August 31, 2009

Charlene Frizzera  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1413-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW.  
Washington, DC 20201

Re: CMS 1414-P: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates

Dear Ms. Frizzera,

On behalf of our 72,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule regarding “Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates,” published in the July 20, 2009 Federal Register. APTA’s goal is to foster advancements in physical therapy practice, research, and education. The mission of APTA is to further the profession’s role in the prevention, diagnosis, and treatment of movement dysfunctions and the enhancement of the physical health and functional abilities of members of the public.

In this proposed rule, CMS includes provisions related to implementation of cardiac and pulmonary rehabilitation programs as required by the Medicare Improvements for Patients and Providers Act (MIPPA) which could have implications for physical therapists. Our comments primarily address the provisions of the proposal regarding cardiac and pulmonary rehabilitation. In addition, we request that CMS clarify that direct physician supervision of outpatient physical, occupational and speech-language pathology therapy services furnished in the outpatient hospital department is not a Medicare requirement.

**Cardiac Rehabilitation**

In the MIPPA legislation, Congress defines cardiac rehabilitation as a physician-supervised program that furnishes the following: physician-prescribed exercise; cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment; outcomes assessment; and other items or services as determined by the Secretary under certain conditions. These items and services must be furnished in
in a physician’s office, in a hospital on an outpatient basis, or in other settings determined appropriate by the Secretary. A physician must be immediately available and accessible for medical consultation and emergencies at all times.

CMS issued a final revised national coverage decision (NCD) for cardiac rehabilitation on March 22, 2006. In the NCD, CMS concluded that cardiac rehabilitation is reasonable and necessary following: acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, heart valve repair or replacement, percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting, and heart or heart lung transplant.

CMS defines Phase II cardiac rehabilitation as a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. Phase II refers to outpatient, medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate electrocardiographic monitoring.

CMS mandates that the program must be under the direct supervision of a physician, whether provided in the office or outpatient hospital setting. In addition, all services performed by non-physician practitioners in the Phase II Cardiac Rehabilitation Program, per the current NCD, must be “incident to”. To be covered as “incident to” the physicians’ services, the services and supplies must be furnished as an integral, although incidental, part of the physician’s professional service in the course of diagnosis or treatment of an illness or injury.

In the proposed rule, CMS states that an intensive cardiac rehabilitation (ICR) program must provide the same items and services as delineated in the legislation and the current NCD for cardiac rehabilitation programs.

APTA commends CMS in its efforts to further define cardiac rehabilitation under Medicare and clearly articulate the distinction between the current cardiac rehabilitation program and the establishment of an intensive cardiac rehabilitation program. As CMS explores ways to further identify these programs under the NCD process, APTA urges the Agency to consider the following information in regards to the provision of physical therapy to patients with cardiac conditions.

Physical therapists are an integral part of a cardiac rehabilitation program as they provide individualized exercise techniques, and promote increased functionality for patients. Specifically, physical therapists evaluate clients’ needs by gathering data on medical history and other relevant factors such as health habits and co-morbidities, and then identify risk factors and behaviors that may impede optimal functioning.

In the case of patients recovering from a heart valve replacement, angioplasty, bypass, heart failure or a heart or lung transplant, physical therapists will develop a plan of care that is tailored for these specific conditions. This plan is established in collaboration with the patient, caregivers, and other health care practitioners and is based on data from the patient's history, systems review, specific tests and measures (including body mass analysis and endurance testing), diagnosis and co-morbidities.
In designing the plan of care, the physical therapist analyzes and integrates the clinical implications of the severity, complexity, and acuity of the pathology/pathophysiology (disease, disorder, or condition), the impairment, functional limitation, and the disabilities to establish the prognosis and predictions about the likelihood of achieving anticipated goals, expected outcomes, and optimal function in the patient's daily life. Appropriate follow up ensures patient safety and adaptation as physical status, caregivers, tasks demand, and environment change.

Physical therapists serve in a variety of capacities within a cardiac rehabilitation program. They may be staff of the cardiac rehabilitation program who supervise monitored exercise and provide physical therapy care to individuals with additional functional needs. Physical therapists also may be staff in a physical therapy (or other physical rehabilitation) department who consult with the cardiac rehabilitation program and provide physical therapy services to its patients when needs are identified.

