ALSTON&BIRD LLP

TO: American Orthotic and Prosthetic Association

FROM: Alston & Bird LLP

DATE: January 12, 2017

RE: **Proposed Rule on Medicare Requirements for Qualified Practictioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics**

On January 11, 2017, the Centers for Medicare & Medicaid Services ("CMS" or "the Agency") released a proposed rule to specify the qualifications needed for qualified practitioners ("QPs") to furnish and fabricate, and qualified suppliers ("QSs") to fabricate, prosthetics and custom-fabricated orthotics; requirements an organization must meet to accredit QSs to bill for prosthetics and custom-fabricated orthotics; and a timeframe by which QPs and QSs must meet the applicable licensure, certification, and accreditation requirements ("Proposed Rule").[1] The rule would remove the current exemption from accreditation and quality standards for certain practitioners and suppliers who furnish prosthetics and custom-fabricated orthotics. Comments will be accepted on the proposed rule through March 13, 2017.

In general, CMS is proposing to:

- Define the terms "custom-fabricated orthotics," "positive model of the patient," "qualified supplier," "qualified practitioner," and "fabrication facility;"
- Specify training, licensure, and certification requirements that QPs must meet to furnish or fabricate prosthetics and custom-fabricated orthotics;
- Require that claims for prosthetics and custom-fabricated orthotics that are submitted by QSs or by beneficiaries must have been furnished by a QP and fabricated by a QP or a QS;
- Define the requirements that must be met by organizations that are designated and approved by CMS to accredit suppliers that bill for prosthetics and custom-fabricated orthotics;
- Specify the requirements that a fabrication facility must meet in order for QPs and QSs to be able to fabricate prosthetics and custom-fabricated orthotics that can be paid for by Medicare; and

[1] Medicare Program; Establishment of Special Payment Provision and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics, *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-00425.pdf. The Proposed Rule is scheduled to be published in the Federal Register on January 12, 2017, after which it will be available here: https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR&browsePath=2017%2F01&isCollapsed=true&leafLevelBrowse=false&ycord=0.

- Describe the Agency's intent to modify the DMEPOS quality standards to reflect the provisions of the Proposed Rule and to provide the list of services and supplies that are subject to the requirements of the Proposed Rule.

A. Legislative History

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")[2] added a provision to the Social Security Act that states that no payment may be made for custom-fabricated orthotics or for an item of prosthetics unless furnished by a QP and fabricated by a QP or a QS at a facility that meets criteria the Secretary deems appropriate.[3] That section defines "custom-fabricated orthotic" as one individually fabricated for the patient over a positive model of the patient and also requires education, training, and experience to custom-fabricate. A "QP" is defined as a physician or other individual who is a qualified physical therapist or a qualified occupational therapist; or is licensed in orthotics or prosthetics, in the cases where the state provides such licensing; or, in states where the state does not provide such licensing, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or fabricated orthotics and is certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics ("ABC") or the Board for Orthotist/Prosthetist Certification International, Incorporated ("BOC"); or is credentialed and approved by a program that the Secretary determines has training and education standards that are necessary to provide such prosthetics and orthotics. A QS is defined by BIPA as any entity that is accredited by the ABC or the BOC or is accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Boards.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[4] required the Secretary to establish and implement DMEPOS quality standards that suppliers must meet in order to furnish and bill for certain covered items and services, including prosthetics and orthotics. It also stated that to obtain a Medicare Part B billing number, a DMEPOS supplier must be accredited by one of the approved accreditation organizations.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)[5] added a requirement that a DMEPOS supplier furnishing covered items and services, directly or as a subcontractor for another entity, must submit to the Secretary evidence of being accredited as meeting the applicable quality standards. The Secretary was given the authority to exempt "eligible professionals" and such "other persons" from the quality standards and accreditation requirements, unless the Secretary determined that the standards are designed specifically to be applied to such eligible professionals and other persons, or if the Secretary determined that

[2] Pub. L. 106-554.

[3] 42 U.S.C. § 1395m(h)(1)(F).

[4] Pub. L. 108-173.

[5] Pub. L. 110-275.

licensing, accreditation, or other mandatory requirements apply to such eligible professionals and other persons. Section 1834(a)(20)(F) (ii) of the Act specifically refers to orthotists and prosthetists as examples of "other persons." CMS said: "Since orthotists and prosthetists specifically were mentioned in the statute, we believe that the Congress intended for those persons to be exempt unless there were standards designed specifically to be applied to such eligible professionals and other persons."

