PEDORTHIC FOOTCARE ASSOCIATION

3/13/2017

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To: Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS–6012–P
Mail Stop C4–26–05

7500 Security Boulevard,
Baltimore, MD 21244–1850

Website: http://www.regulations.gov

From: Pedorthic Footcare Association

1610 East Forsyth Street, Suite D
Americus, GA 31709

Re: *CMS-6102-P: Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics*

Dear Centers for Medicare and Medicaid Services (CMS),

We are writing to provide comments on the proposed rule entitled: CMS-6102-P: Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics which was published in the Federal Register on January 12, 2017.

The Pedorthic Footcare Association (PFA), founded in 1958, is the not-for-profit professional association which represents the interests of the certified and/or licensed pedorthist and supports the pedorthic profession at large. Through PFA's efforts, pedorthics – the management and treatment of conditions of the foot, ankle, and lower extremities requiring

fitting, fabricating, and adjusting of pedorthic devices – is a well-established allied health profession contributing greatly to public health.

PFA's mission is to enhance the effectiveness and efficiency of credentialed providers of lower extremity pedorthic modalities through education; increase the demand for services through marketing; and promote the right to practice through government affairs activities.

Overview and Summary Observations and Comments

The Pedorthic Footcare Association would like to express its concern that after 14 years past the point of going through the negotiated rulemaking process to implement BIPA 427, CMS feels the need to move forward with this implementation without updated information and without convening another negotiated rulemaking committee. In those14 years licensure, certification and accreditation have become more part of the current process and has diminished greatly the amount of unqualified practitioners/suppliers providing prosthetics and custom fabricated orthotics. With access rapidly becoming a larger issue additional regulations will only serve to exacerbate the issue for patient's.

The proposed rule also raises significant concerns in the following areas:

(1) *Enforcement Mechanisms*. The statute says Medicare should not pay unlicensed/unaccredited parties. The proposed rule largely ignores this and focuses only on revocation of Medicare privileges AFTER Medicare has improperly paid. This seems to ignore the intent of the law which was to prevent improper payment in the first place.

(2) *Compliance with the 'equivalency to American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) or Board of Certification (BOC) standards by all deemed accrediting organizations*. PFA disagrees that simply adding the presence of an ABC or BOC certified O&P professional on their team equates to equivalency for purposes of accreditation of orthotic and prosthetic suppliers. Each and every one of the deemed accrediting organizations must maintain standards for O&P that are substantially equivalent to those of ABC or BOC. The presence of an ABC or BOC certified O&P professional on the team of such other accrediting organization must be in addition to the accrediting organization's requirement to meet the statutory prerequisite of equivalency of their O&P standards with those of ABC or BOC, and not in lieu of standards equivalency. Congress' intent for the implementation of BIPA Section 427 was clearly that the actual standards of those deemed accrediting organizations was to be equivalent to that of ABC and BOC.

(3) *Regulation of fabrication of O&P devices*. PFA believes that CMS in this proposed rule

has overlooked a critically important distinction when it comes to fabrication facilities:

> a) *Fabrication in the same facility/physical location where patient care/treatment* occurs— this is the norm in pedorthic patient care, and CMS is not authorized to regulate how care is delivered by certified/licensed health professionals in a patient care facility.
>
> b) *Fabrication in a facility physically distinct from a site where patient care is delivered*. CMS needs to defer to the certification bodies on this. CMS has not been given authority by Congress (who delegated to the Food and Drug Administration (FDA) on such matters) or any other entity to mandate the type of laundry list of requirements as are set forth in the proposal, and these should be dropped.

The proposed rule needs to be modified to acknowledge that fabrication which occurs within a facility where patient care is delivered is exempt from CMS rules, similar to patient care in offices of physicians and other health care professionals. With respect to fabrication at facilities that are not the site for delivery of patient care (central fabrication facilities), CMS needs to revise this proposal by;

> (a) referring to the independent accrediting bodies and their existing standards as defining the scope of requirements; and
>
> (b) withdrawing that portion of the proposed rule that prescribes extensive and exacting descriptions of proposed specific new regulatory requirements in recognition of the fact that any authority Congress has delegated for direct federal government regulation of physically distinct fabrication facilities (central fabrication facilities) was bestowed upon the FDA, not CMS.

