptive qualification because the code alone may not clearly represent the need for IRF care, we believe that this combination of IGC and ED still represents a hip fracture that is listed as a qualifying condition in 42 CFR 412.29(b)(2). Though it may be possible to identify a more specific code through additional physician queries or a further review of medical documentation and/or acute care X-rays, we question whether the additional burden on providers is absolutely necessary.

b. Hip and knee replacement IGCs (08.51–08.72) with various osteoarthritis ED codes (715.XX). As stated in 42 CFR 412.29(b)(2), the list of conditions includes:

   (xiii) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

   (A) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

   (B) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

   (C) The patient is age 85 or older at the time of admission to the IRF.

Furthermore, as indicated for inclusion of arthritis conditions, 42 CFR 412.29(b)(2) states, “A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.” Excluding arthritis codes as the ED for a joint replacement will cause records to become presumptively noncompliant for conditions that the patient “no longer is considered to have.”

This proposed refinement will presumptively exclude replacements without consideration for the three criteria specifically identified in 42 CFR 412.29(b)(2). The exclusions will be based on the most common causes for this procedure even though the procedure itself creates a situation in which the patient is no longer considered to have the excluded condition.

c. IGC 01.9, Other Stroke, with an ED of code 438.20, Late effects of cerebrovascular disease, hemiplegia affecting unspecified side. This ICD-9-CM code is not excluded for any other stroke IGC, but the exclusion in this instance appears to indicate that the case under review would not be identified as a presumptively compliant stroke.

d. IGC 02.22, TBI, Closed Injury, with an ED of code 850.5, Concussion with loss of consciousness of unspecified duration. The case is being coded with a concussion but appears to be excluded from presumptive compliance because the duration for which the patient lost consciousness is not specified. However, the loss of consciousness can be interpreted as not required in this case because IGC 02.22 would qualify with an ED of code 850.0, Concussion with no loss of consciousness.
e. IGC 02.21, TBI, Open Injury, with an ED of code 800.69, Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified. Similar to the exclusion noted in item (d) above, it appears that the case would be excluded from presumptive compliance because the loss of consciousness is not specified. However, the loss of consciousness can be interpreted as not required in this case because IGC 02.21 would qualify with an ED of code 800.61, Open fracture of vault of skull with cerebral laceration and contusion, with no loss of consciousness.

Because of the potential inconsistencies noted above, as well as others of a similar nature within the presumptively qualifying IGCs, we believe that the refinements to Appendix B should be removed.

2. UDSMr is concerned that the programming of the presumptive compliance methodology does not allow all conditions to be reviewed.

As detailed in “Specifications for Determining IRF ‘75% Rule’ Compliance,” dated October 1, 2007, a record fails presumptive compliance immediately upon identification of an IGC with an “excluded” ED. This implies that any patient that would otherwise presumptively qualify via age or comorbid condition would not be considered presumptively compliant. Given the proposed refinements of “excluded” EDs, we recommend that programming be updated so that all cases can be evaluated for presumptive compliance on all criteria and/or conditions prior to being designated noncompliant.


CMS needs to clarify specific etiologic diagnosis exclusions that are inconsistent between ICD-9-CM and ICD-10-CM. These inconsistencies could deny patients access to IRF care at one point in time due to a noncompliant diagnosis while allowing them to be admitted as compliant at a later date, when ICD-10-CM codes are used.

For example, noting the exclusions for replacement IGCs, ICD-9-CM code 714.0, Rheumatoid arthritis, is excluded. According to the CMS ICD-10 General Equivalence Mappings (GEMs), the corresponding ICD-10-CM code would be M06.9, Rheumatoid arthritis, unspecified. This ICD-10-CM code is not listed among the excluded EDs for replacement IGCs in the file labeled “Draft IGCs meet presumptive compliance criteria_ICD10_FY 2015 proposed rule.”

In this example, a patient who had a bilateral hip replacement secondary to rheumatoid arthritis would fail presumptive compliance based on ICD-9-CM codes in September 2015 yet pass presumptive compliance based on ICD-10-CM codes in October 2015.

UDSMr recommends that CMS review the various presumptive compliance code listings and the GEMs.

4. UDSMr projects that the overall impact of these refinements will limit patients’ access to care.

Utilizing the UDSMr® database, the refinements to the presumptive compliance methodology provided in both the FY 2014 IRF PPS final rule and the FY 2015 IRF PPS proposed rule change the presumptive compliance from pass to fail for over 15% of IRF Medicare (02 and 51) discharges from April 2013 to March 2014.
This refinement places roughly 330 IRFs, or 40% of IRFs in the UDSMR® database alone, at risk of not meeting presumptive compliance, and it creates the potential that over 180,000 patients in need of intensive rehabilitation may be faced with a lack of facilities to provide that care. Patients and their families may have to travel long distances to access the needed rehabilitative care, or the patients may have to be cared for in a less intensive rehabilitation setting that, in the long run, may not result in any savings for the entire episode of care if function is not adequately restored.

