September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted Electronically

RE: CMS–1613–P Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data

Dear Administrator Tavenner:

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 respectfully submit the following comments regarding the Medicare Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems (OPPS) proposed rule for Calendar Year (CY) 2015. 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 typically 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. In summation, APTA recommends the following:

I. CMS remove physical therapy from the potential services packaged in the proposed comprehensive Ambulatory Payment Classifications. Further, CMS should clarify its definition of the perioperative period for purposes of this policy to ensure that only the appropriate services are included as adjunctive services in the comprehensive Ambulatory Payment Classification.

II. CMS remove the direct supervision requirement for therapy services that are paid under the OPPS.

III. CMS collect data regarding cost and utilization of the proposed packaged ancillary services and the proposed policy’s effect on patient outcomes. CMS should publicly report this detailed cost and utilization data as well as the impact on outcomes to better inform stakeholders on the impact of the policy.

IV. CMS ensure adequate payment for prosthetic supplies under the OPPS so that patients have access to these medically necessary items in the hospital setting. We also recommend that CMS collect and share data regarding cost, utilization, and the effect on patient outcomes.

V. CMS finalize the proposal to remove the physician certification requirement for inpatient admissions with the exception of long stays and outlier cases. APTA agrees that the admission order, medical record, and progress notes will contain sufficient information to support the medical necessity of the inpatient admission without a separate requirement of an additional, formal physician certification.
I. Implementation of Comprehensive APCs

Clarify CMS Definition of Perioperative Period for C-APCs

In this rule, CMS proposes to implement the policy for comprehensive Ambulatory Payment Classifications (C-APCs) that was finalized in the CY 2014 OPPS final rule.¹ The policy bundles payment for the most costly medical device implantation procedures under the OPPS. CMS defines the bundle of services assigned to 28 C-APCs as the provision of the primary service along with all adjunctive services and supplies provided to support the delivery of the primary service, which would result in a single Medicare payment and a single beneficiary copayment under the OPPS.

APTA is generally supportive of this policy, which seeks to incentivize the most efficient and collaborative delivery of care for these C-APCs by the health care team. We are concerned about the effect this proposal may have on necessary physical therapy services that are provided in conjunction with these 28 C-APCs and any C-APCs that may be added in the future. Therefore, we strongly urge CMS to more clearly delineate the therapy services that are excluded from the C-APC payment.

CMS and APTA agree that therapy services offered under a plan of care following one of these device-dependent procedures would be separately reimbursable under Section 1834(k) of the Social Security Act and subject to the MPFS regulations. However, CMS finalized the policy in CY 2014 which states that therapy services provided in the perioperative period for these C-APCs will be considered adjunctive services for the purposes of the bundled payment. We are concerned about the lack of clarity regarding what will constitute therapy within the “perioperative period,” and we believe CMS should clarify its definition of what will be considered an adjunctive service “in the perioperative period.”

In the CY 2014 OPPS final rule, perioperative period is defined as the time “during the delivery of [the] comprehensive service that is bracketed by the OPD registration to initiate the service and the OPD discharge at the conclusion of the service.”² In response to our concerns regarding the CY 2014 OPPS proposed rule, CMS stated the following in the CY 2014 OPPS final rule:

“…the comprehensive procedure includes only the perioperative period, a brief period of time immediately before and immediately

¹ 78 FR 74826, December 10, 2013.
² Id. at 74866.
following the procedure. We would not expect that an evaluation performed immediately following the surgery would establish the beneficiary’s needs for rehabilitation because the beneficiary is still under the influence of the completed primary surgical procedure. Rather, services reported with therapy codes during that brief time period may represent interventions to promote breathing and ambulation, traditional post-operative nursing services, or may represent assessments to provide the surgeon with specific clinical information relative to the immediate effects of the surgery. We would not expect therapy assessments or rehabilitative therapy until after the patient has recovered from the immediate effects of the procedure and associated anesthesia. With respect to the statement that it may be beneficial to increase the beneficiary’s endurance prior to surgery, we agree with the commenter that this can be a desirable and necessary service, but we would not expect that therapists are routinely increasing “mobility, function and endurance” in the hour or two immediately before the surgery.”

In its response to our comments, CMS states that the perioperative period ends “after the patient has recovered from the immediate effects of the procedure and associated anesthesia.” However, as noted above, the final rule also states that the perioperative period ends at “the OPD discharge at the conclusion of the service.” These two timeframes – the discharge at the conclusion of the service and the recovery from immediate effects and anesthesia from the procedure – are not always the same. In fact, many patients who undergo, for example, a total knee replacement surgery, require therapy services in the perioperative period which is generally post-op day 1. On post-op day 1, the physical therapist evaluates the patient and based on the evaluation develops a plan of care that starts that same day with bed mobility, moving from the bed to a sitting position and often includes standing at the side of the bed and/or gait training with a walker depending on the patient’s response to treatment. On post-op day 2, the patient requires therapeutic exercise, gait training, and functional mobility as well as patient and caregiver education to ensure safe transition to the home or the next level of care. The therapy care does not end after hospital discharge, and this is the episode of care that CMS seems to recognize in its policy. Post-hospital discharge is when patients require and can tolerate more intense therapy services to increase the knee range of motion to a functional level so activities such as stair climbing, moving from a sitting to standing position safely, ability to perform activities of daily living, safe transfers in and out of a car can be performed. In addition, physical therapy evaluations and instruction may also occur prior to the surgery to determine the plan of care for the patient with the goals of increasing mobility,

3 Id. at 74867.
function, and endurance. Often, this may be done during the patient’s pre-op visit with their surgeon in the hospital.

