

August 31, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1633-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Proposed Rule: Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs: Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System (CMS-1633-P)

Dear Mr. Slavitt:

On behalf of the American Physical Therapy Association (APTA) and its 90,000 member physical therapists, physical therapist assistants, and students of physical therapy, I appreciate the opportunity to submit the following comments regarding the Medicare Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems (OPPS) proposed rule for Calendar Year (CY) 2016. Physical therapy is an integral service in the hospital setting, and therefore we are very interested in the proposed changes and their effect on physical therapy.

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 outpatient hospitals and ambulatory surgical centers, physical therapists deliver medically necessary services to patients with varying medical diagnoses and conditions that are generally reimbursed under the Medicare Physician Fee Schedule (MPFS), but outside of reimbursement, physical therapists are subject to a number of the policies that are included under the OPPS.

As CMS moves forward with finalizing the policies set forth in this proposed rule, we strongly urge the agency to consider the following comments.

Two-Midnight Rule

In the proposed rule, CMS requests feedback regarding proposed changes to the two-midnight rule under CMS's short inpatient hospital stay policy. This request follows the promulgation of rulemaking in FY 2014 intended to address concerns about hospitals' use of observation stays and short inpatient stays. In that rulemaking CMS stated that a hospital inpatient admission will be considered reasonable and necessary if a physician (or other qualified practitioner) orders the admission based on the expectation that (1) the beneficiary's length of stay will exceed two midnights, or 2) the beneficiary requires an inpatient-only procedure specified under section 419.22 of the regulations.

In the proposed rule, CMS acknowledges that stakeholder concerns about limitations on physician judgment on expected duration of medically necessary hospital care have some merit. Thus, CMS proposes to change its medical review policy for short hospital stays to provide for Part A payment for inpatient hospital stays of less than two midnights. Under the rare and unusual circumstances exceptions, CMS proposes that if the admitting physician expects a patient to require hospital care for only a limited period of time that does not exceed two midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. However, CMS indicates that these shorter stays would generally involve at least one overnight, though CMS recognizes that the patient could be unexpectedly discharged or transferred to another hospital. Thus, whether payment under Part A for these "one-midnight stays" is appropriate would be determined on a case-by-case basis, taking into account the following factors (among others):

- Severity of patient signs and symptoms;
- Medical predictability of something adverse happening to the patient; and
- Need for diagnostic studies that are appropriately outpatient.

CMS indicates that inpatient admissions of less than one midnight will be prioritized for medical review.

APTA commends CMS for considering changes in its policies regarding short-stay inpatient admissions, particularly the recognition of the importance of clinical judgment regarding inpatient admissions. APTA has significant concerns with the two-midnight policy implemented in the FY 2014 IPPS/LTCH PPS final rule. The two-midnight policy is an arbitrary time-based approach that disregards the role of clinical judgment. APTA believes that the decision to admit a patient for an inpatient stay should be made by the physician and interdisciplinary team, including the physical therapist, and based solely on the clinical condition of the patient. Setting an arbitrary two-midnight rule can be harmful to patients, particularly those who are short stay with acute illnesses. Therefore, we strongly urge CMS and its contractors to recognize that an inpatient admission should be based on patient characteristics and allow the clinician to make appropriate decisions regarding inpatient admissions based on the unique clinical condition of the patient.

Medical Reviews of Inpatient Hospital Admission

CMS also announced that effective no later than October 1, 2015, QIO contractors will conduct reviews of short inpatient stays rather than MACs. This change will occur regardless of whether the proposals described above are finalized. CMS believes QIOs are well suited to conduct these short-stay medical reviews by virtue of their statutory mandate and experience.

QIOs will review a sample of post-payment claims to determine the medical appropriateness of the inpatient admission. Under the revised policy, QIOs will refer claims denials to MACs for payment adjustment, and provider appeals will be adjudicated under section 1869 of the Act. QIOs will educate hospitals about claims denials under the two-midnight policies as well as collaborate with hospitals on development of quality improvement frameworks. Claims from hospitals with a pattern of high denial rates, consistently failing to adhere to the two-midnight rule, or failing to improve performance after QIO intervention will be referred to RACs. CMS notes that RACs may resume patient status reviews for claims with admissions dates of October 1, 2015, or later, and the agency indicates that RACs will conduct these reviews focused on providers with high denial rates that are referred by the QIOs.

APTA appreciates CMS's proposal to use QIOs to perform reviews of the appropriateness of inpatient admissions. It will be important for CMS to ensure that there is communication and coordination among the QIOs and MACs regarding inpatient admissions. However, there have been significant communication problems between MACs and other contractors involved in review and these communication challenges have resulted in inappropriate denials and recoupment requests.