Upon entry into the cardiac rehabilitation program, a staff member will perform an intake assessment on a new patient that is referred to the service. These intake processes identify functional limitations that may interfere with participation in the cardiac rehabilitation program. These limitations may be a result of the cardiovascular dysfunction, or may be in addition to the cardiovascular dysfunction and may include a musculoskeletal, neuromuscular or integumentary impairment.

When such a limitation is detected, the cardiac rehabilitation program would use its own staff PT, or refer to a PT in another department, to obtain a complete physical therapy evaluation. From this evaluation a physical therapy plan of care would be developed that may include:

a) modifications required to safely participate in the cardiac rehabilitation program (including staff education about these modifications);

b) physical therapy treatments (distinct from cardiac rehabilitation services) to address limitations in posture, balance, activities of daily living, transfer, gait, stair climbing, as well as requirements for energy conservation, pain management and skin and wound care.

The physical therapy evaluation and plan of care would be performed separately from the normal cardiac rehabilitation program.

Considering the independent nature in which physical therapy is performed, we contend that direct physician supervision of physical therapy services is not necessary in the cardiac rehabilitation setting, when the physical therapist is delivering treatment that clearly meets the criteria of a physical therapy benefit as defined by CMS. It has been recognized and codified that physical therapy is a separate benefit, and physical therapists are qualified to perform certain services independent of physician direct 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 without physician direct 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 Manual1 states that:

“Therapy services have their own benefit under § 1861 of the Social Security Act and shall be covered when provided according to the standards and conditions of the benefits described in Medicare manuals.”

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.

The Medicare Claims Processing Manual offers the following guidance in the contrast of skilled therapy services and non-therapy (unskilled) services:

“Outpatient rehabilitation therapy” refers to skilled therapy services, requiring the skills of qualified therapists, performed for restorative purposes and generally involving ongoing treatments. In contrast, a non-therapy service (usually a one-time service) is a service performed by non-therapist practitioners, without rehabilitative plan or goals, e.g., application of a surface (Transcutaneous) neurostimulator – 64550, and biofeedback training by any modality – 90901 may be non-therapy services when not done by therapists. When performed by therapists, these are therapy services.3

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.” 4

Secondly, we contend that, there are often secondary co-morbidities that exist in these patient populations that are treated by the physical therapist that should be conducted in accordance with Medicare laws that govern the physical therapy benefit. We believe that a number of services offered by the physical therapist to patients in cardiac rehabilitation programs are “skilled

1 Pub. 100.2, chapter 15, § 230.5
2 References 1861(s)(2)(A), 42 C.F.R. 410.10(b), and 42 C.F.R. 410.26
3 Pub. 100-04, chapter 5, §20.B
4 Pub. 100-02, chapter 15, § 230.1
physical therapy services” and should be billed under the physical medicine and rehabilitation 97000 series of codes.

Therefore, we strongly urge CMS in the final OPPS rule and any implementing instructions that will accompany the final national coverage decision on cardiac rehabilitation/ICR to state that: “skilled therapy services rendered in the cardiac rehabilitation setting by a qualified physical therapist as defined in 42 CFR §484.4 and Section 230.1 B of Chapter 15 (Covered Medical and Other Health Services) of the Medicare Benefit Policy Manual should be billed and conducted in accordance with the Social Security Act §1861(p) and Section 220.2 of Chapter 15 (Covered Medical and Other Health Services) of the Medicare Benefits Manual.”

Pulmonary Rehabilitation

In the MIPPA legislation, pulmonary rehabilitation is defined as a physician supervised program that furnishes all of the following items and services: physician prescribed exercise; education or training; psychosocial assessment; outcomes assessment; and other items and services determined appropriate by the Secretary. These items and services must be provided in physicians’ offices, hospital outpatient settings, and other settings determined appropriate by the Secretary. A physician must be immediately accessible for medical consultation and medical emergencies at all times.

Physical therapists are an integral part of a pulmonary rehabilitation program. Following an extensive examination of the patient, physical therapists develop appropriate plans of care and provide individualized exercise techniques that promote increased functionality for patients in their home and community environment.

