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Via Electronic Submission

March 13, 2017

Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1612-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1612-P, Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics; Proposed Rule (published January 12, 2017).

Dear Acting Administrator:

This letter represents the collective comments of the Alliance for Physical Therapy Quality and Innovation (the "APTQI") to the Centers for Medicare and Medicaid Services (CMS) regarding the above referenced proposed rule for the "**Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics"**, published in the Federal Register on January 12, 2017 ("Proposed Rule"). The Proposed Rule includes provisions addressing qualified suppliers, fabrication facilities, requirements for accreditation organizations, and payment for prosthetics and custom-fabricated orthotics. Of particular relevance for physical and occupational therapists, the Proposed Rule specifies the qualifications needed for practitioners and suppliers to furnish and fabricate prosthetics and custom-fabricated orthotics to Medicare beneficiaries.

By way of introduction, we are among the nation's leading providers of outpatient rehabilitation care, and collectively employ or represent several thousand physical and occupational therapists, and furnish physical and occupational therapy services on an annual basis to hundreds of thousands of Medicare beneficiaries. Our member companies also collectively employ approximately one thousand certified hand therapists who provide custom-fabricated orthoses to patients throughout the United States. The APTQI membership consists of affiliate and board member entities of varying size and geographic scope, which in aggregate operate and represent over 5,000 outpatient rehabilitation clinics. The following is a brief description of each of our APTQI board member level entities:

- **Athletico Physical Therapy** currently operates approximately 425 outpatient rehabilitation clinics in 9 states;

- **ATI Physical Therapy** currently operates approximately 700 outpatient rehabilitation clinics in 25 states;

- **Drayer Physical Therapy Institute** currently operates approximately 150 outpatient rehabilitation clinics in 14 states;

- **Physical Therapy Business Alliance** is a not for profit professional organization representing approximately 1,000 independent physical therapy clinics in 27 states;

- **Select Medical** currently operates approximately 1900 outpatient rehabilitation and/or occupational therapy clinics in 37 states and the District of Columbia;

- **Upstream Rehabilitation** currently operates approximately 368 outpatient rehabilitation clinics in 23 states; and

- **U.S. Physical Therapy** currently operates approximately 558 outpatient rehabilitation and/or occupational therapy clinics in 42 states.

I. Preliminary Statement

We appreciate the opportunity to comment on the Proposed Rule. Many of the areas where feedback is sought regarding therapy services are important to the APTQI's core mission: "*Ensuring patient access to value driven physical therapy care*." We support CMS' commitment to enhance its partnerships with a delivery system in which providers are supported in achieving better patient outcomes at a lower cost for Medicare beneficiaries. The Proposed Rule as written does not advance the triple aim of healthcare – i.e., improve patient experiences (satisfaction, quality and outcomes); decrease program costs, and improve population health. To the contrary, the Proposed Rule would adversely affect beneficiary access, quality and continuity of care for orthotics and prosthetics; increase programs costs; and negatively impact a significant population of beneficiaries by disconnecting orthotic services from qualified physical and occupational therapists.

II. Proposed Rule Overview

Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) defines a qualified practitioner as a physician or other individual who is a qualified physical therapist or a qualified occupational therapist; or is licensed in orthotics or prosthetics, in the cases where the state provides such licensing; or, in states where the state does not provide such licensing, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or fabricated orthotics and is certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) or the Board for Orthotist/Prosthetist Certification International, Incorporated (BOC); or is credentialed and approved by a program that the Secretary determines has training and education standards that are necessary to provide such prosthetics and orthotics. (See §1834(h)(1)(F) of the Social Security Act). Within the rule, CMS states it is imperative to have both licensure and

certification requirements for all qualified practitioners (i.e., eligible professionals and other persons who furnish or fabricate prosthetics and custom-fabricated orthotics).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to establish and implement DMEPOS quality standards that suppliers must meet in order to furnish and bill for certain covered items and services, including prosthetics and orthotics. It also provided that to obtain a Medicare Part B billing number, a DMEPOS supplier must be accredited by one of the approved accreditation organizations. Subsequently, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a requirement that a DMEPOS supplier furnishing covered items and services, directly or as a subcontractor for another entity, must submit to the Secretary evidence of being accredited as meeting the applicable quality standards. However, CMS was given the authority to exempt "eligible professionals" and such "other persons" from the quality standards and accreditation requirements, unless CMS determined that the standards are designed specifically to be applied to such eligible professionals and other persons, or if CMS determined that licensing, accreditation, or other mandatory requirements apply to such eligible professionals and other persons.

The Proposed Rule establishes the qualifications and requirements that must be met in order to be considered a qualified practitioner. Among other proposals, CMS:

- Defines qualified practitioner as an eligible professional that meets the education, training, licensure, and certification requirements of the Social Security Act.

