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September 2, 2014

Marilynn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1614-P
Mail Stop
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: The American Physical Therapy Associations Response to CMS-Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule

Submitted Electronically

Dear Administrator Tavenner:

On behalf of our 90,000 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 "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Equipment, Prosthetics, Orthotics and Supplies published in the July 11, 2014 *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.

APTA is committed to advancing the quality of health care and promoting access to appropriate health care services and supplies in the current environment of fiscal constraints. We support the reduction of fraud, abuse, and waste in the health care industry and we educate and provide numerous resources to our membership regarding regulations and compliance. At the same time, it is imperative that senior citizens and people with disabilities have timely access to the appropriate health care services and supplies that they medically require. While we commend CMS on the efforts to curtail fraud, waste, and abuse with DMEPOS usage and to control health care expenditures, APTA is concerned that certain proposed changes regarding provision of DMEPOS could impede or delay access to timely medically

necessary care, decrease patient safety, possibly increase the costs of care and create excessive administrative burdens to the providers and suppliers. We discuss these in more detail in these comments.

Background: Physical Therapist's Role in DMEPOS

Before addressing specific provisions in the proposed rule, we would like to provide some background information regarding provision of DMEPOS by physical therapists in order to give context to our comments.

Physical therapists are often involved in fitting patients with orthotics, prosthetics, or the appropriate wheelchair or other medical devices during therapy treatment to facilitate function. The clinical judgment and expertise of the physical therapist is critical in selecting a particular DMEPOS item for the patient and is based on the therapist's evaluation of the individual patient. These services, which include determining the appropriate durable medical equipment, prosthetics and orthotics supplies (DMEPOS) for the patient, are crucial to improving a beneficiary's ability to function, participate in daily living, maintain productivity and improve the quality of health outcomes. These services and supplies are particularly important for the Medicare population, who often are dealing with multiple health issues and co-morbidities that impact their quality of life. Timely access to the appropriate and medically necessary durable medical equipment and prosthetics and orthotic devices is important for these individuals' safety and for minimizing deterioration of their condition. The appropriate DMEPOS allow beneficiaries to safely and productively continue their activities of daily living and optimize their quality of life.

Physical therapists are involved with DMEPOS on a number of fronts, including but not limited to, in the inpatient setting to address function and mobility assessment for assistive devices, in the outpatient setting for the assessment of appropriate wheelchair or power mobility devices or fabricating and fitting orthotics, and in the home care setting, as prescribed by the physician, for items such as negative pressure wound therapy devices.

The physical therapist's power mobility device (PMD) assessment often includes identifying seating and mobility problems, assessing the patient's potential, setting goals, and determining the necessary equipment and accessories required to achieve these goals. Many physicians refer their patients to physical therapists who specialize in seating and mobility to insure the best outcome for the patient and to preserve Medicare funds. This process requires not only a physician face-to-face visit, but extensive assessment and documentation to support a claim for a power mobility device.

Overarching Concerns Regarding the DMEPOS Competitive Bidding Program and Oversight of the Program

APTA has major concerns with the DMEPOS competitive bidding program and its impact on access to medically necessary DMEPOS items. We know from the discrepancies between the March 2014 GAO Report, *Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid,* and feedback from beneficiaries and providers on the front lines, that there are substantial issues with the program. Some of these issues include problems with the timely delivery of DMEPOS equipment. Some beneficiaries are waiting a month or longer to receive items. After receipt of a bid contract, some suppliers stop supplying certain supplies. After utilizing that supplier for years to obtain the equipment and/or supplies, beneficiaries have to search for a new supplier and may have difficulty locating a supplier who carries that item. After discharge from a hospital or skilled nursing facility (SNF), some suppliers will not deliver DMEPOS directly to the beneficiary. The beneficiary must wait delivery of the item which leaves the beneficiary having to cope without medically necessary equipment which could worsen the beneficiary's medical condition and creates an unsafe environment for the patient. Additionally, some beneficiaries are experiencing difficulties with getting repairs for their wheelchairs and must seek out another supplier to repair the chair. In rural areas, this is particularly burdensome as the supplier that agrees to fix the wheelchair may be located a substantial distance from the beneficiary. Continuity of care is crucial to this population of beneficiaries who are typically dealing with multiple and/or chronic conditions. Just as they are dependent on their health care provider, they are also dependent upon their supplier. When having to switch suppliers, supplier knowledge of a patient's conditions and needs is compromised.