VIII. Proposed Data Collection of the Amount and Mode (Individual, Group, and Co-Treatment) of Therapy Provided in IRFs According to Occupational, Speech, and Physical Therapy Disciplines

The amount and type of therapy provided in the IRF setting are two of the significant criteria that set IRF care apart from the care provided in other post-acute venues. UDSMR appreciates CMS’s establishment of definitions for individual, group, and co-treatment therapies but sees a significant difference between treating two patients at the same time with different activities/interventions (concurrent treatment) and conducting a group treatment session in which all patients work together on a common activity and benefit from the group interaction.

In addition, we are concerned about the increased burden on clinicians who will be asked to collect data on the amount and mode of therapy provided. Adding to our concern, the proposed collection method changes the collection criteria for the weeks subsequent to the second week. This introduces the potential for confusion and error because facilities will have to monitor every patient on the unit to determine when the third week of the stay will begin.

Finally, the proposed collection of this data does not seem to provide any value to the patient; instead, it adds to the growing list of practices IRF clinicians must adhere to in order to be compliant.

We request that CMS clarify the benefits of this data and describe how it will be used. If the purpose of the data is to compare outcomes by the percentage of different therapy delivery modes each patient receives, we recommend that CMS better delineate these modes. We also suggest that CMS ask clinicians to provide a one-time summary of the hours spent in each type of therapy at the time of discharge rather than ask them to collect this data throughout the stay according to two different sets of criteria.

IX. Proposed Revision to the IRF-PAI to Add Data Item for Arthritis Conditions

Although we support CMS’s proposal to include arthritis conditions as part of inpatient rehabilitation compliance, we believe that the method proposed may create additional confusion, burden, and/or duplicative coding.

The addition of twelve fields to the IRF-PAI for coding arthritis conditions that may potentially be compliant will increase the likelihood that IRFs will have to record arthritis codes twice on the IRF-PAI: once as an impairment group, an etiologic diagnosis, or a comorbidity, and a second time in these new compliance fields. Because these codes are already available in the existing IRF-PAI data, we question the necessity of coding them again.

We also note that the removal of arthritis codes from presumptive compliance may cause additional confusion about which codes would be eligible for identification in the twelve newly available fields.
Because a “limited” medical review is to be conducted on patients with an arthritic condition, our recommendation is to ask a yes/no question as to whether the case has an arthritic condition that meets the severity and prior treatment requirements outlined in 42 CFR 412.29(b)(2). This would simplify the collection of information, eliminate the potential need for duplicative coding, and ease the technical burden during presumptive compliance determinations.

XI. Proposed Revisions and Updates to the Quality Reporting Program for IRFs

UDSMR commends CMS for its efforts in attempting to measure the quality of care in the inpatient rehabilitation industry.

We appreciate the effort involved in creating a cross-cutting measure for quality across post-acute care settings, but we emphasize that the percentage of cases in the IRF setting with the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital – Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717), National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital – Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), and Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) each have a currently reported occurrence of less that 2%. Although these conditions cause concern and are difficult to treat, reporting the percentage of patients that acquire the listed conditions does not measure quality or indicate the quality of care received.

We are also concerned that since there is such a low incidence of pressure ulcers among IRF patients that the level of expertise of the staff could lend itself to erroneous documentation resulting in poor quality data and payment penalty. A wound care specialist or additional training may not be readily available and adds additional expense.

In addition, Influenza Coverage among Healthcare Personnel (NQF #0431) requires the inclusion of all persons, regardless of clinical responsibility or patient contact, who step onto the IRF unit. We believe that this tracking will constitute a tremendous burden and that it may result in double counting between the facility and the IRF unit for employees who may just be on the IRF unit in a very limited capacity (for example, to deliver supplies). We recommend that CMS consider allowing the IRF units within a hospital to report on only those individuals who are designated as employees on the IRF unit.

