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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6012-P]

RIN 0938-AR84

Medicare Program; Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom-Fabricated Orthotics

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify the qualifications needed for qualified practitioners to furnish and fabricate, and 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. In addition, this rule would remove the current exemption from accreditation and quality standards for certain practitioners and suppliers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-6012-P. Because of staff and

resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6012-P,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-6012-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

John Spiegel, (410) 786-1909.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>.

Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. General Overview

Medicare services are furnished by two types of entities, providers and suppliers. The term "provider of services" is defined in sections 1861(u) and 1866(e) of the Social Security Act (the Act). Based on the statute definition of "provider of services" in sections 1861(u) and 1866(e) of the Act we define and use the term "provider" in our regulations. At §400.202, the term "provider" is defined as a hospital, a critical access hospital (CAH), a skilled nursing facility (SNF), a comprehensive outpatient rehabilitation facility (CORF), a home health agency (HHA), or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to

furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

The term supplier is defined in section 1861(d) of the Act. Supplier is defined as a physician or other practitioner, facility or an entity other than a provider of services that furnishes items or services under Medicare. A supplier that furnishes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is one category of supplier. Section 424.57(a) of our regulations defines a DMEPOS supplier as an entity or individual, including a physician or Part A provider, that sells or rents covered DMEPOS items to Medicare beneficiaries that meets the DMEPOS supplier standards. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists. If a supplier, such as a physician, nurse practitioners, or physical therapist, also furnishes DMEPOS to a patient and bills for those items, then the supplier is also considered to be a DMEPOS supplier and must be screened and enrolled in Medicare as a DMEPOS supplier, meeting all standards and requirements applicable to DMEPOS suppliers in order to be enrolled in and bill Medicare.

Section 1861(n) of the Act defines "durable medical equipment." See https://www.ssa.gov/OP_Home/ssact/title18/1861.htm. Also, the term DME is included in the definition of "medical and other health services" in section 1861(s)(6) of the Act, see https://www.ssa.gov/OP_Home/ssact/title18/1861.htm and also included in the definition of medical equipment and supplies in section 1834(j)(5) of the Act. See https://www.ssa.gov/OP_Home/ssact/title18/1834.htm. Furthermore, the term is defined in § 414.202 as equipment furnished by a supplier or a HHA that--

- Can withstand repeated use;

- Effective for items classified as DME after January 1, 2002 has an expected life of at least 3 years;

- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to an individual in the absence of an illness or injury; and
- Is for use in the home.

Prosthetics and orthotics which are defined under section 1861(s)(9) of the Act as leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition, are included under the coverage definition under section 1861(s)(9) of the Act. We are using this definition of prosthetics and orthotics for the purposes of this proposed rule. They are also described in the Medicare Benefit Policy Manual (100-02), Chapter 15, Section 130 that specifies that these appliances are covered under Part B when furnished incident to physicians' services or on a physician's order.

B. Legislative History

1. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) added section 1834(h)(1)(F) of the Act, which states that no payment shall be made for 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. Section 1834(h)(1)(F) of the Act describes custom-fabricated orthotics as individually fabricated for the patient over a positive model of the patient and also requires education, training, and experience to custom-fabricate.

A qualified practitioner is defined by BIPA 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 qualified supplier 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 Congress directed the Secretary to implement section 427 of BIPA no later than 1 year after the date of the enactment using a negotiated rulemaking process. The negotiated rulemaking committee (the Committee) on Special Payment Provisions for Prosthetics and Certain Custom-fabricated Orthotics was established following the requirements set forth by the Federal Advisory Committee Act (FACA). The Committee held nine meetings from October 2002 to July 2003 and failed to reach a consensus on the rulemaking. Given the continued need to address payment provisions for prosthetics and certain custom-fabricated orthotics, we are proposing policies and inviting public comment on our proposals as described section II. of this proposed rule.

2. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added a new paragraph (20) to section 1834(a) of the Act requiring the Secretary to establish and implement DMEPOS quality standards that suppliers must meet in order to furnish and bill for covered items and services described in new section 1834(a)(20)(D) of the Act, which includes prosthetics and orthotics. The new paragraph (20) also required the Secretary to designate and approve one or more independent accreditation organizations to apply the quality standards. In addition, the new section 1834(a)(20) of the Act required that to obtain or retain a Medicare Part B billing number DMEPOS suppliers must be accredited by one of the approved accreditation organizations.

The DMEPOS quality standards were posted on our website at www.cms.gov/medicareprovidersupenroll as required by section 1834(a)(20)(E) of the Act. On May 1, 2006, we published a proposed rule (71 FR 25654) and a subsequent final rule on August 18, 2006 (71 FR 48354) that specified the criteria that all approved accreditation

organizations must meet, set forth in § 424.58. In December 2006, we approved 11 accreditation organizations. As a result of a merger of two of the accreditation organizations, there are now 10 accreditation organizations.

All DMEPOS suppliers must meet the quality standards. The quality standards required by section 1834(a)(20) of the Act are used by the approved accrediting organizations as the basis for their accrediting decisions.

3. Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)

Section 154(b) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275 amended section 1834(a)(20) of the Act by adding a new subparagraph (F) to require DMEPOS suppliers furnishing covered items and services, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of being accredited as meeting the applicable quality standards on or after October 1, 2009. Section 1834(a)(20)(F)(ii) of the Act provided the Secretary the authority to exempt "eligible professionals" and such "other persons" from the quality standards and accreditation requirement 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 licensing, accreditation or other mandatory quality requirements apply to such eligible professionals and other persons. Eligible professionals are defined at section 1848(k)(3)(B) of the Act as a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, physical or occupational therapist or a qualified speech-language pathologist. Section 1834(a)(20)(F)(ii) of the Act specifically refers to orthotists and prosthetists as examples of "other persons." 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.

To date there have not been accreditation or quality requirements designed specifically to be applied to such eligible professionals and thus as a result, all eligible professionals and other persons, including orthotists and prosthetists, that furnish, fabricate, and bill for prosthetics and certain custom-fabricated orthotic items are currently exempt from the quality standards and the accreditation requirement.

II. Provisions of the Proposed Regulations

This proposed rule would implement certain provisions of section 1834(h)(1)(F) of the Act. It would establish the qualifications and requirements that must be met in order to be considered a qualified practitioner or a qualified supplier. This proposed rule would also amend the special payment rules for items furnished by DMEPOS suppliers set forth at § 424.57 and the accreditation organization requirements in § 424.58. 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.

Specifically, we are proposing the following:

- Removing 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.

- Revising § 424.57 to include a definition of custom-fabricated orthotics as an item as listed in section 1861(s)(9) of the Act that must be individually made for a specific patient, constructed using one of the positive model techniques listed in § 424.57(a).

- Revising §424.57(a) to include a definition of positive model of the patient as a particular type of custom fabrication in which one of the following modeling techniques is used:

- ++ Molded to the patient model as a negative impression of the patient's body part and a positive model rectification are constructed.

- ++ Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) system.

- ++ Direct formed model.

- Defining "qualified supplier" as a DMEPOS supplier that is accredited in accordance with the section 1834(a)(20) of the Act.

- Defining "qualified practitioner" as an eligible professional or other person that meets the education, training, licensure, and certification requirements of the section 1834(h)(1)(F) of the Act.

- Specifying training, licensure, and certification requirements that qualified practitioners must meet in order to furnish or fabricate prosthetics and custom-fabricated orthotics.

- Requiring that claims for prosthetics and custom-fabricated orthotics that are submitted by qualified suppliers or by beneficiaries must have been furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier as defined in this proposed rule. Suppliers that do not meet these requirements are at risk of revocation of their Medicare enrollment.

- Defining 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.

- Define "fabrication facility" and specify the requirements that a facility must meet in order for qualified practitioners and qualified suppliers to be able to fabricate prosthetics and custom-fabricated orthotics that can be paid for by Medicare.

Separately, in this proposed rule we also--

- Describe our intent to modify the DMEPOS quality standards to reflect the provisions of this rule, including the effective date for meeting the revised quality standards; and
- Provide the list of services and supplies subject to the requirements of this rule (www.cms.gov/medicareprovidersupenroll).

We provide a link to the list of items and describe our intent to revise the quality standards as information only. We are not soliciting comments on the content of or the process for updating the quality standards, which will be addressed through the regulatory process we reference in section II.A.6.a. of this proposed rule. Nor are we soliciting comment on the content of or process for updating the list of items and supplies, which is described in section II.B. of this proposed rule. Comments on those matters will be considered outside the scope of this rule.

A. Updating of Accreditation and Certification Requirements

1. Removing the MIPPA Exemptions for DMEPOS Suppliers and Certain Eligible Professionals and Other Persons Who Furnish or Fabricate Prosthetics and Custom-fabricated Orthotics

Consistent with the provisions of the Act, including those provisions added by BIPA, MMA, and MIPPA, we have put in place a framework for accreditation of suppliers that fabricate DMEPOS and bill for DMEPOS services. However, qualified practitioners and qualified suppliers are currently exempt from having to meet the quality standards or to be accredited as suppliers in order to be able to bill Medicare for prosthetics and custom-fabricated orthotics. We are removing the exemptions in order to implement the provisions of section 1834(a)(20) of the Act.

As noted previously, section 1834(a)(20)(F)(ii) of the Act provided the Secretary the authority to exempt "eligible professionals" (as defined in section 1848(k)(3)(B) of the Act) and

such "other persons" from the quality standards and accreditation requirement 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 licensing, accreditation or other mandatory quality requirements apply to such eligible professionals and other persons. The Secretary did not determine that there were standards designed specifically to be applied to such eligible professionals and other persons and the Secretary did not determine that licensing, accreditation or other mandatory quality requirements apply to such eligible professionals and other persons. Therefore, we issued a fact sheet on our website announcing the exemption at www.cms.gov/medicareprovidersupenroll.

Through this proposed rule, we are now designing standards specifically to apply to such eligible professionals and other persons. We believe that it is imperative to have both licensure and certification requirements for all qualified practitioners (eligible professionals and other persons who furnish or fabricate prosthetics and custom-fabricated orthotics) and to have accreditation requirements for all qualified suppliers (DMEPOS suppliers that fabricate or bill for prosthetics and custom-fabricated orthotics that are subject to the requirements of this proposed rule). Moreover, we believe that the provisions in section 1834(a)(20) of the Act were enacted to achieve that objective.