B. Provisions of the Proposed Rule

1. Updating Accreditation and Certification Requirements

CMS proposes to remove the exemption from having to meet the quality standards and the exemption from having to be accredited that currently exists for eligible professionals and other persons who furnish, fabricate, or bill for prosthetics and custom-fabricated orthotics.

2. Definition and Accreditation Requirements for Qualified Suppliers

CMS proposes to define "qualified supplier" at 42 C.F.R. § 424.57(a) as an entity that is enrolled in Medicare as a DMEPOS supplier and accredited by one of the CMS-approved accreditation organizations (described in Sec. B.5 of this summary). In its existing regulations, CMS requires DMEPOS suppliers to be accredited by an approved organization to receive and retain a supplier billing number, and it would revise 42 C.F.R. § 424.57(c)(22) by adding a new paragraph with such requirements for DMEPOS suppliers that fabricate and bill for prosthetics and custom-fabricated orthotics.

The accreditation would have to indicate the specific products and services for which the DMEPOS supplier is accredited in order for the QS to receive payment. CMS also is proposing that part of compliance with the ongoing accreditation process would be notifying the accrediting organization of "any changes in personnel, including changes in status or qualifications of employees of the QS or of any personnel utilized by the QS via contract or other business relationship."

Per the statute, no payment may be made for prosthetics or custom-fabricated orthotics that are not fabricated at a facility that meets such criteria as the Secretary deems appropriate. The Agency proposes to define "fabrication facility" as a physical structure that is utilized by a QP or QS to fabricate prosthetics or custom-fabricated orthotics and meets the following requirements (to be set forth at 42 C.F.R. § 424.57(d)(4)):

- Be located in the U.S. or one of its territories;
- Be a business that is organized, established, and licensed under applicable state and federal laws;
- Have a process for maintenance and production of certain fabrication records;

- Have a quality assurance process to identify non-standard outcomes and improve fabrication outcomes;
- Have a periodic review and employee demonstration of fabrication, safety, communication, and operations competencies with corrective action plans for staff who do not meet the minimal standards;
- Have full-time, appropriately-credentialed staff members who are QPs or QSs onsite to fabricate and to supervise fabrication;
- Have a laboratory area with appropriate safety equipment;
- Have a separate waiting area and chairs with armrests, as necessary;
- Have patient care and fitting rooms with appropriate levels of privacy and sanitation (patient fitting and care areas should be separate from the fabrication area);
- Have disinfecting supplies for contaminated materials;
- Have a fabrication facility information system that can track the production, list component part numbers, and quantity, that is linked to patient information and be HIPAA-compliant;
- Have parallel bars, full-length mirror, and appropriate assessment tools;
- Have repair and disinfecting areas clearly labeled;
- Have the ability to handle all potentially hazardous materials properly;
- Have an emergency management plan and a safety management plan;
- Have a policy for detecting/reporting counterfeit suppliers; and
- Have the proper tools, equipment, and computers commonly used in the fabrication of particular items and typically associated with the particular technical approach.

These requirements would apply even if the fabrication facility is in the same location as that of the DMEPOS supplier. CMS intends to require that an accrediting organization "cannot accredit a QS or renew the accreditation of a QS unless the QS uses a fabrication facility that meets the above criteria."

3. Definition of Qualified Practitioner

The Proposed Rule would permit certain eligible professionals and other persons who are not enrolled as accredited DMEPOS suppliers to become QPs to furnish or fabricate prosthetics and "custom-fabricated services and supplies" that are billed to Medicare if the eligible professional or other person meets the training, licensure, and certification requirements in proposed 42 C.F.R. § 424.57(d)(3).

The types of eligible professionals and other persons who could become QPs would be an occupational therapist (as defined at 42 C.F.R. § 484.4); an ocularist (defined as a "trained technician skilled in the arts of fitting, shaping, and painting ocular prosthesis who is certified by the ABC, the BOC, or the National Examining Board of Ocularists); an orthotist (as defined at 42 C.F.R. § 485.70(d)); a pedorthist (defined as a specialist in using footwear to solve problems in, or related to, the foot and lower limb); a physical therapist (defined at 42 C.F.R. § 484.4); a physician who meets the qualifications at 42 C.F.R. § 484.4 and who is specifically educated, certified, or trained in the area of prosthetics and custom-fabricated orthotics; and a prosthetist (as defined at 42 C.F.R. § 485.70(f)).