UDSMR believes that any quality indicators used for the post-acute care settings must consider the overriding goal of restoring the patient’s health and rehabilitating functional deficits affected by the patient’s illness or injury, which is paramount in the episode of care.

b. All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities (NQF #2502, Review Pending)

UDSMR commends CMS for including planned readmissions criteria within this measure. This is critical for the rehabilitation industry, which serves many patients with various conditions that require multiple stays for proper rehabilitative treatment. No one disputes that an unplanned readmission to acute care is an adverse event, but the assumption that this can be avoided is problematic. Furthermore, the use of this measure as defining quality of care is faulty, especially in the context of the time-period, thirty days post-discharge. We believe readmission data should be collected and reported, as it is well-established that readmissions are costly, are disjointing to patient care, and may increase the risk that the patient will contract an infectious disease or a health-related complication. Data should be routinely assessed in an attempt to reduce acute
readmission rates, but the longer the interval of assessment post-discharge, the greater the likelihood the readmission is unrelated to the initial condition the patient had presented with to the acute hospital. For instance, if a patient is hospitalized for a stroke, discharged home, and readmitted seven days post-discharge, one can assume that the patient may have experienced another stroke and may not have received the proper care at the initial hospitalization. In contrast, another patient may have been hospitalized for a stroke and readmitted twenty-five days post-discharge for gastroenteritis; in this case, the second acute admission had nothing to do with the initial hospitalization, but the hospital will be penalized because it was unplanned and occurred within the thirty-day period, thus this will be reflected as “poor quality” of care.

The proposed data that would be compiled for this measure is a three-year average that is constantly changing, which does not allow rehabilitation facilities to compare their results to a national benchmark. If this measure is truly intended for quality improvement, the reporting must be immediate and must occur at the patient level to allow for improvement. We suggest that greater refinement of this proposed measure is needed.

**National Quality Strategy Priority: Patient Safety**

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674)

**National Quality Strategy Priority: Patient and Caregiver-Centered Care**

- Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676)

- Not Endorsed/Under Development – IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients

- Not Endorsed/Under Development – IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients

- Not Endorsed/Under Development – IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients

- Not Endorsed/Under Development – IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients

UDSmr supports functional outcome measures for IRFs, but we are concerned by the aforementioned proposed measures because they duplicate items the IRFs are currently assessing. Forcing clinicians to collect data on similar items with different rating scales will increase the burden of data collection and cause confusion. The quality of the data will be distorted, and the potential for error will be high. This change could simultaneously affect the validity of both the quality of the data and payments. We also question how measures that are not yet developed, and therefore cannot be risk-adjusted or stratified by RIC, would even be considered for implementation.

We recommend functional quality measures that are based on the FIM® instrument, which is severity-adjusted. The FIM® instrument, developed by UDSmr, plays a major role in the Research Triangle Institute’s (RTI’s) analysis of the functional outcome measures submitted for consideration. However, it is important to note that the items from the measure submitted by RTI do not come from the FIM® instrument. The RTI measures have not been extensively studied, do
not have the same longevity and experience in multiple rehabilitation venues, and have not been proven for utility or applicability in all post-acute care venues. RTI appears to have taken the approach of using IRF-PAI data, which includes the FIM® items, in many of its analyses. This leads us to suspect that RTI’s measures may lack validity data and thus may not be suitable for implementation at this time.

Additionally, the proposed measures have not demonstrated the ability to measure quality of care. Statistical analysis demonstrates a measure’s reliability (i.e., its consistency and repeatability) and construct validity (i.e., whether all the items measure the same “construct” of interest), but this speaks only to the development of the measure. The predictive validity of the proposed measures has not been ascertained. In other words, we do not know whether these measures actually do what they are intended to do. The quality of care, as measured by the functional items, has not been tested. Facilities will be asked to invest heavily in data collection, data entry, IT programming, staff training, and more without any data indicating that the measures actually assess quality.

We have previously commented on the numerous flaws in the RTI CARE demonstration project. Given the need for a tool that does not put an unnecessary burden on facilities—one that has been demonstrated to be a reliable and valid measure of functional outcome and quality—we encourage CMS to retain the use of the FIM® instrument, which has been used in IRFs, LTCHs, SNFs, and home healthcare agencies for over twenty-five years. The FIM® instrument was initially developed to measure quality and has been successfully proven to provide risk-adjusted functional quality outcomes at the facility and patient levels. For the past twelve years, the FIM® instrument has been embedded in the IRF-PAI tool, which CMS mandates for use by IRFs as part of the Inpatient Rehabilitation Facility Prospective Payment System. We believe a responsible approach by CMS would be to use the FIM® instrument, which UDSMR has offered royalty-free, for the purpose of functional quality outcomes measurement rather than to impose additional administrative costs on providers by adding new, unproven measures.

Conclusion

Because of our long-standing leadership position in the industry, we are recognized as objective evaluators of rehabilitation data used to measure outcomes and quality of care. UDSMR’s clinical and analytical staff constantly monitor our very large, representative inpatient rehabilitation database for norm deviations and proactively analyze the potential effects of external and policy influences. We are compelled to express our assessment of the potential impact this proposed rule may have on IRFs and the patients they serve. We trust that our comments will be given serious consideration by the Centers for Medicare and Medicaid Services, and we welcome the opportunity to discuss any of these concerns further.

Sincerely,

Beth Demakos, RN
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