Medicare patients are typically older or have disabilities and have a greater risk of multiple and chronic co-morbidities. This population is the group that benefits most from continuity of care due to their medical complexity and poorer health status. Competitive bidding, although appearing to initially control costs, could also result in worsened continuity of care and admissions to hospitals, SNFs, and other institutional settings. Ultimately, the savings are reduced or lost due to sacrifices in quality and continuity of care.

Providers are concerned that a substantial population of beneficiary issue data is not being captured as beneficiaries return home and CMS cannot monitor those issues if they do not result in a hospital admission, emergency room or physician visit. Despite reported "generally positive" CMS post-bid beneficiary 2011 satisfaction survey data of approximately 400 recipients,

there is much missing in the current data to give an accurate representation of this program's effects.

APTA is also concerned that this proposed rule leaves open the opportunity for a supplier to focus on low-cost DMEPOS items or "simple" wheelchairs and/or supplies and equipment so as not to deal with the higher costs and administrative burdens associated with complex DMEPOS, such as power wheelchairs and other complex rehabilitative technologies (CRTs). The bidding methodology is a quality-reduction process. For example, suppliers now balance providing the least expensive item or chair possible versus the costs associated with providing higher quality, higher priced items in anticipation of submitting a winning bid. Feedback from the 2004 competitive bidding demonstration projects showed that some wheelchair suppliers significantly reduced the number of accessories they provided in attempts to cut costs.[1]

APTA recommends that a monitoring process be implemented to verify that each winning vendor has supplied and continues to supply all products in all categories in all the competitive bidding areas (CBAs) it won. APTA has also received feedback from members that vendors have won contracts when, in fact, they are not certified to provide rehabilitative seating which negatively impacts the beneficiary. Other issues have included a failure of vendors to continue to supply the same items or specified brand names that they listed in their initial bid.

APTA would like to see additional supplier performance mechanisms in place. A small number of secret shoppers sent to suppliers does not provide an adequate representation of the issues beneficiaries are facing. We encourage CMS to monitor suppliers to ensure they are in compliance with nondiscrimination requirements, such as providing beneficiaries the same items it would provide to other consumers. We recommend that CMS routinely survey physicians, physical therapists, occupational therapists, and post-acute care facilities, beneficiaries, and consumer organizations on the quality and availability of DMEPOS items in their geographical area. Until CMS implements more effective monitoring strategies and data collection to prove the program effectiveness, APTA is concerned that beneficiaries and the health care system will be negatively impacted in the long term.

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[1] Thompson, T. (2004). Final report to Congress: Evaluation of Medicare's competitive bidding demonstration for durable medical equipment, prosthetics, orthotics, and supplies. *Department of Health and Human Services.* Washington, D.C.

Wheelchairs and Power Mobility Devices

Due to the incentives under the program to provide the least expensive item, APTA recommends that CMS consider excluding certain items from competitive bidding that would be considered complex rehabilitation technology (CRT). Complex rehabilitation technology (CRT) is a subset of assistive technology (AT) and includes individually configured manual wheelchair systems, power wheelchair systems, adaptive seating systems, alternative positioning systems, and other mobility devices that require significant customization. Congress has exempted certain CRT from competitive bidding largely due to the customization that is required for patients using these devices. Other types of devices included in the standard manual and power wheelchair proposed to be subject to competitive bidding also require individualization of chair features, functions and accessories to best meet a beneficiary's medically necessary needs. Competitive bidding results in a narrowing of choices for the consumer. Substitution of wheelchairs and accessories due to non-availability can have detrimental effects on the beneficiary. Below are examples of two patients that demonstrate the negative consequences that result from receiving the incorrect wheelchair.

