THE ORTHOTIC AND PROSTHETIC ALLIANCE

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Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1614-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies [CMS-1614-P]

Dear Administrator Tavenner:

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 13,000 O&P professionals and 3,575 accredited O&P facilities, we appreciate the opportunity to comment on the proposed rule, *Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*. The O&P Alliance is committed to ensuring that Medicare beneficiaries and all individuals with injuries, illnesses, and disabilities have access to, and coverage of, the full spectrum of professional orthotic and prosthetic patient care.

In light of this commitment, we wish to express our thoughts and concerns about the proposed Medicare definition of "minimal self-adjustment" for purposes of covering the provision of off-the-shelf (OTS) orthotics under the Medicare program. Although the proposed rule does include some important concepts for the provision of quality O&P patient care, the O&P Alliance has serious concerns about the proposal. We also question CMS's recent release of a new version of the DMEPOS quality standards, effective June 2014, that effectively adopts the proposed rule ***before*** any public comment was solicited or considered. We urge CMS to immediately rescind this new set of quality standards until such time as CMS meaningfully considers stakeholder input on the proposed rule and issues a rule in final form.

OTS orthotics are defined by statute as orthoses that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[1] The current CMS regulatory definition of "minimal self-adjustment" is set forth at 42 C.F.R. § 414.402 as "an adjustment that the beneficiary, caretaker, or supplier of the device can perform and does not require the services of a certified orthotist . . . or an individual who has specialized training." CMS proposes to modify this definition by re-defining who is considered to be "an individual who has specialized training." Specifically, CMS proposes to include the following individuals, as long as they are in compliance with all applicable Federal and state licensure and regulatory requirements:

- A physician, as defined in § 1861(r) of the Social Security Act (42 U.S.C. § 1395x(r));
- A treating practitioner defined at § 1861(aa)(5) of the Social Security Act (42 U.S.C. § 1395x(aa)(5)) (i.e., a physician assistant, a nurse practitioner, or a clinical nurse specialist);
- An occupational therapist as defined under 42 C.F.R. § 484.4; or
- A physical therapist as defined under 42 C.F.R. § 484.4.
- A certified and /or licensed orthotist

Missing from this list are certified orthotic fitters, who have specialized training and experience to provide all but custom-fabricated orthoses. CMS acknowledges certified orthotic fitters in its proposed rule but only by noting that the states do not have consistent licensure requirements for such individuals. Therefore, the proposed rule excludes them from qualifying as individuals who have specialized training. This issue, in itself, could prompt extensive comments and legal analysis. While CMS usually defers to state licensure when regulating Medicare policy, CMS simply ignores state law in this area in the proposed rule, leaving itself vulnerable to challenge under the Constitution and existing federal preemption statutes and case law.

The O&P Alliance Continues to Oppose CMS's Modification of the Definition of "Minimal Self-Adjustment" and Offers Additional Comments on the Proposed Rule

We continue to object to CMS's modification of the statutory term, "minimal self-adjustment," for the reasons described in more detail below. In addition, we offer the following comments involving the remainder of the proposed rule.

1. CMS Continues to Misinterpret the Definition of OTS Orthotics

The O&P Alliance continues to believe that CMS's definition of "minimal self-adjustment" is contrary to the plain language of § 1847(a)(2) of the Social Security Act. CMS has exceeded its statutory authority in re-defining OTS orthotics. As such, we continue to urge

[1] 42 U.S.C. § 1395w-3(a)(2).

CMS to rectify this improper interpretation by revising significantly its OTS regulations issued to date.

As already stated, the Social Security Act explicitly defines OTS orthotics as orthoses that "require *minimal self-adjustment* for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual." While the statute does not provide a definition of "minimal self-adjustment," CMS has effectively written the word "self" out of the term "minimal *self*-adjustment" by defining minimal self-adjustment as "an adjustment that the beneficiary, *caretaker for the beneficiary, or supplier of the device* can perform and does not require the services of a certified orthotist . . . or an individual who has specialized training." In short, most persons defined by CMS to make adjustments to OTS devices are NOT the beneficiary him***self*** or her***self***, as the statute undeniably states.

