March 13, 2017

Dr. Patrick Conway, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6012-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

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

Dear Acting Administrator Conway,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments on issues related to the Proposed Rule CMS-6012-P, the Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics. AdvaMed member companies produce the medical devices and technologies that are covered under Medicare’s DMEPOS benefit. These devices and technologies play a critical role in allowing beneficiaries to lead healthy, productive, and independent lives in their homes and communities, thereby serving to fulfill the intent of Congress when it created this benefit.

Our comments below are limited to the impact of the proposed rule on custom-fabricated orthotics. In summary, AdvaMed does not believe that this proposed rule should be finalized, but if CMS decides to move forward with it, it must incorporate several major changes. The proposed rule would apply new regulatory burdens on orthotic device manufacturers, physicians, other licensed practitioners, and orthotic suppliers, based on requirements established in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) that have remained unimplemented for 16 years – with no known adverse impact on Medicare beneficiaries. The provisions of the proposed rule are now largely obsolete after years of innovation by orthotic manufacturers and fail to reflect the current process for manufacturing and furnishing custom-fabricated orthotics to Medicare beneficiaries. The proposals also fail to recognize the full-range of professionals who are qualified to furnish custom-fabricated orthotics to beneficiaries, and currently do so because of innovation that has occurred in the
manufacturing process for custom-fabricated orthotics. We also note that the proposed rule is duplicative of State regulations established for these devices.

For all of the reasons identified above, AdvaMed believes that CMS should evaluate the proposed rule in the context of the Administration’s recent executive orders. On February 24, 2017, the Administration issued an Executive Order directing each Federal agency to establish a Regulatory Reform Task Force tasked with identifying for repeal those regulations that “are outdated, unnecessary, or ineffective” or that “impose costs that exceed benefits.” Separately, another Executive Order issued January 30, 2017 states that “it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.”

Given the passage of time since the BIPA provisions were enacted but never implemented, and the costs that would be imposed by the rule, the directives from the President argue in favor of CMS withdrawing the proposed rule. The proposed rule estimates that 12,250 physicians, orthotists, prosthetists, and other practitioners would be required to obtain special accreditation to provide services they are already qualified to provide under applicable state law and consistent with their scope of practice. Moreover, the Proposed Rule is expected to require 5,000 physicians, orthotists, prosthetists, and other practitioners to obtain additional training and certification, which is estimated to cost practitioners over $5 million in the first year alone.

Developing a proposed rule for an obsolete statute serves no useful purpose for Medicare beneficiaries, the Medicare program, or manufacturers. Even more problematic is the adverse impact the proposed rule would have on beneficiary access to care: “[w]e acknowledge that there may be some discontinuity of care in instances where a beneficiary seeks or has been receiving items from an individual or supplier that does not meet the requirements of the statute.”

In the absence of evidence that the current regulatory framework and requirements are not effective, CMS should not be introducing yet another administrative and financial burden on suppliers while drastically limiting those individuals authorized to provide care to Medicare beneficiaries.

**Today’s Process for Providing Custom-Fabricated Orthotics to Medicare Beneficiaries**

During the past 16 years, major changes have occurred in both the specialized fabrication process used for custom-fabricated orthotics -- especially custom knee braces, and the way many Medicare beneficiaries obtain access to these products through their physicians’ offices.

Whereas in the past a single individual with specialized training in orthotics would measure a patient and craft an orthotic device for that patient, today almost all custom-fabricated knee orthotics are made in large centralized facilities using advanced composite materials and super alloys that allow products to be tailored to an individual patient’s needs so as to maximize joint protection and compliance with a specific care plan.

In addition, most measuring for custom orthotic devices is now done with Computer Aided Design-Computer Aided Manufacturing systems that allow trained individuals to accurately
measure and fit orthotic braces without specialized orthotics training. Persons measuring Medicare patients for custom-fabricated orthotics go through extensive training programs designed by manufacturers in conjunction with clinical personnel to provide overviews of applicable disease states and dysfunction, as well as in-person training and workshops on how to correctly and safely measure and fit custom-fabricated knee braces.

As a result of these developments, many physicians now delegate the measurement and fitting of custom-fabricated knee braces to trained professionals in their own offices, rather than sending patients to orthotists. These trained professionals can also include manufacturer representatives with expertise in specific brands of orthotics used by the physician’s practice. In recognition that patients can be effectively measured and fitted for orthotics in physicians’ offices by qualified but unlicensed individuals, the majority of states do not require a license to practice orthotics, and those States that do have some form of licensing often include exemptions to allow measuring and fitting by certain unlicensed persons, including fittings by specially trained representatives of manufacturers, under the supervision of a physician or other licensed health care professional.

