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June 21, 2011

Dr. Donald M. Berwick
Administrator, Centers for Medicare and Medicaid Services
Room 445-G, Hubert H. Humphrey Building
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: [CMS-1349-P] RIN 0938-AQ28: Medicare Program: Inpatient Rehabilitation Facility Prospective Payment System for FY 2012. (Vol. 76, No. 83), April 29, 2011

Dear Administrator Berwick:

We are writing to comment on the April 29, 2011, publication of the Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2012: proposed rule.

UDSMR is the world's largest government-independent repository of rehabilitation outcomes and IRF-PAI data, representing more than 850 acute units and freestanding rehabilitation hospitals. Because of our longstanding leadership position in the industry, we are recognized as objective evaluators of the data used to measure the outcomes and quality of care, effectiveness, efficiency, timeliness, safety, patient-centeredness, and equity in inpatient rehabilitation.

We trust that our comments will be given serious consideration by the Centers for Medicare and Medicaid Services.

Proposed Updates to the Policies in 42 CFR Part 412

We commend CMS for putting forth the revision to allow for inpatient rehabilitation facilities (IRFs) to increase or decrease their bed size at any one time during the cost reporting period, as opposed to having to wait until the beginning of the period to add new beds or delete existing beds. We believe this revision will allow IRFs to more efficiently react to changing business conditions in their respective markets.

Quality Reporting for Inpatient Rehabilitation Hospitals

We appreciate that CMS seeks to promote higher quality and more efficient health care for Medicare beneficiaries; however, in our review of the chosen indicators, we find that they are not particularly significant in the inpatient rehabilitation setting. We base this finding upon a review of our large IRF database and our two decades of experience in assessing the meaningfulness of proposed indicators. Below, we provide our thoughts on each of the two proposed quality measures.

FY 2014 Measure #1: Healthcare Associated Infection Measure (HAI): Urinary Catheter-Associated Urinary Tract Infections (CAUTIs)

Although we agree that urinary tract infections (UTIs) are a common cause of morbidity and mortality in an inpatient acute care hospital, we question the use of such an indicator in the inpatient rehabilitation facility setting.

A recent analysis of our IRF database, which consists of nearly 70 percent of the IRF market share, shows that only 13.9 percent of 414,516 patients seen in IRFs in FY 2010 (October 2009 to September 2010) were noted to have a UTI. We identified such cases through the recording of ICD-9-CM code 599.0, Urinary tract infection, site not specified, in either item 24, Comorbid Conditions, or item 47, Complications, on the IRF-PAI. Only 15.2 percent of the 255,352 Medicare fee-for-service patients were identified as having a UTI. We do not believe there is a large underreporting bias involved.

Based on the current IRF-PAI coding system, there is no way to determine the percentage of these cases that had a UTI due to an indwelling urinary catheter (CAUTI). If we were to assume that all UTIs identified on the IRF-PAI were, in fact, CAUTIs—which we believe to be an erroneous assumption[1]—the relatively small percentage of such infections leads us to believe that this may not be the best choice as a quality indicator in the IRF setting.

When looking solely at the Complications section of the IRF-PAI, defined by CMS as conditions that occur after a patient's admission to an IRF, only 6.7 percent of all patients are coded as acquiring a UTI. Among Medicare fee-for-service patients only, 7.2 percent have a UTI coded in the Complications section. Because we cannot assume that all these cases are CAUTIs, we feel that this small number of new UTIs in the IRF setting reflects that the indicator chosen by CMS is not the most appropriate choice.

In addition, it is unclear how the data will be managed so that CMS can determine the setting in which the CAUTI occurred. Specifically, it is unclear how CMS will distinguish between a CAUTI that began in the acute care hospital unit and continued through the admission of the patient to the IRF setting and a CAUTI that a patient acquired in the IRF. Unless the reporting system provides a clear method of distinguishing the setting in which the initial infection occurred, this quality indicator may reflect poorly on the IRF setting for an infection acquired prior to an IRF admission.