(4) Education ACE

Comments on Provisions of the Proposed Regulations

Section II.A.2 – Proposed paragraph 2424.57 (d)(4) would contain a listing of tools, equipment, and computers deemed necessary for all fabrication facilities. The listing is stated as a minimum and includes items that are unnecessary and not commonly found in a fabrication facility located within the physical location where pedorthic patient care/treatment occur. This would force practitioners who wish to be qualified to invest in equipment that is not useful, beyond the needs for the devices being manufactured and purchased to have on hand simply to meet the proposed requirement. This equipment list includes computerized CAD/CAM type equipment that is not the standard manufacturing method for most pedorthic and orthotic fabrication facilities and would represent an

unnecessary burden by CMS forcing these manufacturing methods onto fabrication facilities with no data to support that this will improve patient outcomes. Other examples of equipment that is inappropriate for a fabrication facility producing only orthoses and pedorthic devices are a lathe, paint-spraying equipment, welding equipment, an alignment jig, and an air compressor. PFA would support a listing of ***suggested*** tools, equipment, and computers.

In regards to requiring that claims for prosthetics and custom fabricated orthotics are submitted by qualified supplier or by beneficiaries must have been furnished by qualified practitioner and fabricated by qualified practitioner or a qualified supplier as defined in the proposed rule. The Pedorthic Footwear Association is in agreement with the practitioner or supplier needs to be licensed or certified but not in agreement that one must be licensed or certified to fabricate. Mandating that one must be licensed or certified to fabricate provides no patient protection whatsoever. The patient protection is insured by the practitioner or supplier needing to be licensed or certified because that individual has seen the patient, made the treatment decisions, is providing oversight over the fabrication and is responsible for the outcome, not the technician in the lab.

Section II.A.3.a – The proposed definition of Pedorthist should be that of the taxonomy code assigned through the National Uniform Claim Committee that reads that the pedorthist is "an individual who is trained in the management and treatment of conditions of the foot, ankle, and lower extremities requiring fitting, fabricating, and adjusting of pedorthic devices." The qualifications PFA is proposing would be:

> – licensure by all states in which practicing, if applicable, ***OR***
>
> – having successfully completed a training program in pedorthics that is jointly recognized by:
>
> > 1. the *National Commission on Orthotic and Prosthetic Education* (NCOPE) or the *Commission on Accreditation of Allied Health Education Programs* (CAAHEP) and;
> >
> > 2. the *American Board for Certification in Orthotics, Prosthetics and Pedorthics* (ABC) or the *Board of Certification/Accreditation* (BOC).

Pedorthists who are accredited by a CMS approved AO should be able to fabricate and furnish prostheses and custom fabricated orthoses that are within their scope of practice as established by licensure in the states within which they practice, if appropriate, or those established by ABC or BOC.

The current draft names ABC in several places as the recognized accreditation agency for accrediting orthotics and prosthetics educational programs. This is not accurate. This role is fulfilled by CAAHEP. Reference to ABC in this section should be replaced with CAAHEP. Similarly, reference to the American Council on Education (ACE) should be replaced by the Council for Higher Education Accreditation (CHEA). Please note that ACE is a membership organization and not a recognizing or certifying agency. Inclusion as a member of ACE is purchased and in no way based on accreditation standards they may or may not require. Their inclusion in this proposal is inappropriate.

The proposed rule states that in order to be defined as an Orthotist or Prosthetist, individuals must be licensed (if state requires it), ***and*** must complete a training program that is jointly recognized by ABC and ACE, ***and*** must be eligible to take either the BOC or ABC certification exam. The original statute does not stipulate that all of these requirements must be met. It is an "or" situation rather than an "and" situation, and the proposed regulations should be modified to conform with that "or" iteration for any and all qualified practitioners that this effects. PFA opposes any requirement for any type of qualified provider to be required to maintain both licensure and certification as unduly burdensome.