The result of these changes, both in the production and furnishing of orthotic devices to patients, has meant significant improvements in the quality of orthotic bracing services available in the physician’s office and under the physician’s supervision, as well as greater convenience for patients who no longer have to travel to other providers for measurement and fitting.

The proposed rule’s provisions fail to reflect these significant changes. CMS indicates that it consulted with a number of different stakeholder groups in developing the proposed rule. The agency, however, did not consult with AdvaMed or its member companies on the content for the rule. We believe that our member companies, which play a central role in furnishing these products to Medicare beneficiaries, could have provided important insights into how new standards in response to BIPA requirements and other statutory changes should be shaped to reflect today’s fabrication process for custom orthotics. We are happy to do so now, however, in order to ensure that a final rule include changes that we believe are needed to reflect today’s fabrication and delivery process for providing high quality custom orthotics to Medicare beneficiaries.

The Proposed Rule’s Impact on Beneficiary Access to Custom Orthotics

Scope of Application of New Standards for Custom-Fabricated Orthotics. AdvaMed is concerned that the proposed rule fails to distinguish between custom-fabricated orthotics as a whole and the small subset of molded-to-patient-model custom-fabricated orthotics (MTPM orthotics) that are individually fabricated for the patient over a positive model of the patient. BIPA provided that the new custom-fabricated orthotics standards apply only to items that are individually fabricated for the patient over a positive model of the patient. Despite this limitation, the proposed rule defines a “positive model” as a particular type of custom fabrication in which one of the following modeling techniques is used: (i) molded to the patient model as a negative impression of the patient’s body part and a positive model rectification are constructed; (ii) computer aided design-computer aided manufacturing (CAD-CAM) system; (iii) direct formed model in which the patient serves as the positive model.
AdvaMed points out that the separate proposed rule category in which the orthotic is molded to the patient model as a *negative* impression is by definition not a *positive* model of the patient, as required by BIPA. Likewise, a CAD-CAM system which transmits data to software that rectifies the model on a computer screen does not utilize a positive model of the patient. Therefore the direct formed model is the only type of fabrication technique identified by CMS that should be considered individually fabricated for the patient over a *positive* model of the patient. AdvaMed believes that with the proposed definition for positive model, CMS has extended the scope of application of standards beyond the original intent of Congress as specified in the BIPA statutory authority for the requirements.

With the expansive scope of application of the new standards, CMS assumes that all custom-fabricated orthotics require exactly the same type of measuring and fitting expertise, provider credentials, and fabrication facilities, when in fact they do not. The proposed rule does not reflect the major changes in the custom-fabricated orthotic manufacturing process since the enactment of BIPA.

**Requirements for Fabrication Facilities of Custom Orthotics.** Under its proposed rule, CMS would establish new requirements for fabrication facilities of custom orthotics that in several instances are simply inappropriate for today’s production and delivery system for such products. As discussed above, custom orthotics, and particularly knee orthotics, are rarely if ever fabricated by individual practitioners. Rather they are fabricated in centralized facilities that are separate from patient care sites. The proposed rule’s requirements that fabrication facilities have a separate waiting area and chairs with armrests, have patient care and fitting rooms with appropriate levels of privacy and sanitation, have parallel bars, a full-length mirror, etc. assume that patients are always measured and fitted in the same facilities where devices are made. This is not the case and these specific requirements would exclude virtually all current manufacturers of orthotics, including sophisticated knee braces represented by HCPCS code L-1846, from providing custom orthotics to Medicare beneficiaries.

The proposed rule also requires that fabrication facilities have full-time appropriately credentialed staff who are qualified practitioners or qualified suppliers onsite to fabricate and to supervise fabrication. The proposed rule identifies and defines the types of eligible professionals who can be considered qualified practitioners. These include occupational therapist, ocularist, orthotist, pedorthist, physical therapist, physician, and prosthetist. This requirement for credentialed and supervisory staffing by specified qualified practitioners again reflects a lack of understanding of the current custom orthotics production process where standardization is the rule and where high levels of trained personnel are not required.