Perioperative generally refers to the three phases of surgery: preoperative, intraoperative, and postoperative. The goal of perioperative care is to provide better conditions for patients before operation, during operation, and after operation. Physical therapy is often essential during this time. Early mobilization of the patient immediately following surgery is integral to the patient’s overall recovery as it improves the health care of the patient by preventing complications associated with bed rest and increases functional ability which allows the patient to transition to a less expensive setting.

Specifically regarding arthroplasty or implantation with prosthesis—one of the 28 C-APCs labeled under Level V Musculoskeletal—physical therapists are an essential member of the health care team who provide evaluation and treatment for the total joint replacement population. Physical therapists provide services to these patients in a variety of treatment settings with the goals of improving muscle performance, activity and participation, and promoting physical activity to decrease the risk of subsequent disability. Physical therapy interventions are designed to restore, maintain, and promote maximal physical function for people with total joint replacements. For example, physical therapist interventions for individuals with total knee replacements aim to reduce pain; increase and maximize joint mobility, muscle strength, flexibility, and aerobic capacity; and prevent functional loss. Interventions may include: therapeutic exercise; manual therapy; functional training in self-care, home management, and work; physical agent modalities; and use of orthotic, assistive, adaptive, protective, and supportive devices, combined with patient-related instruction/education. Evidence clearly demonstrates the importance of these physical therapy services in the post-op hospital setting.

APTA contends that such services should be separately reimbursed under the MPFS when provided independently by the physical therapists, as we are not wholly convinced that a single prospective payment will be sufficient to account for the extensive services that the physical therapist provides during the perioperative period. For example, if the classification is limited to adjunctive services provided in the perioperative period, important time-intensive services that require the skills and clinical judgment of the therapist, such as an extensive evaluation of the patient that would aid in the creation of a post-operative plan of care followed by intensive interventions, may not be

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adequately accounted for or reimbursed. Therefore, we request that CMS clarify its definition of the perioperative period for purposes of this policy to ensure that only the appropriate services are included as adjunctive services in the C-APC.

**Direct Physician Supervision Unnecessary for Adjunctive Therapy Services**

Further, in the CY 2009 OPPS/ASC final rule, CMS established a requirement of direct physician supervision for all hospital outpatient therapeutic services covered by the OPPS.\(^5\) As a result, for therapy services considered adjunctive services under the comprehensive APCs and paid under the OPPS, direct physician supervision would be required. We do not believe that direct physician supervision for adjunctive therapy services is appropriate. Considering the collaborative, team approach to physical therapy, we contend that direct physician supervision of physical therapy services is inappropriate. It has been recognized and codified that physical therapy is a separate benefit, and physical therapists are qualified to practice without direct physician supervision. Congress has defined physical therapy services without requiring physician direct supervision in §1861(p) of the Social Security Act. The provision allows outpatient physical therapy services to be furnished in a physical therapy private practice office, outpatient hospital, rehabilitation agency, and other outpatient settings independent physician supervision.

Specifically, the physical therapy benefit is defined under Social Security Act §1861(p), which states:

“The term “outpatient physical therapy services” means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—who is under the care of a physician, and with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician or by a qualified physical therapist and is periodically reviewed by a physician”

The Medicare Benefits Policy Manual\(^6\) states that:

“Therapy services have their own benefit under § 1861 of the Social Security Act and shall be covered when provided according to the

\(^5\) 73 FR 68702-68704, November 18, 2008.
\(^6\) Pub. 100-02, chapter 15, § 230.5
standards and conditions of the benefits described in Medicare manuals.”\(^7\)

Therefore, CMS has clearly established bright line standards that distinguish skilled therapy services from other services rendered and has created a distinct benefit when these services are performed by a qualified physical therapist.

CMS further defines “physical therapy services” as, “those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical functions and health status.”\(^8\)

The example given of an adjunctive therapy service under the previous CY 2014 proposed rule of a therapist providing detailed documentation of patient weakness would require an evaluation of the patient using the clinical judgment and skills of the therapist to determine and document impairments, functional limitations, and disabilities.\(^9\) As a result, adjunctive services such as the example given by CMS would meet the criteria of a physical therapy benefit, and physical therapists are qualified to perform those services independent of physician supervision. Under Medicare regulations, only physician certification of the therapy plan of care is required, and certification of the facility plan of care, including the physical therapy component, is satisfactory. Therefore, direct supervision of the adjunctive therapy services included in the C-APC would be unnecessary. APTA recommends that CMS make this distinction in the CY 2015 OPPS final rule.

