



March 13, 2017

Patrick Conway, M.D.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-6012-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: ITEM Coalition Comments on Section 427 of the Benefits Improvement and Protection Act of 2000 (BIPA); CMS-6012-P:**

Dear Acting Administrator Conway:

The Steering Committee of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition writes to express our support for the proposed rule interpreting Section 427 of the Benefits Improvement and Protection Act (BIPA) of 2000. While we support publication of a final rule in a timely manner, we have several recommendations to improve the rule that, we believe, are critical to ensuring that Medicare beneficiaries continue to have access to quality prosthetic and custom orthotic care.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as limb loss (e.g., limb amputation), multiple sclerosis, paralysis, cerebral palsy, spinal cord injuries, brain injuries, stroke, spina bifida, Osteogenesis Imperfecta ("OI"), vision loss, and other life-altering conditions. Quality orthotic and prosthetic care is important to each of these beneficiary groups.

The ITEM Coalition strongly supports the intent of the rule; to protect Medicare beneficiaries from unqualified practitioners and suppliers of custom-fabricated orthotics and prosthetics and to limit waste, fraud and abuse in the O&P Medicare benefit. Linking Medicare payment to demonstration of practitioner and supplier credentials is an innovative way to achieve the dual goals of the statute. We question why the Centers for Medicare and Medicaid Services (CMS) has taken 17 years to finally publish this proposed rule and believe that once comments have been received, CMS should expeditiously issue a revised, final rule so that implementation can occur.

CMS appears to have interpreted the BIPA Section 427 statutory language broadly by applying to all health care professionals requirements for special training, education,

licensure, or certification/accreditation if these professionals intend to bill the Medicare program for custom-fabricated orthotics and prosthetics. This means that physicians, physical therapists, occupational therapists, and other professionals will need to demonstrate that they meet qualifications in order to receive payment for custom-fabricated orthotics and prosthetics. This raises some concerns with respect to access to care, particularly in rural areas.

However, we also recognize that several factors in the rule mitigate the risk of lack of patient access to these services. First, the proposed rule's practitioner and supplier qualifications do not apply to health care professionals who provide off-the-shelf and pre-fabricated orthotics, only custom-fabricated orthotics. Off-the-shelf orthotics (which are defined by statute as needing only "minimal self-adjustment") and pre-fabricated orthotics constitute the vast bulk of orthoses provided by physicians and therapists in the course of seeing patients and servicing their needs without referring them to an orthotist.

We recognize, however, that there are some physicians and therapists who develop expertise in custom fabrication of orthotics and provide these services to Medicare beneficiaries in the normal course of their practice. The final rule should make some accommodations for these health care professionals. If a certain type of provider can demonstrate that they have sufficient training and education to provide and manage the delivery of a certain range of custom-fabricated orthoses to treat patients they see within the scope of their practice, then CMS should state these accommodations in the final rule. With respect to physicians, we believe that some physicians are more qualified to provide these services than others. For instance, physicians who specialize in physical medicine and rehabilitation, orthopedics, rheumatology, hand surgery, and other orthopedic specialties should be given the opportunity to demonstrate their board certification or other credentials to CMS and be granted a limited exemption from BIPA Section 427.

The ITEM Coalition believes there is great value in a regulation that will truly link quality care with provider qualifications, but it must be tailored to ensure that Medicare beneficiaries continue to have access to high quality O&P care. For instance, custom-fabricated orthoses and prostheses are generally complex and challenging to design, fit and fabricate. Sufficient laboratories are necessary in order to fabricate the O&P devices that meet the specific needs of individuals. The proposed rule requires every qualified supplier to have a full-blown fabrication facility on the premises in which they see patients in order to receive Medicare payment. The proposed rule seems to coningle the concepts of fabrication facilities and patient care facilities. We believe this aspect of the proposed rule needs to be clarified in the final rule to reflect current and future methods of O&P fabrication.

We appreciate the opportunity to submit these comments to the BIPA Section 427 proposed rule. The ITEM Coalition leadership would be happy to meet to discuss this issue further and are available for any questions you may have. To communicate the ITEM Coalition, please contact Leif Brierley at [Leif.Brierley@powerslaw.com](mailto:Leif.Brierley@powerslaw.com), or call 202-466-6550.

Sincerely,

**ITEM Coalition Steering Committee Members**

Dan Ignaszewski, Amputee Coalition

Rebecca Sheffield, American Foundation for the Blind

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Laura Weidner, National Multiple Sclerosis Society

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