For example, a patient with a Foley catheter may be identified as having a CAUTI in the acute care setting the day prior to discharge to an IRF setting. Upon admission to the IRF setting, the patient will still be catheterized and will test positive for a UTI, therefore being identified as having a CAUTI in the IRF setting. However, the initial infection occurred in the acute care hospital, not the IRF. It is not clear how CMS will distinguish between such infections and those that are truly acquired in the IRF.

By adopting this proposed quality indicator, CMS is requiring that IRFs submit CAUTI data via a new data submission process separate from the required IRF-PAI submission process. This new

[1] We stress that this assumption is most likely invalid. The distribution of UTIs identified in our analysis spanned all rehabilitation impairment categories, even those in which urinary catheters would be least likely, such as osteoarthritis cases. Among Medicare fee-for-service osteoarthritis cases, 14.4 percent were identified as having a UTI.

process will require training time and additional FTE time each month for IRF employees. Although CMS estimates that the additional cost for each IRF will be small ($186.14 for the training and $1,247.70 each year for tracking the infections), the additional fees would not be required if CMS were to choose quality indicators already available as part of the IRF-PAI. We will speak to our suggestions below.

FY 2014 Measure #2: Percent of Patients with Pressure Ulcers That Are New or Worsened

Although we agree that new or worsened pressure ulcers are a significant problem in the nursing home arena, we question the use of such an indicator in the IRF setting.

A recent analysis of our IRF database shows that only 0.7 percent of 414,516 IRF patients in all payer sources had an ICD-9-CM code for pressure ulcer recorded in item 47, Complications, on the IRF-PAI in FY 2010 (October 2009 to September 2010).[2] The codes recorded in item 47 are conditions, as defined by *The IRF-PAI Training Manual,* that began after the rehabilitation stay started. Therefore, a new pressure ulcer was recorded for only 0.7 percent of the FY 2010 patients in our database. The percentage is the same among Medicare fee-for-service beneficiaries: 0.7 percent, or 1,844 people. Although an underreporting bias may exist and some facilities may record new pressure ulcers in item 24, Comorbid Conditions, rather than item 47, we do not believe that the number of new pressure ulcers in an IRF setting will be much larger than this data shows.

It is difficult to determine the number of patients with worsening pressure ulcers from IRF-PAI data. However, the data shows that only 4.9 percent of all patients have a pressure ulcer recorded in the Comorbidity section of the IRF-PAI. Assuming that these pressure ulcers exist at admission—most likely an invalid assumption—it means that less than 5 percent of all IRF patients may be included in the quality indicator of worsened pressure ulcers. We do not believe that this indicator affects enough of the IRF population to be used as a gauge of quality in this setting.

We also note that the new pressure ulcer section of the proposed IRF-PAI comes directly from the post-acute assessment instrument known as the Continuity Assessment Record and Evaluation (CARE) tool, which is currently under development through a CMS demonstration. However, the agency has not yet reported the demonstration findings to Congress. We recommend that utilizing sections from an unproven tool is premature, and we believe that CMS should not incorporate any elements of the CARE tool into the regulatory process until the demonstration findings have been reported to Congress and the agency has received and processed Congressional and public comment on the draft CARE tool.

Recommendations

After careful consideration, we have concluded that the proposed measures do not adequately address the rehabilitative objectives for patients seen in an IRF setting. The recommended measures do not allow facilities to substantiate the quality of their restorative care program to CMS. The proposed measures address processes that most likely occurred in the acute setting.

The emphasis on restoration or maintenance of function affected by the patient's illness or injury is paramount in the episode of care. Yet the proposed measures don't adequately capture

[2] We used ICD-9-CM codes 707.0x, Pressure ulcer, to identify these cases.

function or functional improvement. We believe that the IRF patient would be better off if the quality measures established the burden of care, the functional improvement achieved, and the percentage of patients returned to their community setting.