Therefore, in order to ensure that only those who are qualified to do so can furnish, fabricate, and bill for the prosthetics and custom-fabricated orthotics addressed by this proposed rule, we would remove the exemption from having to meet the quality standards and the exemption from having to be accredited that currently exist for eligible professionals and other persons that furnish, fabricate or bill for prosthetics and custom-fabricated orthotics.

2. Definition and Accreditation Requirements for Qualified Suppliers

Consistent with the provisions in section 1834(h)(1)(F) of the Act, which require that no payment will be made unless those furnishing prosthetics and custom-fabricated orthotics are qualified to do so, we are proposing to define qualified supplier, in § 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 that meets the proposed requirements that an organization must meet to accredit qualified suppliers of prosthetics and custom-fabricated orthotics in § 424.58(c) (described in section II.A.5. of this proposed rule).

In our existing regulations at §424.57(c)(22), we require DMEPOS suppliers to be accredited by a CMS-approved accrediting organization to receive and retain a supplier billing number. We also state that the accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the supplier to receive payment. To implement the statutory requirements regarding accreditation requirements for eligible professionals and other persons who want to furnish and bill for prosthetics and custom-fabricated orthotics, we would revise § 424.57(c)(22) by--

- Redesignating the existing text as paragraph (c)(22)(i). We would also make clarifying, technical, and conforming changes. We note that changes would not modify the intent of this provision. We also note that this requirement would still be applicable to all DMEPOS suppliers.
- Adding a new paragraph (c)(22)(ii) to state the additional accreditation requirements for DMEPOS suppliers that would be fabricating and billing for prosthetics and custom-fabricated orthotics. In order to be a qualified supplier, the DMEPOS supplier must be

accredited by a CMS-approved accreditation organization for prosthetics and custom-fabricated orthotics as described in § 424.58(c). The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the qualified supplier (as defined in §424.57(a)) to receive payment for the specific prosthetics and custom-fabricated orthotics. We are also proposing that as part of compliance with the ongoing accreditation process, qualified suppliers must notify the AO of any change in conditions, practices, or operations that were relied upon by the AO at the time of accreditation. This would include, but not be limited to, a requirement for notifying the AO of any changes in personnel, including changes in status or qualifications of employees of the qualified supplier or of any personnel utilized by the qualified supplier via contract or other business relationship. This requirement is included to ensure that qualified suppliers, once accredited, continue to meet all of the accreditation and other supplier standards. (See section II.A.5. of this proposed rule for more detailed information regarding our proposed requirements for accrediting organizations.)

Section 1834(h)(1)(F) of the Act requires, in part, that no payment can be made for prosthetics or custom-fabricated orthotics unless the item is fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate. Therefore, we are proposing to define and establish the criteria that such a facility must meet. We are proposing to define "fabrication facility" to distinguish this facility type from others referenced in our regulations. In §424.57(a), we would define a fabrication facility as a physical structure that--

- Meets the requirements in §424.57(d)(4); and
- Is utilized by a qualified practitioner or a qualified supplier to fabricate prosthetics or custom-fabricated orthotics.

In §424.57(d)(4), based on input from other government agencies and contractors that are involved in ensuring that prosthetics and custom-fabricated orthotics are furnished, fabricated and paid for properly, we would specify that the fabrication facility at which qualified suppliers and qualified practitioners fabricate prosthetics and custom-fabricated orthotics, as defined in §424.57(a), must meet all of the following requirements:

- Be located within the United States 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 fabrication records including the following:

- ++ Job/work orders.
- ++ Record tracking systems.
- ++ Real time recordkeeping, for example, ensuring that records are updated as the fabrication takes place.

- ++ Secure storage of records with electronic and hard copy back-up.
- Have a quality assurance process to identify non-standard production outcomes, and improve fabrication outcomes.

- Have a periodic review and employee demonstration of fabrication/safety/communication/operations competencies with corrective action plans for staff that do not meet the minimal standards.

- Have full time appropriately credentialed staff member(s) who are (qualified practitioners or qualified suppliers) onsite to fabricate and to supervise fabrication.

- Have a laboratory area with appropriate safety equipment (for example, flammable

material storage, gloves, safety glasses, and proper ventilation)

- 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, gloves, masks, and plastic for containing contaminated materials.

- Have a fabrication facility information system, paper or digital, that can track the production, list component part number (and serial number if available) and quantity, and that is linked to patient information and be Health Insurance Portability and Accountability Act compliant. Such a system must allow facility staff and management, including those fabricating, to identify any parts that could be recalled at a later date.

- Have parallel bars, a full-length mirror, and other appropriate assessment tools.
- Have a process that mandates following precautions to handle used patient devices that are contaminated.

- Have repair and disinfecting areas clearly labeled.
- Have the ability to handle all potentially hazardous materials in facility properly.
- Have an emergency management plan and a safety management plan.
- Have policy for detecting/reporting counterfeit supplies.
- Have the proper tools, equipment, and computers commonly used in the fabrication of particular items and typically associated with the particular technical approach (negative impression/positive model, CAD-CAM, or direct formed), as applicable. These tools and equipment would include, but are not limited to the following

- ++ Computers with appropriate graphics/modeling capacity and technology.