- Specifies training, licensure, and certification requirements that qualified practitioners must meet in order to furnish or fabricate prosthetics and custom-fabricated orthotics.[1]

CMS proposes to identify and define the types of eligible professionals and other persons who can become qualified practitioners, and in accordance with BIPA, furnish or fabricate prosthetics and custom-fabricated orthotics. CMS proposes to identify and to add definitions for the following practitioners: occupational therapist, physical therapist, ocularist, orthotist, pedorthist, physician, and prosthetist. In addition to defining the types of professionals that would be eligible to furnish and fabricate prosthetics and custom-fabricated orthotics, CMS is proposing certain licensure, training, and certification requirements that practitioners must meet to be qualified practitioners who furnish or fabricate prosthetics or custom-fabricated orthotics that are billed to Medicare by qualified suppliers. CMS states an eligible professional or other person who wants to be a qualified practitioner who furnishes or fabricates prosthetics or custom-fabricated orthotics must meet either of the following licensure and certification requirements:

- Licensed in orthotics, pedorthics, or prosthetics by the state.

- In states that do not provide licensure for orthotics, pedorthics, or prosthetics, must be both of the following:

[1] The Proposed Rule also includes a definition of custom-fabricated orthotics as an item that must be individually made for a specific patient, and constructed using a positive model technique outlined in the regulation.

- Specifically, trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics.

- Certified by one of the following: ABC, BOC, or a CMS-approved organization that has standards equivalent to the ABC or BOC.

III. The CMS Exemption to Accreditation for Occupational and Physical Therapists Should be Continued.

CMS proposes to remove the accreditation exemption for physical and occupational therapists that currently exists in their status as "eligible professionals." Physical and occupational therapists have a long history of providing high quality custom-fabricated orthotics services to Medicare beneficiaries. No additional regulations or requirements should be imposed upon physical or occupational therapists to serve as a CMS qualified practitioner of custom orthoses to Medicare beneficiaries. The education requirements for occupational therapists (master's degree since 2005) and physical therapists (doctorate degree since 2015) has increased over the past decade, which shows an increasing level of preparedness for practitioners. The education requirements include the examination and intervention of orthotic, protective and support devices. Both physical and occupational therapists must successfully pass a national examination to become licensed and registered in their practicing states. Under the respective state practice act, if a physical and occupational therapist does not possess the requisite skills to provide orthotic interventions, they cannot provide the service. CMS should not encroach upon, or interfere with, the scope of services permitted under the respective practitioner state practice acts.

In addition, nearly 6,000 certified hand therapists have self-imposed higher certification standards, including the requirement to have a minimum of three years of experience with 4,000 hours specific to the proper use and fabrication of upper extremity orthotics. Certified hand therapists must sit for a standardized examination and successfully pass to become certified. Ironically, in private practice settings across the country, significant amounts of custom-fabricated orthotics are fabricated by orthotic assistants and technicians with a high school education under the supervision of orthotists. Moreover, orthotists, prosthetists and pedorthists licensure laws, and the BOC and ABC accreditation boards, have grandfathering provisions ***for experience*** that supersedes education requirements. Ironically, physical and occupational therapists are considered "eligible professional" surveyors by BOC and ABC, but deemed not "qualified practitioners" by CMS. The Proposed Rule imposes additional regulatory accreditation requirements on licensed physical and occupational therapists who custom fabricate orthotics while permitting "eligible professional" status for licensed orthotists and prosthetists practitioners. CMS does not site to any evidence of quality of care issues involving physical and occupation therapists providing prosthetic and orthotic services. To the extent there is practitioner licensure issues, those matters should be left to the various state boards. More importantly, if a practitioner's state practice act permits physical and occupational therapists to provide custom orthoses, CMS should not require additional accreditation requirements.

The definition and interpretation of "Eligible Professional" should remain the same. CMS has not acted to change this definition since the enactment of BIPA (2000), MMA (2003) or MIPPA (2008). To change that definition now, with little, if any, collaboration with all interested stakeholders would lead to significant patient care issues. The definition of "other persons" (including orthotists and prosthetists) should be required to continue to comply with the accreditation requirements. Many of the "other

persons" do not have the level of regulatory oversight required of "Eligible Professionals" (including physical and occupational therapists). The passage of so much time since CMS was asked to review this issue, the absence of any quality of care issues, and the best interests of Medicare beneficiaries collectively provide evidence that the exemption for physical and occupational therapists remain in place.