II. Proposed Packaging Policies

Ancillary Services

In addition, CMS proposes to conditionally package certain services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. Specifically, in the CY 2015 proposed rule, CMS proposes to package the costs of selected APCs that represent ancillary services with a proposed geometric mean cost of less than or equal to $100, including the following APCs that often involve physical therapists:

- Level I Debridement & Destruction (APC 0012)
- Manipulation Therapy (APC 0060)
- Level I Pulmonary Treatment (APC 0077)

\(^7\) References 1861(s)(2)(A), 42 C.F.R. 410.10(b), and 42 C.F.R. 410.26
\(^8\) Pub. 100-02, chapter 15, § 230.1
\(^9\) 78 FR 43559, July 19, 2013.
- Level I Nerve and Muscle Services (APC 0215)
- Level I Pulmonary Tests (APC 0367)

Again, APTA is supportive of the policy to package payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. However, we have concerns about the effect of this policy on access to necessary services, patient outcomes, as well as readmissions if important therapy services are not provided. Thus, we urge CMS to collect data regarding cost and utilization of these services and the effect on patient outcomes. Further, in the interest of transparency, we recommend that CMS publicly report this detailed cost and utilization data as well as the impact on outcomes to better inform stakeholders on the impact of the policy. This will allow CMS and stakeholders the opportunity to collaborate and ultimately achieve patient-centered payment policies based on outcomes.

Prosthetic Supplies

Payment under the OPPS currently includes implantable DME, implantable prosthetics, and medical and surgical supplies. However, under 42 CFR 419.22(j), prosthetic supplies are currently excluded from payment under the OPPS and are paid under the DMEPOS Fee Schedule, even when provided in the hospital outpatient department.

The clinical judgment and expertise of the physical therapist is often critical in the hospital outpatient department to select a particular prosthetic item for the patient. This clinical decision is based on the therapist’s evaluation of the individual patient. The physical therapist also ensures that the item is appropriate to achieve the patient’s functional goals, is properly sized and fitted for the patient, and that the patient and/or caregiver is educated in the proper use of the item. As such, this policy could have large effects on our members and their patients.

It is essential that the patient have timely access to these items because the prosthetic may be necessary to support an injured body part or facilitate safe mobility or post-surgical recovery. Therefore, APTA urges CMS to ensure adequate payment for these items under the OPPS so that patients have access to medically necessary prosthetic supplies in the hospital setting. We again recommend that CMS collect and share data regarding cost, utilization, and the effect on patient outcomes.
III. Proposed Revision of the Requirements for Physician Certification of Hospital Inpatient Services

Under Section 1814(a)(3) of the Social Security, Medicare Part A payment will only be made for such services “which are furnished over a period of time, [if] a physician certifies that such service are required to be given on an inpatient basis.” In current regulations, CMS interprets the statute’s requirement of a physician certification for inpatient hospital services furnished “over a period of time” to apply to all inpatient admissions. In addition to the certification requirement, there must be an order from a physician or other qualified practitioner for all inpatient admissions.10

After considering public comments highlighting the administrative burden of the certification requirement, CMS now proposes to require the physician certification requirement only for long-stay cases of 20 days or longer and outlier cases. In most cases, CMS believes that the admission order, medical record, and progress notes will contain sufficient information to support the medical necessity of the inpatient admission without a separate requirement of an additional, formal physician certification.

This change is significant to ensure that expedient care is provided, and APTA fully supports this change in policy. The admission order requirements are far less burdensome with regard to format and content requirements. In fact, in many hospitals, the order can be made verbally if authenticated by the ordering practitioner. As such, the order requires less time from the physician or other qualified practitioner to complete as opposed to the physician certification. For patients who require expedited care, this time savings can be significant. For example, prior to this proposed change, a patient who required physical therapy services to improve function may often have to wait to receive those medically necessary services until the physician certification was completed. The time saved with the elimination of the physician certification requirement will allow physical therapists to initiate the plan of care immediately upon the inpatient order and patients will be able to receive the right care during the optimal timeframe.

Conclusion

APTA appreciates the opportunity to comment on the CY 2015 Medicare Hospital Outpatient Prospective Payment System proposed rule, and we look forward to working with the agency to craft patient-centered reimbursement policies that reflect quality health care for all Medicare beneficiaries. If you have any questions regarding our comments, please contact Gillian Leene,

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10 42 CFR § 412.3
Senior Regulatory Affairs Specialist, at (703) 706-3189 or gillianleene@apta.org.

Sincerely,

[Signature]

Paul Rockar, Jr. PT, DPT, MS
President

PR: grl