Example 1*: A 67 year old male sustained a complete C4 spinal cord injury and requires a power tilt wheel chair to perform independent pressure reliefs. The DME supplier does not have a power tilt wheelchair and delivers a manual tilt-in-space wheelchair. Since the individual is unable to perform pressure reliefs independently, he develops a stage 4 pressure ulcer and requires flap surgery for wound closure.*

Example 2*: A 70 year old female suffered a stroke resulting in right sided hemiplegia and requires a light weight wheelchair with a drop seat to allow her to propel the wheel chair in her home and perform transfers independently. The DME supplier delivers a manual wheelchair that fits the specification, however, they do not have the drop seat. The patient is now unable to use her foot to assist in propelling her wheelchair and she is not able to transfer from her bed to the wheelchair by herself. As a result, she cannot be left home alone.*

Adjusting DMEPOS Payment Amounts Using Information from the Competitive Bidding Programs

Under section 1834(a)(1)(F)(ii) of the Social Security Act, the Secretary may (and beginning January 1, 2016 must) use information on the payment determined under the Competitive Bidding Program (CBP) to adjust the fee schedule payment amounts for DME items that are not in the competitive

bidding area. The rule includes proposed methodologies for adjusting Medicare DMEPOS fee schedule amounts in non-competitive bidding areas using information from DMEPOS CBPs. APTA is concerned that the expansion of the payment rates based on information from the competitive bidding programs nationwide will be disastrous for vulnerable senior citizens and people with disabilities who rely on these DMEPOS items.

As stated earlier in these comments, we have heard reports from physical therapists that indicate the competitive bidding program and its method for setting payment rates has negatively impacted Medicare beneficiaries ability to obtain specific products and services in the bid areas described by a code category. For example, physical therapists will recommend a model and then find that the model is not available or they find that the patient has been provided a substitute device with dissimilar features and functions that is included in the same code category. We have received reports of suppliers increasing the beneficiary's burden for obtaining services by requesting that they bring their products, such as wheelchairs, to the supplier's facility for repairs. Also, we have heard of cases where products, such as beds, were provided to the beneficiary without being assembled. We believe that these situations can be attributed in part to bid prices being set at rates below product and service related costs. As a result, patient access to medically necessary items has been hindered.

Before expansion of the competitive bidding program rates to non-bid areas, CMS should provide further study into identification of key factors that influence the cost in different regions. Due to geographic differences in local costs, a supplier may not be able to afford to furnish items of DMEPOS at a lower cost determined under the competitive bidding program, which could result in difficulty accessing items for Medicare beneficiaries. Factors that may impact the cost of the products include location (rural vs. urban), population size, case mix (complexity of population served), delivery costs (e.g. gas, tolls), and costs of running a business (e.g. salary, insurance, rental of office space, etc.). In addition, holding suppliers in other regions to a price obtained by a competitive bidding process through which winning suppliers presumably obtain some advantages such as increases in market share is unsustainable. Most likely, small suppliers would not have the "economies of scale" that enable them to afford to accept the lower payment rates derived under competitive bidding. We urge CMS to develop a clear method for accounting for all these factors that contribute to the cost of the items before adjusting the prices.

It is also essential that technical and administrative problems that underlie payment for DMEPOS and the existing competitive bidding program be addressed before expansion of the pricing to non-bid areas. To determine

appropriate reimbursement for DMEPOS items, the HCPCS codes used to represent these items must accurately depict the items. The HCPCS coding system needs to be changed because different products with varying features and functions are included within the same code under the current system. As an example, some products with more sophisticated features and functions that result in greater costs are grouped under the same code as less complex products. As a result, the prices determined under competitive bidding are not sufficient to cover the costs of the more sophisticated products, which ultimately results in decreased access to these medically necessary items. To protect access to these medically necessary products, the HCPCS codes need to be changed to group only similar products within the code.

In addition, it is also essential to better define services related to the provision of the DMEPOS product that should be included in the payment amount for the product and those services that should be paid for separately. For example, complex rehabilitation technology items (CRT) typically require additional services, such as simulations and trials, to make sure that the product meets the beneficiary's needs. If the supplier has to absorb the cost of these additional services due to insufficient payment, Medicare beneficiaries will have difficulty accessing these products.