Physical therapists are uniquely qualified, by virtue of the content of professional curricula, to address impairments, limitations, and disabilities related to changes in pulmonary, musculoskeletal and neuromuscular system function that are either the source or the consequence of respiratory dysfunction. The Guide to Physical Therapist Practice describes multiple interventions performed by physical therapists for patients with pulmonary disorders and validates that physical therapists have the requisite education and skills to facilitate management of patients with chronic pulmonary conditions.

In fact, CMS has an established history of recognizing the importance of physical therapy services to patients with pulmonary and respiratory conditions. In the 2002 Physician Fee Schedule, CMS created three new G codes to clarify coding of respiratory therapy services. In its reasoning for the creation of these codes, CMS stated that,

“These codes are designed to provide more specific information about the services being delivered. The availability of codes for services to improve respiratory function will make billing of CPT codes 97000-97799 inappropriate for professionals involved in treating respiratory conditions, unless these services

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6 2002 Physician Fee Schedule Update (66 FR 55246)
are delivered by physical and occupational therapists and meet the other requirements for physical and occupational therapy services.”

CMS has also reiterated this rationale in the Medicare Claims Processing manual. The manual states,

“Some HCPCS/CPT codes that are not on the list of therapy services should not be billed with a modifier. For example, outpatient non-rehabilitation HCPCS codes G0237, G0238, and G0239 should be billed without therapy modifiers. These HCPCS codes describe services for the improvement of respiratory function and may represent either "incident to" services or respiratory therapy services that may be appropriately billed in the CORF setting. When the services described by these G-codes are provided by physical therapists (PTs) or occupational therapists (OTs) treating respiratory conditions, they are considered therapy services and must meet the other conditions for physical and occupational therapy. The PT or OT would use the appropriate HCPCS/CPT code(s) in the 97000 – 97799 series and the corresponding therapy modifier, GP or GO, must be used.”

As evidenced above, CMS has clearly articulated the importance of physical therapy to this patient population and has recognized the importance of these services being delivered by a physical therapist under the physical therapy benefit. We strongly urge CMS to continue this longstanding policy and clearly state in the final rule and subsequent national coverage decision that this pulmonary rehabilitation coverage policy does not in any manner inhibit Medicare beneficiaries access to physical therapy as established under the Social Security Act § 1861 (p) when being treated for COPD or other pulmonary disorders.

Medical Necessity of Physical Therapy Services to Patients with Pulmonary Dysfunction Pursuant to § 1862(1) of the Social Security Act

The Social Security Act §1862(1) states in part, “payment may not be made under [Medicare] part A or part B for any expenses incurred for items or services – which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Specifically the Medicare Benefits Policy Manual states:

“To be considered reasonable and necessary the following conditions must each be met:

• The services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient’s condition. Acceptable practices for therapy services are found in:

  o Medicare manuals,

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7 Medicare Claims Processing Manual, chapter 5, section 20.A
Contractors Local Coverage Determinations, and
Guidelines and literature of the professions of physical therapy, occupational therapy
and speech-language pathology.

The services shall be of such a level of complexity and sophistication or the condition of the
patient shall be such that the services required can be safely and effectively performed only by a
qualified therapist, or in the case of physical therapy and occupational therapy by or under the
supervision of a qualified therapist. Services that do not require the performance or supervision
of a therapist are not skilled and are not considered reasonable or necessary therapy services,
even if they are performed or supervised by a qualified professional.

If the contractor determines the services furnished were of a type that could have been safely
and effectively performed only by or under the supervision of such a qualified professional, it
shall presume that such services were properly supervised when required. However, this
presumption is rebuttable, and, if in the course of processing claims it finds that services are not
being furnished under proper supervision, it shall deny the claim and bring this matter to the
attention of the Division of Survey and Certification of the Regional Office.

The skills of a therapist are needed to manage and periodically re-evaluate the appropriateness
of a maintenance program as described below.

While a beneficiary’s particular medical condition is a valid factor in deciding if skilled
therapy services are needed, a beneficiary’s diagnosis or prognosis should never be the sole
factor in deciding that a service is or is not skilled. The key issue is whether the skills of a
qualified therapist are needed to treat the illness or injury, or whether the services can be
carried out by non-skilled personnel.