IV. Eliminating The Therapist Exemption Will Significantly Limit Medicare Patient Access and Outcomes.

The Proposed Rule's accreditation requirement would add an additional unnecessary regulatory burden for occupational and physical therapists providing orthotic services to Medicare beneficiaries. Physical and occupational therapists, whether they bill Medicare under their own provider numbers or through a rehab agency, are already subject to the oversight of CMS. The CMS requirements for credentialing and billing of therapy services cover many of the same standards proposed under the DMEPOS accreditation. Physicians have for many decades relied upon the technical expertise and knowledge of licensed physical and occupational therapists. For example, physical and occupational therapists are relied upon by physicians to fabricate custom upper extremity orthosis as part of the post-surgical rehabilitation care process. More specifically, physical and occupational therapists specializing in hand rehabilitation possess condition-specific knowledge for the precise joint positioning required when fabricating orthotics following surgical repairs of nerves, joint replacements and other complex injuries. If physical and occupational therapists are unable to evaluate and make patient adjustments to fabricated orthotics ***during treatment***, the continuity of patient care would suffer since the patient would now be required to travel to an orthotists's office to have the orthosis modified or adjusted. The orthotist would be responsible to fabricate the orthotics in the practice and/or, in many cases, providing direct oversight of a physical or occupational therapist, or even a physician, providing these services. The proposed regulatory accreditation would add significant costs to private practitioners and thereby limit patient access. This would ultimately lead to poor patient outcomes and higher costs. Clearly, this additional layer in the continuity of care is not what Congress or CMS intended.

Access to care would be greatly affected due to the proposed accreditation requirements. There are approximately 7,100 employed orthotists and prothetists in the United States. This small population of practitioners should not be relied upon to service the Medicare beneficiary population requiring orthotics care. There are approximately 114,000 occupational therapists and 210,000 physical therapists in the United States, including nearly 6,000 certified hand therapists. A significant number of physical and occupational therapists, and all certified hand therapists, custom-fabricate orthotics for both the upper and lower extremity. The initial ABC or BOC survey costs for a DMEPOS primary accredited site are approximately $3,000-$4,000, and each additional site is nearly $2,000. In additional, practitioners must pay surveyor travel expenses and miscellaneous costs (application fees, etc.) as part of the accreditation process. Finally, to meet these standards, physical and occupational therapists would be required to attain an additional degree in orthotics and prosthetics! This would impose an impracticable and unreasonable cost burden on several thousand currently qualified practitioners. If the accreditation exemption is eliminated for physical and occupational therapists, many of these practitioners will opt out of being a DMEPOS provider given the additional financial and regulatory burdens. The accreditation requirements in the Proposed Rule would also restrict a physician's ability to direct referrals to currently qualified physical and occupational therapists. Physicians may be forced to consider a more costly alternative or face the real and likely option of increased failure post-operatively with secondary surgeries. This would negatively impact patient choice and disrupt continuity of care. For several decades, physical and occupational therapists have been recognized as qualified orthoses practitioners by CMS. CMS should not implement the additional requirements in the Proposed Rule.

V. Conclusion

There are quite a number of challenges for CMS to address that weigh statutory limitations with available administrative flexibility. We strongly urge CMS to exercise that discretion with this Proposed Rule. The Proposed Rule as written does not advance the ***triple aim of healthcare*** – i.e., improve patient experiences (satisfaction, quality and outcomes); decrease program costs; and improve population health. To the contrary, the Proposed Rule would adversely affect beneficiary access, quality and continuity of care; increase programs costs; and negatively impact a significant population of beneficiaries by disconnecting orthotic services from qualified physical and occupational therapists. This will lead to widespread dissatisfaction among beneficiaries and providers, an unintended increase in program health care costs, and a disruption in access to high quality orthotic services.[2]

The APTQI appreciates the opportunity to provide comments to CMS on the Proposed Rule that help address these challenges. APTQI is in favor of a payment program for qualified practitioners and suppliers of prosthetics and custom fabricated orthotics, including the inclusion of reliable and valid outcome and quality measures. We encourage CMS to continue to work with AMA and professional societies such as the APTQI through the rulemaking process to determine payment and quality requirements for practitioners who furnish and fabricate prosthetics and custom-fabricated orthotics. The APTQI looks forward to continued dialogue with CMS officials about these and other issues affecting therapy services. If you have any questions, or would be interested in further collaboration, please feel free to contact Troy Bage, PT, DPT, Executive Director, at 410-627-7533 or tdbage@gmail.com.

Very truly yours,

ALLIANCE FOR PHYSICAL THERAPY
QUALITY AND INNOVATION

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[2] If CMS determines that it must implement the requirements in the Proposed Rule, then the effective date of compliance should be extended for a minimum of two years to avoid significant provider disruption and patient harm.