The O&P Alliance strongly opposes this definition as it is contrary to the statutory language established by Congress under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[2] If fitting an orthosis requires the assistance of a supplier, then, by definition, it is not being self-adjusted. We assume that CMS interpreted this term in this manner so as to achieve maximum federal savings through competitive acquisition of OTS orthotics, the only type of orthotics subjected to competitive bidding. But an overly broad definition of this term will have real consequences for Medicare patients as more and more orthoses will be delivered to the patient with little or no clinical fitting or instruction as to appropriate use. Many of these orthoses will be "drop shipped" to the beneficiary's home, potentially exposing patients to unnecessary harm and risking overutilization and waste under the Medicare program.

As such, we urge CMS to issue a revised regulation that is consistent with the statute by not including fitting by suppliers within the meaning of minimal self-adjustment. We again urge CMS to issue regulations to clarify that, in order to be considered "off-the-shelf," the beneficiary or untrained caretaker must be capable of self-adjusting the OTS orthosis, without any involvement by the supplier, as is consistent with the text and intent of the statute.

2. <u>CMS's Proposal Utilizes the Definition of OTS Orthotics to Improperly Regulate Non-OTS Orthotics</u>

Just as the definition of OTS orthotics is established by statute, the types of medical personnel that may provide certain categories of non-OTS orthotics is also established by law. Specifically, Congress has determined that only qualified practitioners or qualified suppliers may furnish custom fabricated orthoses to Medicare beneficiaries.[3] The term, "qualified practitioner" is defined as a physician, a qualified physical or occupational therapist, a state-licensed orthotist

[2] *See* § 302(b)(1), Pub. L. No. 108-173, 117 Stat. 2225.
[3] 42 U.S.C. § 1395m(h)(1)(F)(i). O&P certification can be given by the American Board for Certification in Orthotics, Prosthetics and Pedorthics, the Board of Certification/Accreditation, or another deemed authority.

or prosthetist, or an appropriately certified orthotist or prosthetist (in states without O&P licensing).[4] In addition, a "qualified supplier" is defined as an entity that holds appropriate accreditation, such as accreditation by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC)[5], the Board of Certification/Accreditation (BOC)[6], or another authority that is "essentially equivalent." Only these entities are permitted to furnish custom-fabricated orthoses to Medicare beneficiaries; no reference is made in the statute to "an individual who has specialized training" if that individual does not also fall within the categories of medical personnel specified.

There are three basic categories of orthoses, custom-fabricated, prefabricated/custom fitted (with varying levels of clinical intervention necessary), and off-the-shelf (OTS). In this proposed rule which addresses the least clinically-involved category of orthotics, OTS orthotics, CMS essentially seeks to regulate most of the field. It is bootstrapping the OTS regulation to also define what OTS is not (i.e., prefabricated/custom-fitted orthoses) and thereby impact most of the orthoses provided to Medicare beneficiaries while simultaneously ignoring a federal statute that has never been regulated, which directly addresses custom-fabricated orthotics and prosthetics. The O&P Alliance believes strongly that CMS is exceeding its authority in proposing this rule without also issuing regulations on Section 427 of the BIPA 2000 law.

Furthermore, under the Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) Quality Standards (Appendix C) established by CMS, a custom-fabricated orthosis is defined as:

> [An item] that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device, which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part. The fabrication may involve using calculations, templates, and components. This process requires the use of basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the patient.[7]

While CMS has yet to create the statutorily required list of orthotics to be identified as custom-fabricated (and therefore only reimbursed under Medicare when provided by a qualified practitioner and supplier), the O&P Alliance believes that CMS has limited discretion in determining the appropriate personnel who may provide custom-fabricated orthoses and

[4] *Id.* § 1395m(h)(1)(F)(iii).
[5] Previously known as (and referred to in the statute as) the American Board for Certification in Orthotics and Prosthetics, Inc.
[6] Previously known as (and referred to in the statute as) the Board for Orthotist/Prosthetist Certification.
[7] *Available at* http://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html.

prostheses under BIPA 2000, and no authority whatsoever to regulate this issue in the context of a regulation on OTS orthotics.