Lastly, there are a number of additional administrative and technical problems that exist with regard to DMEPOS payment. Expansion of the pricing to non-bid areas without appropriate resolution of these other challenges will exacerbate access problems that currently exist.

Special Payment Rules for DMEPOS (Bundled Payment)

In the rule, CMS raises concerns about the rising cost of separate payment for DMEPOS supplies. CMS proposes to establish separate payment rules in 12 CBAs for DME equipment that differ from those currently in place. One set of these payment rules would provide for payment on a continuous monthly rental basis under future CB competitions for certain categories, including standard manual wheelchairs, standard power wheelchairs, hospital beds, and several others. Under this proposal, the SPA for the monthly rental of DME would cover each item and service associated with the rental equipment, including ongoing maintenance and servicing of the rental equipment and replacement of supplies and accessories that are necessary for effective use of this equipment.

We share CMS' goal of ensuring that Medicare beneficiaries be able to receive ongoing maintenance and services and replacement of their supplies, and agree that significant reform is needed in this area. However, we believe that CMS should first thoroughly review and

address the problems in the existing payment system that have impeded access to servicing repairs and supplies. These challenges are due to numerous issues, including: "abandoned beneficiaries" when the supplier is no longer in business; requiring the beneficiary to restart the entire face to face examination process merely to obtain a simple repair; complicated policies and confusion surrounding the distinction between repairs and replacement; and reduced payment rates in the competitive bidding (CB) areas.

One of the concerns with bundled payment is that it would be very difficult for a supplier to determine the appropriate amount to bid under a bundled payment method because there are many factors that would influence the costs associated with supplies, maintenance, and repairs. There would be distinctions in costs based on rural verses urban areas, population size, catchment area, case mix, and complexity of the population. Also, the cost of trials, fittings, trainings, and modifications would need to be considered. The need for repairs and maintenance will vary depending on the end user's needs, home environment, and their activity level. As an example, younger people with disabilities who are earlier in their journey may be more active in the community as compared to a 90 year old Medicare beneficiary. Based on this activity level, it is more likely that the younger individual will require more servicing and repairs on their wheelchair. With all of these factors, it would be difficult for suppliers to access the necessary data to make an educated bid. They would be forced to make future projections on repair costs that could result in miscalculations and that negatively impact their ability to continue with wheelchair repairs.

If CMS decides to go forward with bundled payment approaches, we recommend that it be pilot tested first with a small subset of items, such as walkers and that it exclude the more complex items. Before proceeding, CMS should establish and convene an advisory group to establish a methodology that would enable more educated bids and would consider all the factors that would impact the cost if payment were bundled. Prior to implementing any bundled system, there should be meaningful beneficiary satisfaction and outcome measures and a mechanism for surveying providers (e.g. physical therapists, occupational therapists, physicians) to determine patient impact.

HCPCS codes

In the rule, CMS solicits comments on whether all standard wheelchairs should be described under 1 HCPCS codes in order to simplify bidding

and claims processing procedures. In addition, CMS asked whether standard power wheelchairs could be described under a single HCPCS codes. APTA strongly opposes the reduction of HCPCS codes to describe wheelchairs as proposed in the rule. It is important that the subcategory of chair can be properly selected and identified by code. It may simplify burdens for some stakeholders, but not for the provider who is attempting to select the most appropriate chairs and accessories for the patient's medical needs. Utilization of a single HCPCS code for one category of wheelchair could result in unsuitable chairs be provided to a beneficiary. Such inexact coding incentivizes suppliers to provide less expensive equipment under a code in order to maximize profits.

Additionally, HCPCS codes can be utilized to measure the accuracy of the price-setting process by extrapolating data on select HCPCS items with the largest dollar claims, determining actual units allowed for each vendor for the HCPCS code year-to-year and whether the median price was calculated accurately for that product. By attempting to consolidate items with very different features and functionalities under one HCPCS code, the ability to measure the data and the success or failure of the program is compromised.

However, APTA agrees that the current HCPCS codes are antiquated and the first step in the process should include HCPCS code re-evaluation. APTA recommends that CRT codes be retained and new codes created for wheelchairs and accessories.