- ++ Band saw.
- ++ Disc sander.
- ++ Sanding paper.
- ++ Flexible shaft sander.
- ++ Lathe.
- ++ Drill press.
- ++ Sewing machine.
- ++ Grinding equipment.
- ++ Paint-spraying equipment.
- ++ Welding equipment.
- ++ Alignment jig.
- ++ Ovens capable of heating plastics for molding.
- ++ Computer controlled milling machine.
- ++ Lockable storage areas for raw materials and finished devices.
- ++ Air compressor.

We note that these requirements would apply even if the fabrication facility is the same location as that of the DMEPOS supplier.

We intend to require that AO's cannot accredit a qualified supplier or renew the accreditation of a qualified supplier unless the qualified supplier uses a fabrication facility that meets these criteria. We are seeking comment on the definition of a fabrication facility and its requirements.

3. Definition of Qualified Practitioner

We are also proposing to define qualified practitioner in § 424.57(a). Our proposal would permit certain eligible professionals and other persons who are not enrolled as an accredited DMEPOS supplier to become a qualified practitioner to furnish or fabricate prosthetic 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 § 424.57(d)(3).

a. Specific Eligible Professionals and Other Persons

In § 424.57(a), we would identify and define the types of eligible professionals and other persons who can become qualified practitioners, and therefore, in accordance with the BIPA provisions, furnish or fabricate prosthetics and custom-fabricated orthotics. Specifically, we propose to identify and to add definitions for the following practitioners: (1) occupational therapist; (2) ocularist; (3) orthotist; (4) pedorthist; (5) physical therapist; (6) physician; and (7) prosthetist.

- Occupational Therapist. Our current regulations at § 484.4 specify in detail the personnel qualifications for an occupational therapist. We are proposing to define an occupational therapist as an individual who meets the requirements in § 484.4. We are specifically requesting comments on these proposed qualifications for an occupational therapist to furnish/fabricate prosthetics and custom-fabricated orthotics.

- Ocularist. The American Society of Ocularists defines an ocularist as a trained technician skilled in the arts of fitting, shaping, and painting ocular prostheses. We note, as indicated by the National Examining Board of Ocularists, that in addition to creating ocular prostheses, the ocularist typically shows the patient how to handle and care for the prosthesis, and provides long-term care through periodic examinations. We are proposing to define an

ocularist as a trained technician skilled in the arts of fitting, shaping, and painting ocular prostheses who is certified by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC), the Board for Orthotist/Prosthetist Certification International, Incorporated (BOC) or the National Examining Board of Ocularists. We are specifically requesting comments on these proposed qualifications for an ocularist to furnish/fabricate prosthetics and custom-fabricated orthotics.

- Orthotist. Our current regulations in § 485.70(d) specify the following personnel qualifications for an orthotist:

- ++ Be licensed by all states in which practicing, if applicable.

- ++ Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics.

- ++ Be eligible to take that Board's certification examination in orthotics.

We are proposing to define an orthotist as an individual who meets the personnel qualifications in § 485.70(d). We are specifically requesting comments on these proposed qualifications for an orthotist to furnish or fabricate prosthetics and custom-fabricated orthotics.

- Pedorthist. The Pedorthic Footcare Association defines a pedorthist as a specialist in using footwear -- which includes shoes, shoe modifications, foot orthoses and other pedorthic devices -- to solve problems in, or related to, the foot and lower limb. We are proposing to define pedorthist in this manner. We are specifically requesting comments on these proposed qualifications for a pedorthist to furnish or fabricate prosthetics and custom-fabricated orthotics.

- Physical Therapist. Our current regulations at § 484.4 specify in detail the personnel qualifications for a physical therapist. We are proposing to define a physical therapist as an

individual who meets the requirements in § 484.4. We are specifically requesting comments on these proposed qualifications for a physical therapist to furnish or fabricate prosthetics and custom-fabricated orthotics.

- Physician. Our current regulations at § 484.4 specify the personnel qualifications for a physician. In addition to those requirements, we propose to require that for purposes of furnishing or fabricating prosthetics and custom-fabricated orthotics, a physician must be specifically educated, certified or trained in the area of prosthetics and custom-fabricated orthotics. The physician must be knowledgeable and competent (as evidenced by education and experience) in the assessment, furnishing, fabrication, care, and follow-up needs of the patient as specifically delineated in the DMEPOS quality standards (discussed in section II.A.6. of this proposed rule). We are proposing such knowledge and competency requirements because we believe it is only specialty physicians who are trained and experienced, and who understand the specialized needs of the beneficiary requiring prosthetics and custom-fabricated orthotics. We are specifically requesting comments on these proposed additional qualifications for a physician to furnish prosthetics and custom-fabricated orthotics.

Doctors of dental surgery or dental medicine, doctors of optometry, psychiatrists, and chiropractors do not customarily furnish or fabricate prosthetics and custom-fabricated orthotics. Therefore, we have not proposed requirements for these eligible professionals or any others who do not typically furnish or fabricate the prosthetics and custom-fabricated orthotics that are subject to the provisions of this proposed rule. However, any qualified practitioner who furnishes or fabricates prosthetics or custom-fabricated orthotics and any qualified supplier that fabricates or bills for such services must meet the applicable requirements as specified in this rule.

- Prosthetist. A prosthetist is able to provide all types prosthetics, with the exception of facial prosthetics. Our current regulations at § 485.70(f) specify the personnel qualifications for a prosthetist as follows:

- ++ Be licensed by all states in which they are practicing, if applicable.

- ++ Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics.

- ++ Be eligible to take that Board's certification examination in prosthetics.

We are proposing to define a prosthetist as an individual who meets the personnel qualifications in § 485.70(f). We are specifically requesting comments on these proposed qualifications for a prosthetist to furnish or fabricate prosthetics and custom-fabricated orthotics.

b. Training, Licensure, and Certification Requirements for Qualified Practitioners

In addition to defining the types of professionals that would be eligible to furnish and fabricate prosthetics and custom-fabricated orthotics, we are proposing certain licensure, training, and certification requirements that these practitioners must meet to be qualified practitioners who furnish or fabricate prosthetics or custom-fabricated orthotics that are billed to Medicare by qualified suppliers. Furnishing and fabricating prosthetics and custom-fabricated orthotics for Medicare beneficiaries, who need these items and services, is multifaceted and complex. We have proposed a framework of requirements designed to ensure that eligible professionals possess the skills and training to furnish and fabricate these items and services. It is important that the qualified practitioners who furnish and fabricate these items meet the requirements specified in this proposed rule.

Therefore, in proposed § 424.57(d)(3), we would specify that an eligible professional or

other person who wants to be a qualified practitioner who furnishes or fabricates prosthetics or custom-fabricated orthotics must meet either of the following licensure and certification requirements:

- ++ Licensed in orthotics, pedorthics or prosthetics by the state.

- ++ In states that do not provide licenses for orthotics, pedorthics or prosthetics, must be both of the following:

- Specifically, trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics.

- Certified by the one of the following:

- +++ ABC.

- +++ BOC.

- +++ A Secretary-approved organization that has standards equivalent to the ABC or BOC.

We believe these proposed requirements would ensure that the specialized needs of Medicare beneficiaries who require prosthetics and custom-fabricated orthotics are met. We are specifically seeking comment on these requirements and, in particular, we are very interested in comments regarding standards by which we should determine that qualified practitioners are specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics. For example, we solicit feedback on any relevant metrics, data sources or methods and processes to gauge competencies. We would appreciate comments on whether a qualified practitioner who is also a qualified supplier that is enrolled in Medicare as a DMEPOS supplier should be required to obtain certification from ABC or BOC in addition to meeting the qualified supplier requirements in this proposed rule.

We also clarify that, to the extent that a qualified supplier does not fabricate a prosthetic or a custom-fabricated orthotic, such prosthetic or custom-fabricated orthotic must be fabricated by a qualified practitioner, and that it is the responsibility of the qualified supplier to verify the practitioner's qualified status.

4. Claims for Prosthetics and Custom-Fabricated Orthotics

As stated previously, we are proposing that all DMEPOS suppliers that bill for prosthetics and custom-fabricated orthotics must meet the supplier standards in § 424.57, the quality standards (discussed in section II.A.6. of this proposed rule) and be accredited by one of the CMS-approved accrediting organizations.

We have proposed in § 424.535(a)(2)(iii) that we may revoke a qualified supplier's enrollment from Medicare for billing for prosthetics and custom-fabricated orthotics that are not 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 is particularly important because for those qualified practitioners who are not eligible to be enrolled in Medicare or who are not permitted to opt out of Medicare, there will be no CMS repository of information about their licensure or certification. The qualified supplier would be responsible for ensuring that the qualified practitioners who furnish or the qualified practitioners and qualified suppliers who fabricate the items for which the qualified supplier submits a bill meet the requirements of this rule. The decision about revocation based on the authority in § 424.535(a)(2)(iii) will be made based on the facts and circumstances of the particular situation, and will not be based on a single individual billing or miscoding mistake alone on the part of a supplier. We are specifically seeking comment on the implementation of this requirement, including how DMEPOS suppliers envision that they would comply with the requirements that

they can bill only for prosthetics and custom-fabricated orthotics that have been furnished by qualified practitioners and fabricated by qualified practitioners or qualified suppliers at a facility that meets such criteria as the Secretary determines appropriate.

5. Requirements for Accreditation Organizations

Section 1834(a)(20)(B) of the Act requires the Secretary to designate and approve one or more independent accreditation organizations to apply the quality standards required in section 1834(a)(20)(A) of the Act. In the August 18, 2006 final rule (71 FR 48354), we implemented our regulations at § 424.58 that specified the criteria that all approved accreditation organizations must meet. In this proposed rule, we would specify requirements for any of the CMS-approved accreditation organizations that accredit suppliers fabricating prosthetics and custom-fabricated orthotics. In § 424.58, we are proposing to redesignate paragraphs (c) through (e), as paragraphs (d) through (f), and adding a new paragraph (c). In paragraph (c), we would specify that any approved accreditation organization must meet the following additional accreditation requirements to accredit suppliers that bill for prosthetics and custom-fabricated orthotics. In addition to meeting the current requirements set forth under § 424.58, the accreditation organization must be one of the following:

- The ABC.
- The BOC.
- An approved DMEPOS accreditation organization that has standards equivalent to the ABC or BOC.

We are proposing to define "a DMEPOS accreditation organization that has standards equivalent to the ABC or BOC" as one that employs or contracts with an orthotist, prosthetist, occupational therapist, or physical therapist who meets the qualified practitioner 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 qualified suppliers.

We believe that these proposed requirements are in concert with the provisions of section 1834(h) of the Act requiring that the supplier be accredited by the ABC, the BOC or accredited by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board. We are specifically seeking comment on the proposed definition.

6. Quality Standards Required in Section 1834(a)(20) of the Act

a. Overview of and Process for Updating the 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 a 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, continue to bill or fabricate Medicare Part B prosthetics and custom-fabricated orthotics.

After issuance of the final rule, we would update the DMEPOS quality standards to reflect the provisions contained in the final rule resulting from this proposed rule. The revised quality standards would include specifically 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. We plan to solicit comments on the proposed updates to the quality standards as we have done in the past, and as set forth in section 1834(a)(20)(E) of the Act, by posting the proposed updates to the quality standards on our website at:

www.cms.gov/medicareprovidersupenroll. The quality standards are updated via our subregulatory process. Therefore, while we are notifying the public of our intent to update the quality standards, we are not, in this proposed rule, soliciting comment on the quality standards or the process for updating these standards.

b. Effective Date for Compliance with New Quality Standards

We are proposing in § 424.57(c)(22)(ii) 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 1 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 1 year of publication of the final rule. This takes into consideration the average length of time (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 qualified practitioner 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. We are requesting comment on the proposed implementation schedule so that we may ensure that there is no disruption in patient access to services or care.

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 they would not need to meet the specific prosthetics and custom-fabricated orthotics requirements in this 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 this proposed rule.

B. List of Prosthetics and Certain Custom-Fabricated Orthotics

The requirements of section 1834(h)(1)(F) of the Act apply to all prosthetics and certain custom-fabricated orthotics described in section 1834(h)(1)(F)(ii) of the Act. Section 1834(h)(1)(F)(ii)(I) of the Act, as added by section 427 of BIPA, states that an item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary. Section 1834(h)(1)(F)(ii)(I) of the Act also specifies that an item of custom-fabricated orthotics does not include shoes and shoe inserts.

Section 1834(h)(1)(F)(ii)(II) of the Act as added by section 427 of BIPA states that the Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of the same), shall establish and update as appropriate a list of items to which this subparagraph applies. No orthotic may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient as defined later. On August 19, 2005, we issued program instructions (Transmittal 656, CR 3959) implementing the list of HCPCS codes describing prosthetics and custom-fabricated orthotics subject to the requirements of section 1834(h)(1)(F) of the Act. The list of HCPCS codes describing items subject to the requirements of section 1834(h)(1)(F) of the Act has been updated to reflect changes in HCPCS codes that have occurred since 2005. This list of HCPCS codes describing items subject to the requirements of section 1834(h)(1)(F) of the Act would continue to be updated through program instructions, as needed. The list is available on the CMS website at www.cms.gov/medicareprovidersupenroll.

In keeping with the statute's intent to consult with appropriate experts in developing the list, we not only reviewed the Committee's recommendations, but also consulted with the following:

- American Physical Therapy Association.
- Medicare Pricing, Data, Analysis and Coding (PDAC) contractor(s).
- Orthotic & Prosthetic Alliance.
- The American Occupational Therapy Association.
- The American Orthotic & Prosthetic Association.
- The U.S. Department of Veterans Affairs.

To implement this statutory provision, we propose to add the following definitions in §424.57(a):

- Positive model of the patient means a particular type of custom fabrication in which one of the following occurs:

- ++ Is molded to the patient model as a negative impression taken of the patient's body part and a positive model rectification are constructed.

- ++ A Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model.

- ++ A direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all the necessary adjustments are made.

- 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.

Lastly, we would specify in § 424.57(d)(2) that items on the list must be-- (1) furnished by a qualified practitioner; (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate; and (3) billed by a qualified supplier or, submitted as a claim by a beneficiary.

The list would be updated through periodic program instructions to reflect any changes. We intend to update the list as needed on the CMS website at www.cms.gov/medicareprovidersupenroll. We note that the list of services and supplies that are subject to the provisions of this proposed rule is being provided for information only. We are not, in this proposed rule, soliciting comments on the list.

We would continue to consult with experts in orthotics as changes in positive model techniques occur that might impact the definition and list of items subject to section 1834(h)(1)(F) of the Act. Any such changes to the list of items would be issued through program instructions. We would continue to ensure that any change to the list of prosthetics and custom-fabricated orthotics is done in concert with our established processes.

We would issue contractor instructions and a provider educational article detailing the list of HCPCS codes for the prosthetics and custom-fabricated orthotic items to which the requirements apply, as well as instructions to DMEPOS suppliers regarding billing, data collection, and systems operations following the publication of the final rule. Any changes to the list items would also be published in future CMS contractor instructions.

III. Collection of Information Requirements

A. Background

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. ICRs Regarding DMEPOS Suppliers and Eligible Professionals Providing Custom-Fabricated Orthotics (§ 424.57)

1. Accreditation for Physicians and Practitioners Enrolled as DMEPOS Suppliers

Under § 424.57(c)(22), DMEPOS suppliers that furnish, fabricate and bill for prosthetics

or custom-fabricated orthotics must meet all accreditation requirements specified in these provisions, and be licensed in orthotics, pedorthics, or prosthetics in the state in which its practice is located (if the state requires such licensure). Table 1 identifies categories and approximate numbers of individuals who, as of February 2014: (1) are enrolled in Medicare as DMEPOS suppliers; (2) have billed Medicare for prosthetic devices; and (3) are ABC or BOC certified. This data is based on internal CMS statistics, though the figures in Table 1 are merely rough estimates for purposes of this proposed rule. These individuals have met all applicable state licensure requirements (for example, for furnishing prosthetics).

TABLE 1: PROSTHETICS

Category	Number Enrolled as DMEPOS Suppliers	Number Who Are ABC or BOC Certified
Prosthetists	8,000	5,000
Physicians	5,000	3,000
Physical and Occupational Therapists	1,000	500
Ocularists	400	200
Orthotists	1,500	800
Pedorthists	900	500
Total	16,800	10,000

The 10,000 physicians and practitioners in Table 1 who are enrolled as DMEPOS suppliers and are accredited would meet the requirements of proposed § 424.57(c)(22); hence, the information collection requirements in this proposed rule would not affect them. However, the remaining 6,800 would need to obtain ABC or BOC accreditation in order to bill Medicare for prosthetics.

Table 2 identifies categories and approximate numbers of individuals who, as of February 2014: (1) are enrolled in Medicare as DMEPOS suppliers; (2) have billed Medicare for custom-fabricated orthotics; and (3) are ABC or BOC certified. This data, too, is based on internal CMS statistics. All of these persons have met the applicable state licensure requirements (for example, for furnishing custom-fabricated orthotics).

TABLE 2: CUSTOM-FABRICATED ORTHOTICS

Category	Number Enrolled as DMEPOS Suppliers	Number Who Are ABC or BOC Certified
Prosthetists	4,000	2,000
Physicians	3,000	1,500
Physical and Occupational Therapists	1,000	500
Ocularists	300	200
Orthotists	4,000	2,500
Pedorthists	700	400
Total	13,000	7,100

The 7,100 physicians and practitioners in Table 2 who are currently enrolled as DMEPOS suppliers and are accredited would meet the requirements of proposed § 424.57(c)(22).

Accordingly, the information collection requirements in this proposed rule would not affect them. However, the remaining 5,900 would need to obtain ABC or BOC accreditation in order to bill Medicare for custom-fabricated orthotics.

Although it is highly likely that some of the individuals in Tables 1 and 2 provide both prosthetics and custom-fabricated orthotics, we have chosen to assume that the tables reflect unduplicated counts of physicians and practitioners.

We cannot estimate the number of physicians and practitioners in the universe of 12,700 (6,800 + 5,900) who would either decline to obtain accreditation because of cost, other factors or inability to meet the accreditation requirements. We believe that the overwhelming majority of the 12,700 physicians and practitioners would elect to and become accredited to continue to provide, bill, or both provide and bill for these devices. We expect that a lower percentage of physicians, physical therapists, and occupational therapists would seek accreditation than would prosthetists, orthotists, pedorthists, and ocularists. This is because furnishing prosthetics and custom-fabricated orthotics traditionally constitutes a smaller portion of their practices than is the case with the latter four practitioner types. For purposes of this burden estimate only, and as

outlined in Table 3, we project that-- (1) all prosthetists, orthotists, ocularists, and pedorthists would pursue accreditation; and (2) 90 percent of physicians, physical therapists, and occupational therapists would seek accreditation. This results in a base figure of 12,250 physicians and practitioners that is only slightly less than the 12,700-person universe mentioned previously.

TABLE 3: NUMBER OF PHYSICIANS AND PRACTITIONERS SEEKING ACCREDITATION

Category	Approximate Percentage of Universe*	Number
Prosthetists	40.8	5,000
Physicians	25.7	3,150
Physical and Occupational Therapists	7.3	900
Ocularists	2.5	300
Orthotists	18.0	2,200
Pedorthists	5.7	700
Total		12,250

* Rounded to nearest tenth

The hour and cost burdens on these physicians and practitioners of completing and submitting the paperwork associated with accreditation would vary because each physician's and practitioner's specific circumstances differ. However, we believe that an average per physician/practitioner time burden of 10 hours is reasonable, though we welcome comments on this estimate. This 10-hour period would include the time involved in completing and submitting the necessary accreditation paperwork, including obtaining any required supporting documentation.

Many of the 12,250 physicians and practitioners are part of group practices that have administrative personnel who handle various paperwork functions on behalf of the group's physicians and practitioners. It is probable that some administrative personnel would complete and submit the physicians' and practitioners' accreditation paperwork. However, we have no data

that can help us predict the number of instances in which this would occur. In an effort not to underestimate the potential cost burden, we will assume for purposes of our analysis that physicians and practitioners would complete and submit their accreditation applications.