There must be an expectation that the patient’s condition will improve significantly in a
reasonable (and generally predictable) period of time, or the services must be necessary for the
establishment of a safe and effective maintenance program required in connection with a specific
disease state. In the case of a progressive degenerative disease, service may be intermittently
necessary to determine the need for assistive equipment and/or establish a program to maximize
function; and

The amount, frequency, and duration of the services must be reasonable under accepted
standards of practice. The contractor shall consult local professionals or the state or national
therapy associations in the development of any utilization guidelines.”

We assert that physical therapy services delivered to patients with COPD and other pulmonary
disorders satisfies the above illustrated requirements. The following clinical examples illustrate
how the services delivered by a qualified physical therapist to patients with COPD and other
pulmonary disorders fall within the reasonable and necessary criteria established by Medicare
and further demonstrate the justification for billing these services under the physical therapy
benefit:
Clinical Scenario 1:

Patient A is a 66 year old female with past medical history of smoking; diagnosed with COPD 5 years ago and currently on 2 L O2 via nasal cannula. She has frequent bouts of anxiety attacks due to shortness of breath and inability to catch her breath and has made 4-5 visits to ER for these attacks. Pulmonary functions reveal FEV 1.0 of 22% predicted. Patient A lives w/son that helps with transportation, grocery shopping, meals, and some functional activities but she has progressively decreased her out of home activities due to shortness of breath and anxiety attacks. Patient A has 3 grandchildren that she cares for in her home, but has found she is unable to do this lately due to her shortness of breath, anxiety and her limited functional abilities.

Patient A’s physician has referred her to pulmonary rehabilitation to improve her function, increase her independence in ADLs and hopefully decrease the panic and anxiety attacks that are resulting in frequent ER visits.

Upon initial evaluation, the patient was found to have a very poor tolerance to all of the assessments requiring frequent rests to do any activities. She became short of breath raising her arms over her head, is unable to put anything away in cabinets, and was only able to lift a two pound weight with two repetitions before stopping. With her lower extremities, she could lift a three pound weight two repetitions. She could not get up and down from a chair more than once. Her timed up and go test revealed severe endurance impairment, and when she walked for two minutes her SpO2 dropped to 83 (from 93). When standing on one leg she lost her balance immediately. She reported 3 out of 0-4 on the activity scales meaning she had moderate to severe dyspnea with all activities of daily living. She was given a St. Georges Respiratory Questionnaire to complete which was scaled as having very poor quality of life (total score, activity score and dyspnea score).

Her evaluation revealed:
- Poor aerobic capacity and endurance
- Poor strength in upper extremities and lower extremities
- Poor muscle endurance in upper extremities and lower extremities
- Moderate to severe dyspnea with all activities of daily living
- Poor quality of life
- Poor standing balance making her at increased risk of falling
- High anxiety due to dyspnea and frequent ER visits
- Poor self management skills for her disease
- Poor knowledge of her disease

This patient has pulmonary impairments that would benefit from physical therapy due to the functional impairments including poor balance, poor muscle strength and endurance, and poor performance of activities of daily living. The physical therapy plan of care would include skilled physical therapy interventions that are above and beyond the exercise included in the proposed pulmonary rehabilitation program.

Physical Therapy Plan of Care would include:
a) Customized exercise program to increase cardiopulmonary reserve
b) Therapeutic exercise focusing on balance and strengthening of torso to improve posture and improve ability to perform ADLs
c) Airway clearance measures, if required
d) Home exercise program instruction to promote patient self-management
e) Instruction in energy conservation training and breathing retraining
f) All activities will be monitored with heart rate (HR), blood pressure (BP) and Pulse Oximetry (Ps02) and dyspnea level

Clinical Scenario 2:

Patient B is a 68 year old male, former smoker who has been on oxygen since his last hospital admission. Patient cannot go out in the community since the hospital discharge as he requires a wheeled walker and O2 and is unable to handle both. Patient has difficulty getting up and down from chairs and in and out of the car, and can only walk very short distances. His FEV 1.0 is 38% predicted.

Patient B used to travel with his wife and enjoyed seeing different places on cruises but is now unable to do so. He is restricted to his house as his wife still works and has no one to take him anywhere, nor help him at home.

His physician ordered pulmonary rehabilitation as Patient B used to be independent. The physician feels that Patient B might be able to be independent without an assistive device and portable O2 with exercise training and strengthening exercises.

