June 20, 2011

Donald Berwick, M.D., M.P.P.
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1349-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically

RE: Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2012 (CMS-1349-P)

Dear Dr. Berwick:

On behalf of the over 78,000 member physical therapists, physical therapists assistants, and students of physical therapy of the American Physical Therapy Association (APTA), I would like to submit the following comments regarding the Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) for Federal Fiscal Year (FY) 2012 proposed rule published in the Federal Register on April 29, 2011. Physical therapy is an integral service within the IRF setting, and therefore we are concerned about the proposed changes.

Physical therapy is the profession devoted to restoration, maintenance, and promotion of optimal physical function. Physical therapists are licensed health care professionals who diagnose and manage movement dysfunction and enhance physical and functional status in all age populations. Physical therapists help patients maintain health by preventing further deterioration or future illness. In the inpatient rehabilitation facility (IRF) setting, physical therapy is critical to patients with a number of conditions.

Productivity Adjustment

In the Proposed Rule, CMS proposes to implement a productivity adjustment to the annual update which was required under a provision in the Affordable Care Act. The productivity adjustment is forecasted to result in a 1.2% reduction in the market basket update. While APTA recognizes that this productivity adjustment is mandated by law, we are concerned about the negative impact it could have on IRF providers and the beneficiaries they serve. We recommend that CMS take steps to mitigate any negative effects caused by this reduction.
**Proposed Revisions to Enhance Consistency Between the IRF Coverage and Payment Requirements**

In the rule, CMS proposes to enhance the consistency in the requirements for IRFs by incorporating information about coverage and patient admission in the IRF setting into the rehabilitation hospital/unit classification framework. Specifically, CMS would amend the regulations at 42 CFR section 412.29 (d) to require each prospective patient’s preadmission screening be reviewed and approved by a rehabilitation physician prior to the patient’s admission to the IRF. In addition, in section 412.29(e) CMS adds language that ensures patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally. Lastly, CMS proposes to add “discharge planning” to the coordinated interdisciplinary team approach requirement.

The requirements for physician review and approval of the preadmission screening and the 3 face-to-face visits were established in the FY 2010 IRF Rule. If the IRF does not meet these criteria, a determination could be made that the patient should not have been admitted to the IRF setting and the services could potentially be considered non-covered. APTA is concerned with CMS’s proposal to place these coverage and admission criteria in the section of the regulations that pertains to classification criteria for the IRF settings. It is possible that CMS and its contractors could decide to use denials of individual claims based on coverage and payment admission criteria to declassify an IRF facility.

This issue was raised in the FY 2010 Proposed IRF Rule, which initially combined the classification and coverage criteria. In the final 2010 IRF rule, CMS agreed with commenters who had raised concerns, and separated the criteria and distinguished between the requirements to determine whether a service is “reasonable and necessary” and the requirements for a facility to be classified as an IRF setting. Specifically, CMS stated: “We do not intend for any IRF to lose its classification status because an individual patient does not meet the IRF coverage criteria.” The Medicare coverage criteria are based on section 1862(a)(1)(A) of the Social Security Act that requires services to be “reasonable and necessary” while the classification criteria are based on a different section of the law. When the Inpatient Prospective Payment System was established in the 1980’s, Congress recognized that certain providers, such as long term care hospitals, rehabilitation hospitals, and children’s hospitals, needed to be exempt from the system due to longer lengths of stay and different types of patients. These exclusion criteria were established separate and apart from any payment and coverage criteria.

APTA recommends that CMS withdraw the proposal to combine the coverage and IRF admissions requirements with the inpatient rehabilitation hospital/unit classification requirements. This would be consistent with CMS’s decision in the 2010 rulemaking. If CMS decides to combine these criteria in the final rule, we request that CMS clarify that CMS may not use the physician review and approval of the preadmission screening and the 3 face-to-face visit requirements as a basis upon which to remove a facilities classification as an IRF. CMS should clarify that classification is determined based on facility level compliance by the IRF; not individual cases related to coverage.
Quality Measures

Section 3004 (b) of the Act requires CMS to implement a quality reporting program for IRFs that would result in a 2% reduction in its payment increase factor in 2014 if the IRF does not report quality data. APTA applauds the Centers for Medicare & Medicaid Services (CMS) for including quality measures in the IRF PPS FY 2012 proposed rule. APTA strongly supports initiatives to improve the safety and quality of patient care. We are committed to encouraging physical therapists to participate in quality improvement and patient safety programs that are implemented through the Affordable Care Act (ACA).

The IRF PPS FY 2012 proposed regulations detail three quality measures for FY 2014: 1.) Catheter Associated Urinary Tract Infections (CAUTI), 2.) Pressure Ulcers that are New or Have Worsened, and 3.) 30-day Comprehensive All-Cause Risk-Standardized Readmission Measure. The APTA has concerns about each of the measures individually in addition to several overarching concerns, which are discussed in detail below.

Global Quality Measure Concerns

Linking quality measures to payment is a new concept to the IRF setting and poses inherent challenges to the selection and implementation of measures. As noted in the proposed rules, two of the measures, CAUTI’s and pressure ulcers, have been endorsed in other settings and, although CMS has stated and does intend to seek endorsement of these measures in the IRF setting, there is a strong likelihood that setting specific issues may arise in the application of these and other measures.

One such issue that the APTA feels is an overarching theme is the risk adjustment methodology for the IRF setting. There is a general lack of research around risk adjustment methodologies in this setting; although we do recognize that much work has been done in the acute care setting. Quality measures used in a system must be risk adjusted to account for factors, such as patient severity of illness, comorbidities, functional limitations, age, gender, cognitive status, availability of a caregiver, and prognosis that may influence the outcomes of care. Risk adjustment is important to ensure that providers are not deterred from treating patients who might lower their quality scores. IRFs should not be penalized under a value-based purchasing program for treating more complex patients with many serious comorbidities. We believe that more work needs to be done to identify a more effective risk adjustment model. Complex interactions of a variety of potential variables in the recovery of IRF patients’ need to be investigated and better understood in order to appropriately adjust for variations in outcomes in this setting.

Another overarching issue that the APTA would like to highlight is that of sample size. As you are aware, sample size considerations apply to a variety of publicly reported measures. In reviewing the proposed pressure ulcer measure, as it is currently defined for the nursing home short-stay setting, facilities with fewer than 20 residents are excluded due to small sample size. We would anticipate bed capacity and volume issues in the IRF setting. We would point out that IRF’s vary in size, with IRF’s that are affiliated with and housed in acute care hospitals generally being smaller than free standing IRF’s. In fact, in reviewing the publicly reported IRF data files (FY 2012) we note that of the 1,147 facilities with reported volume data, the median number of
discharges for an IRF was only 231 Medicare beneficiaries a year. If an IRF with a small number of beds has one or two patients with a pressure ulcer that is new or worsened or a CAUTI, that IRF’s quality score could be significantly impacted. CMS should ensure that IRFs are not inappropriately penalized for having a small number of beds.

**Individual Measure Issues**

Measure one, CAUTI’s, was originally created for use in the inpatient ICU setting and we recognize that this measure is NQF endorsed (#0138) and well established in the inpatient setting and believe that it is appropriate as a measure in the IRF setting. In reviewing the current measure specifications we are pleased to see that only indwelling catheters are included in the patient population for this measure, versus “straight in-and-out” catheters which are frequently utilized by spinal cord injury (SCI) patients who often require extensive IRF services. In addition, the measure specifications also include a “transfer rule exception”, defined as transfers within an inpatient facility or transfers to a new facility. The transfer rule would exclude patients who develop a CAUTI within 48 hours of transfer to the IRF setting; we feel that this is an important provision.

The pressure ulcer measure was originally created and endorsed (NQF #0678) for use in short-stay nursing home patients. Physical therapists are integral members of the multidisciplinary team of providers involved in the prevention of pressure ulcer development, performing comprehensive skin risk assessment and creating a plan of care to address identified areas of skin risk. Physical therapists also play a primary role in the evaluation and treatment of pressure ulcers including cleansing, debridement, dressing, compression and pressure relief of wounds. Again, as with the previous measure, APTA applauds its inclusion in the proposed rule and feels that it is applicable to the IRF setting. In reviewing the measurement specifications however, we do have some concerns.