CMS is proposing certain licensure, training, and certification requirements that the above practitioners would need to meet to be qualified. Proposed 42 C.F.R. § 424.57(d)(3) would require that a person who wants to be a qualified practitioner who furnishes or fabricates prosthetics or custom-fabricated orthotics would have to meet either of the following licensure and certification requirements: (1) licensed in orthotics, pedorthics, or prosthetics by the state; or (2) in states that do not provide licenses, be both specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics, and be certified by the ABC, BOC, or a Secretary-approved equivalent accrediting organization. The Agency is soliciting comments regarding standards by which it should determine that qualified practitioners are specifically trained to provide and manage the provision of pedorthics, prosthetics, and orthotics. It also seeks comment on whether a QP who also is a QS that is enrolled in Medicare as a DMEPOS supplier should be required to obtain certification from ABC or BOC in addition to meeting the QS requirements in the Proposed Rule. The Agency clarifies that "to the extent that a QS does not fabricate a prosthetic or a custom-fabricated orthotic, such item must be fabricated by a QP, and it is the responsibility of the QS to verify the practitioner's qualified status.

4. Claims for Prosthetics and Custom-Fabricated Orthotics

The Agency is proposing that it may revoke a QS's enrollment from Medicare for billing for prosthetics and custom-fabricated orthotics that are not furnished by a QP and fabricated by a QP or QS at a facility that meet such criteria as the Secretary deems appropriate. The revocation decision would be based on facts and circumstances, and it would not be based on a single individual billing or miscoding mistake alone on the part of a supplier.

5. Requirements for Accreditation Organizations

The Proposed Rule specifies requirements for any of the CMS-approved accreditation organizations that accredit suppliers fabricating prosthetics and custom-fabricated orthotics. In addition to meeting the current requirements set forth at 42 C.F.R. § 424.58, the accrediting organization would have to be one of the following: the ABC, the BOC, or an approved DMEPOS accreditation organization that has standards equivalent to the ABC or the BOC (one that employs or contracts with an orthotist, prosthetist, occupational therapist, or physical therapist who meets the QP 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 QSs).

6. Quality Standards

The quality standards required by Sec. 1834(a)(20) of the Social Security Act are those used by the accreditation organizations to determine whether a supplier meets statutory and regulatory requirements and can be accredited. After the issuance of a final rule, CMS would update the DMEPOS quality standards to reflect provisions resulting from the Proposed Rule. While CMS is notifying the public of its intent to update the standards, it is not soliciting comments on the quality standards or on the process for updating them.

QSs who bill Medicare for prosthetics and custom-fabricated orthotics would need to meet the requirements included in the final rule no later than one year after the posting date of the final quality standards or at the time of the supplier's reaccreditation cycle, whichever is later. CMS would expect QPs to meet the licensure and certification requirements within one year of publication of the final rule. CMS says "this takes into consideration the average length (5.5 months) needed by a DMEPOS supplier to complete the DMEPOS accreditation process, in addition to the time that may be needed for an eligible professional to become a QP and become licensed or certified, as well as an extended period due to the additional numbers of suppliers or individuals that may need to meet the new requirements." If an ocularist, orthotist, prosthetist, physicians, pedorthist, occupational therapist, physical therapist or any other eligible professional is not furnishing or fabricating prosthetics or custom-fabricated orthotics, then s/he would not need to meet the specific prosthetics and custom-fabricated orthotics requirements in the Proposed Rule. Similarly, if an enrolled DMEPOS supplier is not billing for the prosthetics and custom-fabricated orthotics subject to the provisions of this proposed rule, then the supplier would not need to meet the specific prosthetics and custom-fabricated orthotics requirements in the Proposed Rule.

7. List of Prosthetics and Certain Custom-Fabricated Orthotics

The statute directs the Secretary to establish an update an appropriate list of items to which the foregoing requirements apply. CMS proposes to implement this requirement in part by adding the following definitions to 42 C.F.R. § 424.57(a):

- "Positive model of the patient" means a particular type of custom fabrication in which one of the following occurs:
    - A negative impression is taken of the patient's body part and a positive model rectification is constructed;
    - A CAD-CAM system that electronically transmits data to a commercial milling machine that carves a rectified model; or
    - A direct formed model using the patient as the positive model.
- "Custom-fabricated" means an item that is individually made for a specific patient. Specifically, a custom-fabricated item is a device that is fabricated based on clinically derived and rectified castings, tracings, measurements, and other images such as x-rays of the body part. The fabrication may involve using calculation,

> 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, laminating, and finishing prior to fitting on the patient. An item is considered custom-fabricated if it is constructed by using one of the positive model techniques described in the definition of positive model of the patient.

The list would be updated through periodic program instructions to reflect any changes. CMS is not soliciting comments on the list at this time. CMS intends to continue to consult with experts in orthotics as changes in positive model techniques occur that might impact the definition and the list of items subject to the requirements of the Act.

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We hope this summary has been helpful to you. Please let us know if you have any questions.