Prefabricated, custom-fit orthoses are referred to as "custom-fitted" under CMS's DMEPOS Quality Standards and defined as follows:

> A prefabricated device, which is manufactured in quantity without a specific patient in mind. The device may or may not be supplied as a kit that requires some assembly and/or fitting and adjustment, or a device that must be trimmed, bent, molded (with or without heat), or otherwise modified by an individual with expertise in customizing the item to fit and be used by a specific patient.[8]

Some of these orthoses require substantial fitting and modification to be properly serviceable; others require less alteration but still require specialized knowledge and skills to properly fit the patient. In either case, the orthoses at issue are not, and should not be considered, off-the-shelf. This fitting is essential to the safety and effectiveness of the device—performance elements assigned by Congress to the Food and Drug Administration, ***not* to CMS**. The FDA-approved and mandated labeling of these devices describe the techniques and importance of these specialized fittings and adjustments to attain indispensable characteristics for patient safety, effectiveness and health. This appears to be one of the key categories of orthotics that CMS is effectively seeking to regulate through what purports to be a mere clarification about OTS orthotics.

3. <u>The Proposed Rule's Impact on Certified Orthotic Fitters May Be Profoundly Inequitable</u>

In setting forth the requirements for specialized training equivalent to a certified orthotist, CMS noted that "fitters" must work under the supervision of an orthotist or other individual with specialized training. For this reason, CMS asserts, "fitters" are not considered to have specialized training for purposes of providing custom-fitting. CMS also notes that not all states provide licensure for orthotic fitters, but does not fully clarify whether a distinction exists between "fitters" (who are not permitted to independently provide prefabricated/custom-fitted orthotics under the proposed rule) and certified orthotic fitters. Therefore, it is unclear whether CMS intends for certified orthotic fitters to be precluded from providing prefabricated, custom-fitted orthotics to Medicare beneficiaries, a level of care for which they are specifically trained to provide.

If CMS does intend to exclude certified orthotic fitters from being classified as individuals who have specialized training, the results of such exclusion are extremely inequitable and problematic for certified/licensed orthotic fitters and the patients they serve. At this time,

[8] *Id.*

certified/licensed orthotic fitters have proven their competency for providing prefabricated orthoses as covered under their scope of practice. Certified fitters undergo specific training in relevant coursework and have practice and continuing education requirements to maintain their certifications.

Both ABC and BOC provide nationally-accredited certification for orthotic fitters who complete a required orthotic-specific education course, complete 1,000 hours of experience in orthotic fitting/patient care, and pass a comprehensive, psychometrically sound, and legally defensible examination that provides evidence that the orthotic fitter possesses the professional skills to practice in this discipline. Also, CMS has already validated the existing deemed accreditation organizations' implementation and enforcement of the DMEPOS Quality Standards.

CMS should allow the deemed accreditation organizations to continue to maintain their long-established certification and licensing requirements related to approval of suppliers who wish to bill for Orthotics: off-the-shelf (OR03) and Orthotics: prefabricated (OR02). Furthermore, there are several states that license orthotic fitters. These states have consistent scopes of practice for these professionals, which include the provision of prefabricated/custom-fitted orthoses.

4. Only Licensed and/or Certified Clinical Providers Should Be Permitted to Provide Prefabricated/Custom-Fitted Orthotics to Medicare Beneficiaries

As noted above, CMS's proposed rule precludes most unlicensed/non-certified personnel on the office staff in physician practices, therapy offices or orthotic facilities from fitting and adjusting prefabricated/custom-fitted orthoses for Medicare beneficiaries. The O&P Alliance agrees that the unlicensed/non-certified, non-clinical staff and persons who are in the health professional's practice should not be permitted to provide such services.