The pressure ulcer measure and documentation for this measure is currently done utilizing the MDS 3.0 assessment, which is specific to the nursing home setting. The current proposal is to modify the IRF PAI to include the pressure ulcer measure elements that are on the MDS 3.0. We are pleased to see that the MDS 3.0 utilizes clear ulcer staging definitions consistent with the Wound Ostomy and Continence Nurses Society (WOCN) and the National Pressure Ulcer Advisory Panel (NPUAP). The most recent data published with the release of MDS 3.0 suggests that ulcer rating agreement between assessors was very good to excellent5. Upon further examination of the assessment form however, we are concerned about documentation of multiple ulcers of the same stage as the form allows for a count of multiple ulcers of a specific stage, but does not allow for sizes of multiple ulcers of the same stage (see figure 1). In addition, within the skin condition section there is no place to document the location of pressure ulcers; we would suggest the use of a body diagram to better communicate and document pressure ulcer location. We believe that consistent documentation of location of ulcers is essential, especially when tracking new or worsening ulcers over the course of an episode of care and throughout multiple transitions across settings. We believe that this speaks directly to the continuity of care issues that health care reform is attempting to address. In addition, should CMS choose to move to another tool such as the CARE tool, we would reiterate these concerns as we do not feel the
documentation for pressure ulcers on that form, in its current version, would provide clinicians with a tool that allows for concise and consistent documentation.

The MDS 3.0 form does allow for separate documentation of pressure ulcers that are present on admission (POA), utilizing a 48 hour time frame in the documentation of these ulcers. APTA does have concerns around the identification of pressure ulcers on admissions as it is possible for a patient to have a pressure ulcer that is deep below the surface which does not appear on the surface of the skin until several days after admission to the IRF. The latent appearance of these ulcers may create a situation in which the IRF becomes responsible for a “new” ulcer, when in fact the pressure ulcer was truly POA. For example:

Scenario 1
Patient X is an African American male, admitted to an IRF following an acute stroke. The staff closely inspects the skin for a pressure ulcer, realizing the risk given the patient’s immobility and sensory changes following the stroke. The staff does not note significant skin discoloration, an indication of a possible stage 1 pressure ulcer. On day 3 of his admission, a stage 2 ulcer is discovered over his sacrum. Based on the depth of the ulcer and severity of ulceration, the staff recognizes that the ulcer was likely POA, but the changes in the skin discoloration were absent on evaluation. Should this pressure ulcer be attributed to the IRF?

It is important to ensure that the IRF setting is not held responsible for the existence of pressure ulcers that occurred prior to admission to the IRF. The IRF should not be penalized for these ulcers.

In addition to our concerns around the ability to consistently document the location and staging of wounds, we are also troubled about the risk adjustment for this measure in the IRF setting. The current measure, as it applied to the short-stay nursing home patient includes five resident level covariates in its risk adjustment: healed pressure ulcers, require limited or more assistance in bed, have bowel and incontinence at least once a week, diabetes or peripheral vascular disease, or low body mass index. Although we recognize that some and possibly all of these factors may influence the development of ulcers in the IRF, it is also possible that this set is not inclusive of all risk factors in the IRF setting and does not appropriately account for other patient complexities.

CMS also proposes future use of a comprehensive all-cause risk-standardized readmission measure, which APTA recognizes as an important measure of transitions in care and a cornerstone of the Partnership for Patients program. Currently, there are NQF endorsed 30-day condition specific risk-standardized readmission measures that are being utilized in the inpatient setting (AMI, HF, PNE, and PCI), but the all-cause risk-standardized readmission measure would be a new measure that has not yet been implemented in any setting. As approximately 20% of all Medicare patients are readmitted within 30 days of an acute care discharge and readmissions account for an estimated $15 billion in health care spending, this is an issue that demands immediate attention.
Strategies to improve transitions in care from the acute care setting have been documented and include a variety of interventions as outlined recently from patient engagement and education, to follow-up calls to more complex multidisciplinary interventions in high-risk populations. Physical therapists are an essential member of the health care team facilitating transitions in care for patients. Physical therapists, in conjunction with other members of the health care team, assist in discharge planning, including the determination of the most appropriate setting for a patient taking into account their medical status, functional status, prognosis and other factors, such as their home environment and family support. The need for a coordinated effort across the continuum of care is imperative to good outcomes for patients.

APTA feels that risk adjustment will be essential for this metric. In addition, we would also advocate for exclusion criteria to ensure that only preventable readmissions are measured. Exclusions may include such events as planned hospital procedural admissions, planned hospital chemotherapeutic admissions, and trauma. Focusing on preventable readmissions will allow resources and efforts to be directed at true failures in transitions.

