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FACT SHEET
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Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics (CMS-6012-P)

Summary
This proposed rule would implement statutory requirements and specify: the qualifications needed for qualified practitioners to furnish and fabricate prosthetics and custom-fabricated orthotics, and for qualified suppliers to fabricate prosthetics and custom-fabricated orthotics; accreditation requirements that qualified suppliers must meet in order to bill for prosthetics and custom-fabricated orthotics; requirements that an organization must meet in order to accredit qualified suppliers to bill for prosthetics and custom-fabricated orthotics; and a timeframe by which qualified practitioners and qualified suppliers must meet the applicable licensure, certification, and accreditation requirements. This rule would also remove the exemption from quality standards and accreditation that is currently in place in accordance with section 1834(a)(20) of the Act for certain practitioners and suppliers who furnish or fabricate prosthetics and custom-fabricated orthotics. In addition, this rule also includes authority for the Centers for Medicare & Medicaid Services (CMS) to revoke the Medicare enrollment of Durable Medical Equipment, Prosthetics, Orthotics and Supplies **(**DMEPOS) suppliers that submit claims for items that do not meet the requirements of the statute and this proposed rule.

Background
Section 1834(h) of the Social Security Act requires that no Medicare payment shall be made for an item of custom-fabricated orthotics or for an item of prosthetics unless furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria the Secretary determines appropriate. The statute also establishes requirements for both qualified suppliers and qualified practitioners. The proposed rule would implement these provisions.

Provisions of the Proposed Rule
Only qualified practitioners who furnish or fabricate prosthetics and custom-fabricated orthotics and qualified suppliers that fabricate or bill for prosthetics and custom-fabricated orthotics would be subject to these requirements. This rule proposes the following requirements:

- **Qualified Practitioner**. The proposed rule would require that a qualified practitioner must be licensed by the state, or in absence of licensure requirements is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. (ABC) or by the Board for Orthotist/Prosthetist Certification Intl. (BOC), or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics. We are specifically seeking comment on the applicability of these proposed credentialing requirements to physicians.
- Q**ualified Supplier.** A qualified supplier is a DMEPOS supplier that is also accredited by the ABC or by the BOC, or an accredited and approved by a program that the Secretary determines has accreditation and

approval standards that are essentially equivalent to those of such Boards. This rule proposes that the alternative to being accredited by the ABC or the BOC is to be accredited by an organization that employs or contracts with an individual who is certified by the ABC or the BOC to make the accreditation decision.

- **Fabrication Facility.** Fabrication Facility is not defined in the statute. However, because the statute provides that Medicare will pay for items of prosthetics and custom-fabricated orthotics only if furnished by a qualified practitioner and fabricated by a qualified practitioner or qualified supplier at a facility that meets such criteria as the Secretary determines appropriate, we have proposed criteria for facilities at which qualified practitioners and qualified suppliers can fabricate items of prosthetics and custom-fabricated orthotics. We are seeking comment on these proposed criteria.
- **Requirements for Accrediting Organizations.** The statute requires that qualified suppliers must be accredited by the ABC or the BOC or by an accrediting program the Secretary determines is equivalent. We are proposing that accreditation by an organization other than the ABC or the BOC would require that an individual who has been certified by the ABC or the BOC is authorized to make the decision about accreditation for a particular supplier. We are seeking comment on these proposals.
- **Payment for Prosthetics and Custom-fabricated Orthotics.** Only qualified suppliers, or in some cases beneficiaries, can submit a claim to Medicare for items of prosthetics or custom-fabricated orthotics. As required by statutory provisions being implemented by this rule, Medicare will only pay claims for items of prosthetics or custom-fabricated orthotics if the item has been furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate. This rule proposes that qualified suppliers that submit claims for prosthetics or custom-fabricated orthotics that do not meet these requirements may be subject to revocation of their Medicare enrollment and no longer be able to submit claims for payment for any DMEPOS items or services.
- **List of Items**. Section 1834(h)(1)(F)(ii)(I) of the Act requires the Secretary to develop and maintain a list of items to which the provisions of this rule would apply. Only qualified practitioners who furnish and fabricate any of the items on the list and qualified suppliers who fabricate and bill for any of the items on the list are subject to the requirements of this rule. The list is available on the CMS website at cms.gov/medicareprovidersupenroll.
- **Quality Standards**. The quality standards required by section 1834(a)(20) of the Act are used by the accreditation organizations in order to determine whether the supplier meets statutory and regulatory requirements and therefore can be accredited. Any supplier would have to maintain these standards in order to meet the accreditation requirements and be approved as a qualified supplier to bill. After issuance of the final rule, we would update the DMEPOS quality standards to reflect the requirements that qualified practitioners must meet to furnish and fabricate prosthetics and custom-fabricated orthotics and that qualified suppliers must meet in order to fabricate and bill Medicare for prosthetics and custom-fabricated orthotics. In this rule, we announce our intent to solicit comments on the proposed updates to the quality standards as we have done in the past by posting the proposed updates to the quality standards on our website located at the following link: cms.gov/medicareprovidersupenroll. We are not, in this proposed rule, soliciting comment on the quality standards or the process for updating these standards.
- **Effective Dates of the Provisions.** We are proposing that qualified suppliers 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 re-accreditation cycle, whichever is later. For qualified practitioners, we would expect them to meet the licensure and certification requirements proposed and subsequently finalized via rulemaking within one year of publication of the final rule. We are seeking comment on these proposal for effective dates.

CMS will accept comments on the proposed rule until March 13, 2017 and will respond to comments in a final rule. For more information, please visit: https://www.federalregister.gov/.
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