Transitioning from Temporary to Permanent Wheelchairs

As CMS considers its policies regarding payment for wheelchairs and competitive bidding, it is important to recognize that it is common for a patient to receive DMEPOS (e.g. wheelchair) temporarily upon discharge from a hospital or other setting and subsequently require a different DMEPOS item (e.g. wheelchair) based on a change in the patient's condition. Therefore, APTA urges CMS to establish policies that will allow coverage for temporary wheelchairs or mobility devices if CMS proceeds with the continuous rental scheme without creating additional administrative barriers for the beneficiary (and provider) when the beneficiary transitions to the permanent wheelchair. During this process, it is important that physical therapists, physicians, and other health care professionals have additional time to evaluate the patient's condition and make the appropriate recommendations regarding a permanent wheelchair based on medical necessity.

Patient Case Scenarios Involving Challenges with Receiving Wheelchairs

As CMS considers changes in payment policies for wheelchairs, including their repair and maintenance, we would like to share some case scenarios provided by APTA members that illustrate the problems with the existing payment system that CMS should address. We do not think that bundling payment for wheelchairs is the solution to these problems. As stated previously, there are numerous administrative and payment policies that are currently impacting the ability to access medically necessary DME. These scenarios demonstrate the problems with the current administrative and payment policies, and the detrimental health outcomes for patients as a result of not receiving the appropriate wheelchair.

Scenario 1

A 69 year old cognitively intact gentleman with Multiple Sclerosis (MS), on his own, obtained an electric wheelchair through a chain vendor that frequently advertised on television. His understanding was that the wheelchair would recline as he was too weak to do pressure releases and had significant fatigue and generalized muscle and buttocks pain limiting his sitting time to not more than one hour. Because of the associated fatigue and weakness with the MS, he was not able to independently transfer to his bed to lie down hourly which was the only relief for his pain that he could obtain. A reclining electric wheelchair would have afforded him the pain and pressure relief he desperately needed.

He was delivered the electric wheelchair with the understanding that the supplier was "working on" getting a wheel chair that reclined. When he contacted them to follow up he learned they were out of business.

The physical therapist met with the patient with a new Medicare contracted vendor to perform the evaluation for the appropriate wheelchair. The paperwork was in process for the correct chair but by this time the daily struggle of getting in and out of the wheelchair to lie down on his bed, the falls during transfers and the pain became too much for him. The pain resulted in depression and he no longer wanted to live. He was admitted to hospice and died two weeks later.

Although this incident occurred under the current payment and acquisition process, if competitive bidding causes a further narrowing of options for the

patient and delays in obtaining the appropriate equipment, it will be detrimental to beneficiaries.

Scenario 2

A 74 year old man with a progressive neuromuscular disease which presented in his teens, looks much like Cerebral Palsy (CP). He has spastic athetosis (uncontrolled swinging of extremities, trunk and head). He is strong enough to propel his wheelchair in his room with his feet and can transfer using a trapeze over his bed by placing his wheelchair facing the bed, puts his legs on the bed, then pulls himself over with the trapeze. He currently has a Bentley Wheelchair (a manual wheelchair with a hand control allowing him to tilt the wheelchair back independently). He liked the independence the wheelchair afforded him in his room but reclined to rest and to have pressure relief on his bottom. Additionally, he had neck pain and discomfort so reclining allowed him a straight line view of television and his environment.

Over the last few years, he has begun to lose more trunk control. He leans to one side and has worn down the padding on his back rest resulting in pressure sores from the metal which now has direct contact with his skin. He also developed a sore on his neck because he leaned on the front of the push handle frame. The back was replaced and the chair has been repaired multiple times but he is very hard on chairs due to his spasticity. He has desperately requested to have a different chair. The physical therapist advocated for him on two occasions prior to the January 1st DMEPOS rule with the original vendor and was told he could not get a new chair approved because he had only had current chair for 2 years and the minimum number of years for replacement is 5.