**Training, Licensure, and Certification Requirements for Qualified Practitioners.** The proposed rule would also establish new training, licensure, and certification requirements for practitioners who provide custom orthotics to Medicare patients. Qualified practitioners (not enrolled in Medicare as a DMEPOS supplier) would have to be licensed in orthotics, pedorthics, or prosthetics by all States in which they practice, or, in States that do not provide licenses for those three professions, be specifically trained and educated in those professions and certified by specified organizations, including the American Board for Certification in Orthotics, Prosthetics
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and Pedorthics (ABC), the Board for Orhotist/Prosthetist Certification International, Incorporated (BOC), or a Secretary-approved organization that has standards equivalent to the ABC or BOC.

These new requirements would no longer allow physicians to use in their offices trained and highly skilled but unlicensed professionals, including representatives of manufacturers, for measuring and fitting custom orthotics. To justify these new requirements, the proposed rule does not discuss specific instances where CMS has learned that Medicare beneficiaries have been harmed or have received poor quality custom orthotics as a result of arrangements where unlicensed professionals have measured and fitted patients under the supervision of physicians. AdvaMed knows of no such cases, and to the contrary, believes that these arrangements have instead improved the quality and efficiency of care for both Medicare and its beneficiaries. We point out that this is especially true for beneficiaries residing in rural areas where few professionals licensed in orthotics exist.

AdvaMed also notes that the new requirements disregard the majority of State laws that do not require a license to practice orthotics or those State laws that include exemptions to allow certain unlicensed persons, including specially trained representatives of manufacturers, under the supervision of a physician or other licensed health care professional, to measure and fit custom-fabricated orthotics.

Finally we point out that the new regulations could compromise beneficiaries’ timely access to custom products, since BOC has announced that it will not accept new applications for orthotist, prosthetist, and pedorthist certifications. This will leave only one private entity, the ABC, to certify professionals practicing orthotics.

**Accreditation Requirements for DMEPOS Suppliers Fabricating or Billing for Custom-Fabricated Orthotics.** CMS regulations currently require that Medicare DMEPOS suppliers, including suppliers of orthotics, be certified by any one of a number of different accrediting bodies. The proposed rule would establish new and specific accreditation requirements for DMEPOS suppliers fabricating or billing prosthetics and custom orthotics. The proposed rule would require that DMEPOS suppliers fabricating or billing custom-fabricated orthotics be accredited by the ABC, the BOC, or a Secretary-approved organization that has standards equivalent to the ABC or BOC, and employs or contracts with an orthotist, prosthetist, occupational therapist or physical therapist, and is utilized for surveying suppliers for compliance with accreditation standards.

CMS does not explain why it has proposed unique accreditation requirements for suppliers of custom orthotics or if existing options for these suppliers have in some way proved ineffective for ensuring Medicare beneficiaries access to quality custom orthotics. Without an explanation, we only see the burden this new requirement will place on suppliers who will have to use different agencies for accreditation when their business involves several lines of products.
AdvaMed Recommendations for Changes to the Proposed Rule

To address the issues discussed above, AdvaMed recommends that the proposed rule incorporate the following changes:

**Scope of Application of New Standards for Custom-Fabricated Orthotics.** CMS should exempt certain technologically advanced custom-fabricated orthotics, including orthotics classified under HCPCS code L-1846 from the definition of custom-fabricated orthotics and identify other specific codes that should be exempt from the general custom-fabricated orthotics standard.

**Requirements for Fabrication Facilities of Custom Orthotics.** With regard to patient treatment-related fabrication facility standards (separate waiting areas and chairs with armrests, patient care and fitting rooms with appropriate levels of privacy and sanitation, etc.), the final rule should specify that these requirements apply only to those facilities that fit, assess, or otherwise provide patient care on site.

The requirement that fabrication facilities have full-time appropriately credentialed staff members to fabricate and to supervise fabrication a process that today is largely standardized should be removed in the final rule.

**Training, Licensure, and Certification Requirements for Qualified Practitioners.** CMS should expand the types of professionals who are considered qualified practitioners under the proposed rule to include any individual who is authorized under State law to measure and/or fit custom-fabricated orthotics, either directly or under the supervision of a physician, including manufacturer representatives operating under the supervision of a physician or other professionals recognized by State licensure laws.

**Accreditation Requirements for DMEPOS Suppliers Fabricating or Billing for Custom-Fabricated Orthotics.** CMS should broaden the list of approved accreditation organizations to include all accreditation organizations currently listed as approved DMEPOS accreditation organizations for custom-fabricated orthotics.

We appreciate the opportunity to offer comments on the proposed rule. If you have any questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery