



November 8, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Response to Withdrawal of Proposed Regulations for Section 427 of the Benefits Improvement and Protection Act of 2000 (BIPA)

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee write to express disappointment with the recent decision by the Centers for Medicare and Medicaid Services (CMS) to withdraw the proposed rule implementing Section 427 of the Benefits Improvement and Protection Act (BIPA) of 2000. The ITEM Coalition Steering Committee urges CMS to re-examine the issues raised by commenters and explore options and alternatives with stakeholders that will ultimately result in full implementation of BIPA Section 427.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services 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 multiple sclerosis, spinal cord injuries, brain injuries, stroke, paralysis, limb loss, cerebral palsy, hearing and speech impairments, visual impairments, vision loss, spina bifida, myositis, and other life-altering conditions. Quality orthotic and prosthetic care is important to many of these beneficiary groups.

The proposed rule was published on January 12, 2017, sixteen years after regulations were supposed to have gone into effect, according to the statute. Significant public comments were received by the due date, March 13th, earlier this year. Unfortunately, rather than finalizing the proposed rule, taking into account the many legitimate comments, CMS instead chose to withdraw the proposed rule entirely. The ITEM Coalition Steering Committee is concerned that this action constitutes a missed opportunity for CMS to finally issue a common-sense rule that would improve the quality of care for Medicare beneficiaries who use custom orthotic braces and prosthetic limbs (i.e., custom orthotics and prosthetics) while decreasing the likelihood of waste, fraud and abuse in the Medicare program.

The ITEM Coalition Steering Committee strongly supported the intent of the proposed rule and was grateful for its publication by CMS earlier this year. We have questioned why CMS has taken 16 years to finally publish this proposed rule and question further why the proposed rule needed to be withdrawn rather than modified appropriately in response to the various legitimate

comments. ITEM Coalition continues to believe a meaningful rule could be promulgated that addresses the legitimate comments that were provided during the public comment period.

ITEM Coalition submitted comments on March 13, 2017 to CMS that provide our recommendations for modifications to the final rule.¹ We made two critical points in these comments. First, only *custom-fabricated* orthoses and prostheses are impacted by this rule and, therefore, patient access to off-the-shelf and many prefabricated orthoses would not be affected and, second, that CMS should accommodate in the final rule those providers who are able to demonstrate their qualifications to provide custom fabricated orthoses. Our comments to the proposed rule specifically stated:

“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.”

The ITEM Coalition Steering Committee supports publication of a rule that finally implements BIPA Section 427 in a timely manner—with amendments to accommodate the legitimate public comments received—to ensure that Medicare beneficiaries continue to have access to quality prosthetic and custom-fabricated orthotic care provided by practitioners and suppliers with appropriate education, training and experience.

Withdrawing the proposed rule at this stage is inconsistent with the statute, a major waste of effort that have been expended to finally regulate this long-overdue rule, and is in the interests of neither beneficiaries in need of custom fabricated orthotics and prosthetics, nor the Medicare program which seeks to protect against waste, fraud and abuse.

Respectfully, the undersigned members of the ITEM Coalition Steering Committee ***urge you to swiftly re-examine the issues raised by commenters and explore options and alternatives with stakeholders that, ultimately, result in the issuance of a final rule*** on Section 427 of the

¹ See *ITEM Coalition Comments on Section 427 of the Benefits Improvement and Protection Act of 2000 (BIPA); CMS-6012-P*, available online at <https://itemcoalition.files.wordpress.com/2017/05/31317item-coalition-comment-letter-on-bipa-section-427-d07161252.pdf>

Benefits Improvement and Protection Act of 2000, with appropriate amendments to accommodate reasonable public comments.

We would be happy to meet to discuss this issue further and are available for any questions you may have. To contact the ITEM Coalition, please contact the ITEM Coalition coordinators, Peter Thomas, at Peter.Thomas@powerslaw.com or Leif Brierley at Leif.Brierley@powerslaw.com, or call 202-466-6550.

Sincerely,

ITEM Coalition Steering Committee Members

American Foundation for the Blind
Amputee Coalition
Christopher and Dana Reeve Foundation
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association

CC: Demetrios Kouzoukas, Principal Deputy Administrator, CMS
Carla DiBlasio, Office of the CMS Administrator