As his condition deteriorates, his transfers become less controlled and now - in addition to the previous issues - as he pulls himself from the bed to the wheelchair he injures the back of his neck with the tilt control pointed end. As a result, he developed a bacterial infection that has led to spinal meningitis and encephalopathy and, as a result, required hospitalization. He continues to have issues with pressure sores on his trunk. Additionally, he is getting contractures of his pectoral region and neck and can no longer hold his head upright for more than 10 seconds.

The physical therapist has begun to work with a new vendor. Using the rationale of a changed medical condition, a tilt-in-space wheelchair with head rest and appropriate trunk support is being requested and is pending pre-authorization. Because of the face-to-face requirement of Medicare for the new chair, he has had to make an appointment with his physician which takes several weeks. Additionally, the PT wrote a letter of justification for the

physician to sign and the vendor has now submitted it to Medicare for pre-authorization. The physical therapist typically spends 10 or more hours of unreimbursed time to keep this process moving.

By the time the beneficiary even receives a decision, 2 to 3 months will have passed. Commonly, the vendor does not believe the chair will be approved. The alternative option is that if Medicare denies the request, the Department of Developmental Disabilities (DDD) is sent a request to pay for the chair. The DDD will not give an answer until Medicare denies the chair and, therefore, cannot affirm they will cover the chair until receiving a Medicare denial. If Medicare denies the claim, advancing the request through DDD will require an additional 1 to 2 months. If the beneficiary is then approved for the chair, it will then need to be ordered. The total span of time could easily be 6 months. If the beneficiary has difficulty finding the medically specified chair due to a narrowing of options because of fewer available suppliers due to the competitive bidding process, the wait time is further increased.

In the meantime, the individual is miserable due to discomfort and ongoing pressure sore issues. He is spending more and more time in bed and is getting depressed because he is unable to engage in his usual past times of reading and watching TV while seated in a wheel chair. His quality of life continues to deteriorate and he continues to be at risk for re-injury, re-hospitalization and even death if he has re-occurrence of bacterial meningitis.

Scenario 3

A 70 year old man with Multiple Sclerosis (MS) recently moved from California to his son's home in Washington State. His son is now his primary caregiver. The patient is 100% dependent for transfers with a Hoyer lift and dependent for all personal care, meal preparation and household tasks. He has a high end electric wheelchair with recline and height change features. He can control his electric wheelchair independently and enjoys working at his computer and watching television during the day. He can be left alone for up to 4 hours because he is able to recline as needed during the day when he becomes fatigued or to relieve the spasticity and pain in his legs.

One of his foot rests is broken and the padding on his armrests has worn away. The tip of one arm rest is broken off leaving a jagged edge, placing him at risk for injury. The physical therapist called a local vendor who been awarded a bid in the DMEPOS process and was told he either had to get the original paperwork for the chair in order to do the repairs or go through the face-to face process again with his new physician be re-qualified for the chair. Only then could the vendor perform the repairs.

The patient is divorced. His ex-wife has all of the paperwork for his electric wheelchair and they are not on speaking terms and – even if they spoke – he believes she has thrown all the paperwork out. He does not remember where he got the chair, the chair has no identifying vendor information and he does not remember which doctor ordered it so is unable to request the original order, chart notes and signed letter of medical necessity for the chair. When informed of the face-to face process and the time involved to get the repairs made he simply decide he would live with the chair as it is.

APTA is concerned that the proposed rule does not have adequate safeguards in place for beneficiaries who relocate. Although the proposed rule states that a new continuous rental phase will begin if a beneficiary relocates to a capped rental area, there are appear to be no additional requirements to ensure the new supplier will repair the chair that was obtained by the prior vendor in the previous geographic area. Therefore, similar beneficiary scenarios, like the above clinical case example, could still frequently occur.

These examples clearly demonstrate the need to have the proper mechanisms in place so that the DMEPOS competitive bidding does not result in interrupted continuity of care and a decrease in the quality of medically necessary care received by these beneficiaries. Many of these beneficiaries are classified as disabled and, therefore, have additional protections under the Affordable Care Act. The proposed rule is unclear as to how discriminatory impacts which could result under competitive bidding to these beneficiaries can be rapidly remedied.