This patient has severe pulmonary impairments as well as functional impairments that would benefit from a multidiscipline PR program along with physical therapy that would address his getting up and down from chairs, transfers into cars as well as improve his aerobic capacity. Individuals with wheeled walkers and with inability to transfer such as Patient B may also have balance issues and high risk for falling which needs to be addressed in his rehab program as well.

Interventions provided by a physical therapist would include:

- Therapeutic exercise including balance training, postural exercises, thoracic muscle, back muscle and proximal muscle strengthening.
- Instruction in optimal airway clearance techniques and symptom and disease management monitoring
- Functional training in self-care and home management including energy conservation techniques and breathing exercises when performing ADLs.
- Progression to minimal assistive device walking with the goal of walking unassisted on all surfaces, if possible
- Aerobic training on a treadmill and arm and leg bicycles to improve exercise endurance
- Individualized strengthening program based upon this patient’s poor exercise tolerance.
- Incorporation of breathing exercises during all activities
In summary, there is nothing to suggest that by providing the proposed pulmonary rehabilitation benefit under Medicare, the Congress intended in any way to reduce existing Medicare coverage for physical therapy services. In addition, in the September 25, 2007 Decision Memo for Pulmonary Rehabilitation (CAG-00356N), CMS recognizes the importance of physical therapy services to patients with pulmonary conditions and stated that these services should be continued to be billed under the Medicare physical therapy benefit. Specifically, CMS explicitly directed Medicare contractors “to allow coverage for components of pulmonary rehabilitation, including services furnished by physical therapists under section 1861(p) of the Social Security Act.” Therefore, we strongly urge CMS to reiterate this language in the Medicare Fee Schedule final rule and any subsequent correspondence associated with a national coverage decision on pulmonary rehabilitation.

Physician Supervision of Diagnostic and Therapeutic Services

In the August 2000 final rule which established the OPPS, CMS implemented a provision requiring direct physician supervision of diagnostic and therapeutic services in the outpatient hospital setting. In this CY 2000 rulemaking CMS stated that because physical and occupational therapy services are a separate benefit under the Social Security Act established under section 1861(s)(2)(D) and further defined under section 1861(p), direct supervision of outpatient physical therapy, occupational therapy, and speech-language pathologic services by a physician is not required in the outpatient hospital setting. In the 2009 and 2010 OPPS rules, CMS has attempted to provide additional guidance and clarification as to the physician supervision requirements for therapeutic and diagnostic services. Unfortunately this has created some confusion in the provider community. We request that CMS make it explicit in the final 2010 OPPS rule that this direct supervision requirement is not applicable to the provision of physical and occupational therapy services in the outpatient hospital setting.

Specifically, §1861(s)(2)(D) and §1861 (p) of the Social Security Act establish physical therapy as a separate benefit without requiring direct supervision by a physician. Section 1861(p) states, in part:

“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....”

In the OPPS final rule issued on April 7, 2000 (65 Fed. Reg 18525). CMS explicitly stated in its response to public comments regarding whether the direct physician supervision requirements applied to physical and occupational therapy services that this level of supervision was not required.

Specifically, on page 18525 of the rule, the following language is included in the preamble text:
Comment: One commenter asked that we provide an exception to the direct supervision requirement in the case of physical therapy services. The commenter questioned why therapists who furnish the same services in a provider-based entity that they would furnish in an independent practice should be subject to direct physician supervision in one setting and not the other.

Response: The provision on coverage for outpatient physical therapy and occupational therapy services does not require that they be “incident to” physician services (see section 1861(s)(2)(D) of the Act). Therefore, there is no need to exempt them from the supervision requirement for outpatient hospital services incident to a physician service that is furnished at a provider-based entity. We therefore made no change in the final regulation based on this comment.

We request that CMS make an affirmative statement in the final rule that the requirement of direct physician supervision of therapeutic services is not applicable to physical and occupational therapy in outpatient hospitals.

We appreciate the opportunity to provide information on the role of physical therapists in the delivery of care to Medicare beneficiaries in cardiac and pulmonary rehabilitation programs. If you have questions about our comments or need additional information, please contact Sarah Nicholls-Sharp, Assistant Director for Payment Policy and Advocacy, at 703-706-3189 or sarahnicholls-sharp@apta.org.

Sincerely,

R. Scott Ward, PT, PhD
President

RSW:sns