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CMS Proposes Stringent New Medicare Standards for Providers and Suppliers of Prosthetics and Custom-Fabricated Orthotics

by Reed Smith

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CMS has issued a proposed rule that would set forth qualifications that providers and suppliers must meet in order to furnish, fabricate, or bill for prosthetics and custom-fabricated orthotics under the Medicare program. The very prescriptive rule comes more than a decade after the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed CMS to establish standards for such items.

Under the proposed rule, as a condition of Medicare payment, prosthetics and custom-fabricated orthotics (as defined by CMS) must be:

- **Furnished by a qualified practitioner.** CMS proposes to define a qualified practitioner as an occupational therapist, ocularist, orthotist, pedorthist, physical therapist, physician, or prosthetist who meets specified standards. In particular, if the practitioner is not an enrolled Medicare DMEPOS supplier, the practitioner must be: (1) licensed in orthotics, pedorthics or prosthetics, or (2) in states without licensure, specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics, and certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC), the Board for Orthotist/Prosthetist Certification International, Incorporated (BOC), or an organization with equivalent standards. The proposed rule also would remove the current exemption from quality standards and accreditation for certain practitioners and suppliers who furnish or fabricate prosthetics and custom-fabricated orthotics.

- **Billed by a qualified supplier.** CMS proposes to define a qualified supplier as a Medicare DMEPOS supplier that is accredited to furnish prosthetics and custom-fabricated orthotics by a CMS-approved accreditation organization (ABC or BOC, or a program the Secretary determines has standards essentially equivalent to those organizations or that employs or contracts with an individual who is certified by ABC or BOC to make the accreditation decision). Alternatively, the claim may be submitted by a Medicare beneficiary.

- **Fabricated by a qualified practitioner or qualified supplier at a fabrication facility meeting specific standards.** The proposed, highly detailed fabrication facility requirements would include being located in US or its territories and meeting multiple recordkeeping, quality assurance, staffing, and physical facility standards.

CMS has released the list of specific HCPCS codes that would meet the rule's definition of custom-fabricated orthotics and prosthetics and that would be subject to the requirements of the rule. CMS intends to update the DMEPOS quality standards to reflect the provisions of the final rule via a subregulatory process. CMS also proposes that it may revoke a DMEPOS supplier's Medicare enrollment for billing for prosthetics or custom-fabricated orthotics that are ***not*** (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or qualified supplier at (3) a facility meeting the specified criteria.

CMS proposes to require qualified suppliers to comply with the rule no later than 1 year after final quality standards are issued (or by their next supplier revalidation, whichever is later). Qualified practitioners would be required to meet the licensure and certification requirements within 1 year of publication of the final rule. CMS will accept comments on the proposed rule until March 13, 2017.

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