Our remaining concern with the readmissions measure is with respect to measure attribution. As we see this measure being implemented in this and likely other additional settings, attribution for the success or failure of these transitions must be clearly defined as a patient could conceivably be transitioned through a variety of care settings within a 30 day period prior to a readmission. In that event, will the last facility be held accountable? See the below illustrative examples.

Scenario 1
Patient X is admitted to an acute care hospital on June 1, following an acute stroke. He is stabilized and transferred to an inpatient rehabilitation hospital on June 5. He is discharged to home on June 20. He is readmitted to the acute care setting on June 25. Is this readmission attributed to the IRF?

Scenario 2
In the same scenario, if on June 20 after discharge from IRF, the patient is seen by the home health agency and then on June 29, is readmitted to the acute care setting, is the home health agency accountable for the readmission?

Again we support the implementation of the readmission measure in the IRF setting but emphasize that we feel strongly that both measure risk adjustment and attribution must be resolved in order to make this measure meaningful.

Future Considerations

The IRF PPS proposed regulations also include a listing of prospective quality measures to be considered for future inclusion in the quality program. The APTA applauds the consideration of falls with injury, medication errors and functional outcome measures. Falls and medication safety are quality issues that cost the health system billions of dollars annually. Both of these quality metrics are currently reported in the inpatient acute hospital setting; incorporation into the IRF setting would align and imbed these quality metrics across settings allowing practitioners to address these issues throughout the entire episode of care.
In future years, CMS plans to consider implementing additional quality measurements, using the standardized assessment instrument CARE (Continuity Assessment Record, and Evaluation) as a primary data source, that could be used across all post-acute care sites to compare on quality measures related to patient safety, patient care goals, functional outcomes, hospital acquired conditions, acute care hospitalization, care coordination, and bundled care processes.

APTA does not believe that the CARE tool will accurately document medical severity, functional status and other factors related to outcomes. The questions lack sensitivity and therefore the type of information about the patient needed to measure outcomes and severity is not being collected by this instrument. We are concerns about using the CARE tool to measure functional outcomes without having accurate measures of these factors. To do so could create access problems for Medicare beneficiaries. APTA also has concerns that the accuracy of the data will differ depending on the individual who completes the CARE tool. Although a nurse may be able to complete a majority of the tool, the Functional Status section (VI) should be completed by rehabilitation professionals from the appropriate discipline. An individual who is not specifically educated and trained as a physical therapist would probably include different answers to the functional assessment items than a therapist.

While APTA strongly supports the use of functional outcome measures in the future in the IRF and other settings, we believe that a considerable amount of additional work needs to be done to perfect tools to ensure that measures are accurate.

**Public Reporting**

Under section 1886(j)(7)(E) of the Act the Secretary is required to establish procedures for making data submitted by IRFs under the IRF quality reporting program available to the public. In the rule, CMS proposes to establish procedures to make the data available, including a procedure that will ensure that the IRF has the opportunity to review the data to be made public prior to the data being made public. We support CMS’s proposal to allow the IRF the opportunity to preview data and measures and urge CMS to ensure that IRFs have a reasonable period of time for review in order to access and gather supporting information to correct errors, discrepancies, and other concerns. The IRF should have an opportunity to submit these corrections and appeals prior to the information being posted on the website.

**Conclusion**

Despite APTA’s concerns in the measurement and reporting of quality outcomes in the IRF setting, we reiterate that we do believe strongly that quality measures will be a vehicle for improving patient safety and outcomes. In addition, as the CMS quality programs become more aligned with initiatives and measures in a variety of care settings we are hopeful that we can better address the needs of patients across the continuum of care. In closing, APTA thanks CMS for the opportunity to provide comments on the Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) for Federal Fiscal Year (FY) 2012 proposed rule. As stated earlier, physical therapists are committed to providing care to Medicare beneficiaries in the IRF setting by promoting restoration and optimal physical function of these patients. APTA looks
forward to working with the CMS in the development and identification of quality measures for implementation in the IRF setting that will promote improved quality in health care. If you have any questions, please feel free to contact Heather Smith, Associate Director of Quality Initiatives, at 703-706-3140 or heathersmith@apta.org.

Sincerely,

[Signature]

R. Scott Ward, PT, PhD
President

RSW:hls
Figure 1. Excerpt from MDS 3.0 Section M Skin Conditions


   http://proquest.umi.com/pqdweb?did=1598541391&Fmt=7&clientId=76575&RQT=309&VName=PQD.