We remain concerned about the involvement of the RACs in the review process, even for providers with high denial rates. Any attempt to address the issues of the two-midnight policy or short inpatient hospital stays must be combined with meaningful reform and management of the RAC program to be successful. Therefore, we continue to urge CMS to make the following changes to the RAC program:

- Pay RACs through a cost-based contract instead of on a contingency fee structure. The current payment method incentivizes RACs to deny claims.
- When a denial is overturned on appeal, impose a penalty on RACs.
- Eliminate the one-year filing limit to rebill Part B claims when a Part A claim for hospital inpatient admission is reopened and denied as not reasonable and necessary. CMS estimated in 2012 that 75% of inpatient admissions denied by RACs would not be eligible to rebill due to the one-year filing limit. The hospital should be able to submit a subsequent Part B claim for services provided within 180 days of a revised or final determination.

Observation Status

In addition to the changes proposed in this rule, we recommend that CMS revise other policies to alleviate the problems associated with the two-midnight rule and observation status. We believe that beneficiaries requiring short inpatient hospital stays and those placed on observation status should

be considered inpatients with regard to application of certain policies, and cost-sharing obligations should be calculated under Medicare Part A.

We strongly support the following beneficiary cost-sharing protections that MedPAC recommended in its June 2015 report:

- Expand the three-day hospital stay requirement for skilled nursing facility (SNF) coverage to allow up to two outpatient observation days to count toward meeting the criterion; and
- Require beneficiary notification of outpatient observation status.

Observation Status and Therapy Services

Due to the confusion that exists around inpatient admission criteria, APTA continues to be concerned about therapy provided on an inpatient basis that is later denied by auditors and rebilled under Part B. Policies such as the therapy cap and functional-limitation reporting were intended for patients receiving therapy in an outpatient setting and are nonsensical in their application to inpatient or observation stays. It is critical that hospitals have a clear understanding of inpatient or observation status due to the inability to retroactively achieve compliance with the Part B outpatient therapy requirements. Therefore, we recommend that CMS establish an exception to the outpatient therapy cap and functional limitation reporting requirements for observation status patients.

Per statutory requirements, CMS places an annual per beneficiary Medicare financial limitation on outpatient therapy services (“therapy cap”). Each year this annual amount is updated, and the 2015 therapy cap amount is \$1940 for physical therapy and speech language pathology services combined. There is a separate \$1940 amount allotted for occupational therapy services in 2015. In previous years, outpatient hospitals were exempt from the therapy cap, but the Middle Class Tax Relief and Job Creation Act of 2012³ applied the financial limitation to the outpatient hospital setting from October 1, 2012 until December 31, 2012. The application of the therapy cap to hospitals was extended until March 31, 2015, by the Protecting Access to Medicare Act of 2014,⁴ and through December 31, 2017 by the Medicare Reform Law and CHIP Reauthorization Act of 2015 (MACRA) legislation. As part of the therapy cap requirements for 2015, outpatient therapy providers are required to append a KX modifier to claims over the \$1940 limit to receive an automatic exception. For claims exceeding \$3700, Congress has mandated a targeted manual medical review process in which providers are required to send specific documentation to Medicare auditors for review and approval of claims for therapy services. This process is in effect until December 31, 2017.

APTA strongly recommends that CMS consider the effect that payment for inpatient hospital services under Medicare Part B, such as during the observation period, may have on calculations of the therapy cap. Due to risk of denials when classifying patients for an inpatient stay, there are instances where a patient’s entire stay in the hospital, which sometimes spans as much 16 days, is classified as an outpatient hospital stay. Therefore, all physical therapy services received during this period are counted toward the cap. We believe that this is unfair to the patient as it may limit access to physical therapy in the outpatient setting, when in fact these services should have been billed as inpatient services. Further, acute care hospital systems are designed for

compliance with IPPS Part A requirements. It is administratively burdensome and requires extensive staff and financial resources to implement new processes and electronic software to manage Part B cases. Moreover, the additional cost of compliance with Additional Documentation Requests (ADRs) for manual medical review and other audit requests can be untenable.