Unless the state's licensure statute provides otherwise, **those licensed or certified healthcare professionals who regularly engage and/or assist in the care and treatment of patients with conditions requiring orthotic treatment (including certified orthotic fitters) that truly act under the supervision of a physician (or other individual who has specialized training) should be permitted to continue providing such services with respect to custom-fitted orthoses.**

5. CMS's Broad Definition of OTS Orthotics and Proposed Modification May Have Significant Impact on Patient Care

CMS's expansive definition of OTS orthotics has the distinct potential to directly impact the quality of patient care. Specifically, the O&P Alliance believes that the improper classification of some prefabricated, custom-fitted orthoses as OTS orthotics may compromise the care of the Medicare beneficiary. In addition, it can potentially be seen as CMS

inappropriately endorsing a care delivery model that is contrary to both FDA safety and effectiveness determinations and FDA-prescribed labeling requirements.

Although the provision of OTS orthotics requires no orthotic education and training, the provision of prefabricated/custom-fitted orthoses requires both education and experience. CMS must not permit unlicensed/non-certified suppliers to provide what Medicare perceives as OTS orthotics that, in reality, are prefabricated/ custom-fitted orthoses requiring significant clinical and professional involvement to meet the broad spectrum of individual patient needs and anatomical structure. If this happens, the patient is at risk of receiving inadequate care from a supplier with the least possible competence in understanding the fit and function of the orthosis.

Suppliers of OTS orthotics are exempted from complying with Appendix C of the DMEPOS Quality Standards.[9] Importantly, the supplier is not required to provide to the patient any clinical care with respect to the delivery, fitting, or use of the orthosis. In addition, the supplier is not responsible for assuring that the OTS orthosis is delivered to the patient in a manner consistent with the identified beneficiary needs, risks, and limitations of which the supplier is aware.

As a result, many device suppliers, including possibly distributors or manufacturers, may decide to drop-ship orthoses directly to patients' homes. In enacting the statute that specifically authorizes competitive bidding of certain DMEPOS, Congress intentionally limited the scope of competitive bidding to OTS orthotics only, defining "off-the-shelf orthotics" as those that fall squarely among those devices appropriate for use with "minimal self-adjustment" *by the patient*. CMS, perhaps driven by a desire to achieve maximum financial savings, expanded the OTS definition in direct contradiction to FDA-labelling of prefabricated/custom-fitted devices.

CMS's invocation of this model may, in turn, lead to widespread patient noncompliance, lack of efficacy, greater waste, and perhaps unnecessary injury. In the end, patients may self-fit what is truly a prefabricated/custom-fitted orthosis the best they can, or they may appear at the office of the patient's physician or a local orthotist (not the original supplier) seeking assistance with fitting, but with no ability for the physician or orthotist to bill for correcting the fit of the orthosis to the patient.

Conclusion

By issuing this proposed rule, CMS has appropriately acknowledged that as the degree of clinical intervention and customization of orthotic treatment increases, a higher level of provider education, training and expertise is necessary in order to provide quality orthotic care. The O&P Alliance could not agree more strongly with this linkage between quality and qualifications.

[9] MIPPA, Section 154(b).

However, the pathway and authority on which CMS relies to regulate in this area is badly flawed. This is compounded by CMS's untimely publication of a revised set of DMEPOS Quality Standards that implements the proposed rule before any public comment has been received and considered, undercutting the value of stakeholder input on these issues. CMS continues to overreach in both its definition of who is included in the term "minimal self-adjustment" and in the breadth of orthotics that OTS encompass. Rather than regulating orthotics through the principles established in Section 427 of BIPA 2000, which CMS has yet to do thirteen years after its statutory deadline, CMS continues to rely on questionable authority to determine the qualifications necessary to provide more advanced orthotic care. We urge CMS to rethink this strategy and finally regulate orthotics in a comprehensive manner, consistent with ***all*** federal statutory requirements.

Sincerely,

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