Section II.A.4 – PFA believes that the provisions in the proposed rule that authorize the revocation of a qualified supplier's enrollment from Medicare as a result of failure to comply with the requirements of the proposed rule are an improper enforcement mechanism for the statute. The intent of the original statute was to prevent unqualified suppliers from billing Medicare for prostheses and custom fabricated orthoses. The statute says Medicare should not pay unlicensed/unaccredited providers, yet there is no enforcement mechanism (such as claims edits during pre-payment processing) to proactively limit such improper payments. The sole enforcement mechanism mentioned in the proposed regulation is revocation of supplier billing privileges, which would take place AFTER improper payments have already been made by Medicare. This seems contrary to the intent of the statute. While it is always good to weed out bad operators, this may catch some legitimate providers in untenable situations as well. A more tenable option in this scenario is to implement appropriate claim edits that will reject claims from unqualified providers. The power to revoke billing privileges is ripe for misapplication with significant impact on business continuity in cases where billing privileges were revoked inappropriately. PFA believes that there are better methods of enforcing the requirements of the proposed rule than revocation of a supplier's billing privileges. Increased screening during the initial provider enrollment process and subsequent re-enrollment period should prevent most unqualified suppliers from entering the system initially. In the unlikely event that an unqualified supplier is improperly enrolled, existing audit processes should be considered a reliable pathway to preventing or recouping payment from unqualified providers. The authority to revoke a suppliers billing privileges based on unconfirmed information may lead to devastating consequences for

legitimate suppliers. PFA recommends that the final rule either remove the authority of CMS and its contractors to revoke the billing privileges of suppliers that it deems unqualified, or place substantial due process protections in place as protection against this potentially devastating step until the supplier or practitioner has been verified as unqualified. Just as important, the proper and primary enforcement mechanism under this rule MUST reflect the intent of the statue that Medicare should use claim edits and such processes ***so that Medicare does not pay*** claims requested by unlicensed or unaccredited providers in the first place, as was intended in the statute.

Section II.A.5 – The proposed rule states that proof that an accrediting organization meets the definition of "a DMEPOS accreditation organization that has standards equivalent to ABC or BOC." Is that the AO only employs or contracts with an orthotist, prosthetist, occupational therapist, or physical therapist who meets the qualified practitioner definition at §424.57(a) and who is utilized for the purpose of surveying the supplier for compliance, and has the authority to approve or deny accreditation of qualified suppliers." PFA believes this to be inappropriate as the proof does not depend on the standards the AO and the qualified practitioner it is teamed up with. The qualified practitioner may be granting or denying accreditation based on any standards the AO they are teamed with chooses, and the practitioner's mere presence on the team validates the appropriateness of those standards. The final rule must be amended to state that in order to be deemed equivalent to ABC or BOC for accreditation purposes, an AO must maintain standards that are equivalent, if not identical to those maintained by ABC or BOC regardless of who administers those standards and the granting or denial of accreditation.

Section II.A.6.b – PFA believes the proposed effective date of 1 year after the posting date of the final quality standards as too short. This belief is based on the fact that individuals currently enrolled as a supplier with CMS for another discipline will not have adequate time in one year to complete the education, residency/work experience, testing and accreditation activities necessary to be considered qualified practitioners by that date. PFA proposes 2 years from the posting date of the final quality standards to allow those individuals time to complete these activities.

Section II.B – PFA again disagrees that the device must be fabricated by a qualified practitioner for the reasons stated above. The qualified provider who is conducting the direct patient interaction and treatment is responsible for, and qualified under both the standards of accreditation and this proposed rule, to ensure the treatment of the patient is done through appropriate means and with appropriate devices. They have clinical oversight responsibility for this patient. The technician building the device does not.

Thank you for the opportunity to comment on this proposed rule to specify qualifications for practitioners and suppliers who provide orthotic and prosthetic services, specifically for

those suppliers and practitioners who fit custom orthoses and prostheses. If you would like additional information regarding pedorthics or any comments provided in this response, please contact me at c.costantini@pedorthics.org.

Respectfully,

Christopher Costantini, C.Ped.
PRESIDENT

PEDORTHIC FOOTCARE ASSOCIATION