Our most highly effective and respected instrument, the FIM® instrument, is used across the post-acute care continuum. The FIM® instrument has a high overall internal consistency, can capture significant functional gains during rehabilitation, has high discriminative capabilities for rehabilitation patients, and is an indicator of the burden of caring for the patient. Measures of effectiveness, efficiency, timeliness, resource use, and safety are an integral part of the FIM® instrument. CMS already endorses the FIM® instrument as part of the IRF-PAI used to capture functional health in patients seen at IRFs. Utilizing the FIM® instrument as part of your quality indicator set would not create any additional costs to IRFs because IRFs are already transmitting the current IRF-PAI form to CMS.

Quality indicators used in the IRF setting must account for the overriding goal of inpatient rehabilitation: decreasing the burden of care among individuals requiring rehabilitation, thereby allowing patients to return to their community settings. The FIM® instrument is a highly researched tool with several hundred peer-reviewed journal publications that can yield a definitive burden of care for each patient or the amount of time required by a helper for each patient in the home setting.

In particular, we suggest three specific quality indicators:

1. Length-of-stay (LOS) efficiency (FIM® points gained per day—higher is better)
2. Percentage discharged to community (higher is better)
3. Percentage discharged to acute care (lower is better)

The first two indicators address the following objective put forth by CMS: "The measures should address the needs of the individual including improved functional status and achievement of successful return to the community post-discharge." The discharge-to-acute-care indicator may be used as a proxy for a readmission measure.

We suggest that LOS efficiency be utilized as a quality measure at the facility level and the patient level.

- **At the facility level:** Each facility will have its own LOS efficiency average (the average of all the facility's patients' LOS efficiency), and each facility will have its own specific LOS efficiency goal. This goal would be calculated using CMG adjustment, a procedure that UDSMR uses in its reporting set. This procedure is completed using an indirect standardization method that produces a facility-specific, CMG-adjusted LOS efficiency based on national data—essentially, it shows what the LOS efficiency at the national level would be if the nation had the facility's specific CMG distribution. This creates a true apples-to-apples comparison of a facility's outcome to a national expected outcome.
- **At the patient level:** A CMG-based goal could be utilized for each patient, and the patient either meets or exceeds the goal, or falls short of it. The percentage of the facility's patients that meet or exceed the CMG-based LOS efficiency goal could be the quality indicator.

UDSMR also can use an indirect standardization method that weights national CMG-specific values by facility-specific CMG proportions, thereby risk-adjusting the expectation of a discharge-to-acute-care percentage and a discharge-to-community percentage. This process creates facility-specific goals. CMG-adjusted outcomes show each facility's expected value based on the case mix and severity mix of its patients. This is how the nation's outcomes and patient characteristics would look if the nation had that facility's unique case mix and severity mix. We would be happy to share additional details on this procedure with CMS.

The Joint Commission is already using our three recommended quality indicators as part of the ORYX® initiative, its performance measurement initiative for IRFs.

Conclusions

We applaud CMS's efforts to implement an IRF quality reporting program, but we believe that the proposed measures of healthcare-associated infections and pressure ulcers are not as meaningful to the inpatient rehabilitation population as measures that address improved functional status and the achievement of a successful post-discharge return to the community. An in-depth review of the data available to UDSMR reveals that the two proposed measures affect a small percentage of the IRF population and therefore may not be the best indicators of quality for IRFs. We strongly urge CMS to consider quality indicators that are more significant to patients seen in the IRF setting, such as those we have suggested in this letter: LOS efficiency, the percentage of patients discharged to a community setting, and the percentage of patients discharged to an acute care hospital.

In closing, we are grateful for the opportunity to provide comments to CMS on the proposed rule. We welcome the opportunity to work with the government to provide unbiased research regarding the impact of federal regulations on IRFs. If you have any questions about these comments or require additional information, please call us at 716-817-7800.

Sincerely,

Carl V. Granger, MD
Executive Director, UDSMR

CC: The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services