In addition, the Middle Class Tax Relief Act mandated that CMS, as of July 1, 2013, collect information on the claim forms regarding the beneficiaries function and condition. All practice settings that provide outpatient therapy services must include this information. Specifically, the policy applies to PT, OT, and SLP services provided in hospitals, critical access hospitals, skilled nursing facilities, CORFs, rehabilitation agencies, home health agencies (when the beneficiary is not under a home health plan of care), and in private offices of therapists, physicians and non-physician practitioners. Under the functional limitation reporting requirement for outpatient therapy services, nonpayable G-codes and modifiers are mandated on the claim forms to capture data on the beneficiary's functional limitations at the outset of the therapy episode, a minimum of every 10th visit and discharge. By collecting data on beneficiary function over an episode of therapy services, CMS hopes to better understand the beneficiary population that uses therapy services and how their functional limitations change as a result of therapy services. As stated in the Middle Class Tax Relief Act, the purpose of the claims-based data collection strategy is “to assist in reforming the Medicare payment system for outpatient therapy services.” Clearly, inpatient stay and observation status patients do not serve this purpose to inform data that should assist in reforming outpatient therapy payment.

To the contrary, APTA believes that the data gained from observation status patients do not exemplify the typical outpatient therapy episode and may make data analysis more difficult, as these patients may be impossible to distinguish through the current claims-based data collection methodology. Therefore, the data gained from observation status patients will likely not contribute to or benefit the reform of the outpatient therapy service benefit. Likewise, the functional data from the Medicare Part A patients who are rebilled as Part B patients would not be relevant in reform of an outpatient therapy payment system given the fact that these would primarily be short stay patients. For this reason, APTA strongly urges CMS to exempt observation status patients and Medicare Part A patients rebilled under the Part B benefit from reporting functional limitation data. CMS could easily establish this exemption with the use of a modifier when billing. This same modifier could be affixed to therapy services billed under observation status as well as when rebilled under Part B for denied admissions.

APTA strongly believes that hospitals should be appropriately reimbursed for the services they provide during the observation period and the inpatient short stay. The decision to admit should be based solely on the clinical condition of the patient and in which setting their medical needs can be safely and effectively addressed. Therefore, we recommend that CMS take the necessary steps to ensure that payments are accurately aligned in tandem with setting parameters for short stays, observation stays, and the creation of an assessment and intervention stay.

Skin Procedures and APC (5051)

As part of a comprehensive review of the structure of the APCs and procedure code assignments, CMS examined the APCs that describe skin procedures, and proposes in this rule to restructure all skin-related procedure APC assignments by combining the debridement and skin procedure APCs. We are concerned that some of the new APC for skin procedures may result in groupings that are too broad and therefore do not appropriately reflect resource distinctions.

In the proposed rule, CMS assigns the Q1 status indicator to low-frequency ultrasound therapy (97610) (“LFU” Therapy) which is included in APC 5051. We are concerned that this would inappropriately characterize this independent service as an “ancillary service” and bundle payment for LFU Therapy with S, T, and V services. We urge CMS to maintain the status indicator “T” that was previously assigned to low-frequency ultrasound therapy (97610). CMS guidance has made clear that Status Indicator Q1 is assigned only to ancillary services, which include “minor diagnostic tests and procedures that are often performed with a primary service.” CPT Code 97610 is a primary service, not an ancillary service. The CPT descriptor of the service includes not only the LFU Therapy itself, but also wound assessment and instructions for ongoing care, encompassing the full scope of required practitioner services related to providing LFU Therapy. In addition, guidance from the AMA in the June 2014 CPT Assistant clearly describes this service as a standalone procedure. The clinical vignette included therein notes that the service described by 97610 includes “careful wound assessment, measurement, and photography” before cleansing the wound and surrounding tissue. A qualified health care professional must be in “continuous attendance” during the provision of LFU Therapy, and at its conclusion, performs an additional assessment of the wound bed and surrounding tissue and applies an appropriate dressing.

In addition to the clinical guidance that supports that LFU therapy is not an ancillary services, the CMS data show that the Geometric Mean Cost (“GMC”) criteria established by CMS to define “ancillary services” does not support assignment to status indicator Q1. CMS limited the initial set of APCs containing conditionally packaged services to those APCs with a proposed GMC of less than or equal to \$100 on the theory that low-cost procedures are more likely to be ancillary than higher cost procedures. GMC cost data for CY 2015 indicated that the GMC of APC 0012 (to which LFU was placed) exceeded this \$100 threshold.

Similarly, traditional negative pressure wound therapy (97605 and 97606) have been placed in the newly established APC 5051 and assigned a status indicator Q1. We urge CMS to amend the status indicator so that these HCPCS codes are not assigned a Q1 status indicator, which we believe inappropriate categorizes these services as ancillary.

Conclusion

Once again, we thank CMS for the opportunity to comment on these policy changes. If you have any questions regarding our comments, please contact Gayle Lee, Senior Director Health

Finance and Quality at (703) 706-8549 or gaylelee@apta.org. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Sharon L. Dunn". The signature is written in a cursive, flowing style.

Sharon L. Dunn, PT, PhD, OCS
President

PAR: grl