Off The Shelf Orthotics and Definition of "Minimal Adjustment to Orthotics"

In the rule, CMS discusses the fact that off-the-shelf orthotics are among the items subject to Medicare DMEPOS competitive bidding. These items are currently defined as orthotics that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. The regulations define "minimal self-adjustment" as "an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist or an individual who has specialized training."

In the rule, CMS proposes to update the definition of minimal self-adjustment to codify that an individual with specialized training includes: a physician, physician assistant, nurse practitioner, or clinical nurse specialist, occupational therapist, and physical therapists. CMS states that these

individuals possess the specialized training through their individual degree programs and continuing education requirements.

APTA appreciates CMS's acknowledgement that physical therapists would be considered specialized providers who are qualified to make adjustments that require trimming bending, molding, assembling, or customizing to fit the individual**.** Physical therapists often provide patients with orthotics to immobilize a body part, such as fracture braces for humeral fractures, air casts for ankle sprains, or static wrist orthotics for carpal tunnel syndrome. Physical therapist's also use orthotics to facilitate or augment a patient's movement. The physical therapist 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.

In many cases, it is essential that the patient have timely access to these items because the DMEPOS item may be necessary to immobilize and support an injured body part or to facilitate safe mobility or post-surgical recovery. As an example, it is common for a patient who has had a stroke to develop weakness in his or her ankle dorsiflexors, resulting in foot drop during the swing phase of gait. Physical therapists provide the patient with an ankle-foot orthosis to facilitate movement at the ankle so the patient will not risk tripping or stumbling during ambulation. By fitting the patient with the appropriate orthosis in the office, the physical therapist can proceed with gait training to assess whether there are sensory or skin problems and determine whether the orthosis allows the patient to ambulate properly.

Physical therapists are licensed by the state in which they practice. As licensed health care providers in every jurisdiction in which they practice, they are fully accountable for all their professional actions. Furthermore, physical therapists have been educated in programs accredited by the Commission on Accreditation of Physical therapy Education (CAPTE) which is recognized by the U.S. Department of Education and the Commission on Recognition in Postsecondary Accreditation (CORPA). CAPTE accredited physical therapy programs provide education and training in orthotics and prosthetics.

We are concerned that CMS is establishing regulations that would expand the DMEPOS program to include a broad definition of off the shelf orthotics that includes prefabricated, custom fit orthotic care. The broader the definition of OTS orthotics, the more orthotics can be competitively bid by CMS. However, there are major risks with having an over-inclusive definition of off-the shelf orthotics. If an orthosis is defined as OTS, CMS does not require the provider or supplier to provide any clinical care to the beneficiary or have any expertise in fitting orthotic braces. As a result, beneficiaries may lose access

to orthotic care from clinicians. Without appropriate clinical involvement, beneficiaries may have orthoses that do not fit them properly, and risk further injury.

Conclusion

APTA recognizes that oversight of DMEPOS utilization is necessary; however, it is of limited value if delays cause detrimental health impacts on beneficiaries or impose additional administrative and financial burdens on providers and suppliers due to operational and technical issues. The competitive bidding process should not delay the provision of care, result in such limited choices that quality is sacrificed, or be overly burdensome to providers or patients. It is vitally important that individuals, especially vulnerable populations such as the aged and the disabled populations, are able to access DMEPOS that are medically necessary for their health condition. The inability to obtain the appropriate equipment or devices results in a substantial cost to beneficiaries, the Medicare program and the health care delivery system as a whole.

APTA commends CMS on allowing stakeholders the opportunity to comment on this important regulation which could reduce DMEPOS overutilization on select items if properly and efficiently operationalized. APTA looks forward to working with CMS in its efforts to ensure that Medicare beneficiaries timely receive the appropriate medically necessary DMEPOS. Thank you for your consideration of our comments. If you have any questions, please contact Deborah Crandall, J.D., Senior Regulatory Affairs Specialist, at 703-706-3177 or deborahcrandall@apta.org or Gayle Lee, Senior Director, Health Finance and Quality at 703-706-8549 or gaylelee@apta.org.

Sincerely,

Paul Rockar, Jr. PT, DPT, MS
President

PR/dc