Table 4 identifies the mean hourly wages for the Bureau of Labor Statistics (BLS) categories that most appropriately apply to the physician and practitioner types mentioned previously. The data is from May 2015, the most recent month for which information is available; see http://www.bls.gov/oes/current/oes_nat.htm#43-0000. As there are no specific BLS categories for ocularists and pedorthists, we will include them within the larger category of orthotists and prosthetists.

TABLE 4: BLS MEAN HOURLY WAGES USING MAY 2015 DATA

BLS Category	BLS Mean Hourly Wage (\$)	Hourly Wage with Fringe Benefits and Overhead (\$)
Orthotists and Prosthetists*	33.63	67.26
Physicians and Surgeons	97.33	194.66
Physical Therapists	41.25	82.50 **
Occupational Therapists	39.27	78.54 **

*Includes ocularists and pedorthists.

**The average mean hourly wage for physical and occupational therapists combined, which we will use in our analysis, is \$80.52 (or $(\$82.50 + \$78.54)/2$).

Table 5 identifies the total hour and cost burdens for enrolled physicians and practitioners seeking accreditation. The cost burdens are based on the wage estimates in Table 4.

TABLE 5: TOTAL HOUR AND COSTS BURDENS FOR ENROLLED PHYSICIANS AND PRACTITIONERS SEEKING ACCREDITATION

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	5,000	10	50,000	67.26	3,363,000
Physicians	3,150	10	31,500	194.66	6,131,790
Physical and Occupational Therapists	900	10	9,000	80.52	724,680
Ocularists	300	10	3,000	67.26	201,780
Orthotists	2,200	10	22,000	67.26	1,479,720

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Pedorthists	700	10	7,000	67.26	470,820
Total	12,250		122,500		12,371,790

Although this burden would be incurred in the first year of our proposed requirement, 3 years is the maximum length of an OMB approval. Therefore, we must average the totals in Table 5 over a 3-year period. This result in the following average annual figures of: (1) 4,083 affected physicians and practitioners; (2) 40,830 ICR burden hours; and (3) \$4,123,930 in ICR burden costs.

2. Accreditation for Newly Enrolling Physicians and Practitioners

Table 6 outlines the annual number of physicians and practitioners who, based on historical CMS data, would-- (1) seek accreditation in accordance with § 424.57(c)(22); (2) enroll in Medicare as DMEPOS suppliers; and (3) bill Medicare for prosthetics or custom-fabricated orthotics.

TABLE 6: ANNUAL NUMBER OF PHYSICIANS AND OTHER PRACTITIONERS SEEKING ACCREDITATION, ENROLLING IN MEDICARE AS DMEPOS SUPPLIERS, AND BILLING FOR PROSTHETICS OR CUSTOM-FABRICATED ORTHOTICS

Category	Number of Enrollees
Prosthetists	400
Physicians	250
Physical and Occupational Therapists	100
Ocularists	40
Orthotists	400
Pedorthists	100
Total	1,290

Table 7 outlines the annual hour and cost burdens for newly enrolling physicians and practitioners. The table applies the 10-hour and BLS wage estimates mentioned previously.

TABLE 7: ANNUAL HOUR AND COST BURDENS FOR NEWLY ENROLLING PHYSICIANS AND PRACTITIONERS SEEKING ACCREDITATION

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	400	10	4,000	67.26	269,040
Physicians	250	10	2,500	194.66	486,650
Physical and Occupational Therapists	100	10	1,000	80.52	80,520
Ocularists	40	10	400	67.26	26,904
Orthotists	400	10	4,000	67.26	269,040
Pedorthists	100	10	1,000	67.26	67,260
Total	1,290		12,900		1,199,414

3. Reporting Accreditation via the CMS-855S (Medicare Enrollment Application: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers)

The CMS-855S is currently approved under OMB control number 0938-1056. In order to account for the application information collection requirements contained in this notice of proposed rulemaking, we will submit a revised information collection request for OMB review and approval.

a. Enrolled Physicians and Practitioners

Upon becoming accredited, physicians and practitioners would need to report the accreditation to us via a CMS-855S change of information request. We estimate that it would take physicians and practitioners 30 minutes to complete and submit this change request. Table 8 outlines the total hour and cost burdens of this requirement.

TABLE 8: TOTAL HOUR AND COST BURDENS FOR ENROLLED PHYSICIANS AND PRACTITIONERS REPORTING ACCREDITATION VIA CMS-855S

Category	Number of Physicians	Hour Burden	Total Hour	Hourly Wage	Total Cost
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	and Practitioners	Per Submission	Burden	(\$)	Burden (\$)
Prosthetists	5,000	0.5	2,500	67.26	168,150
Physicians	3,150	0.5	1,575	194.66	306,590
Physical and Occupational Therapists	900	0.5	450	80.52	36,234
Ocularists	300	0.5	150	67.26	10,089
Orthotists	2,200	0.5	1,100	67.26	73,986
Pedorthists	700	0.5	350	67.26	23,541
Total	12,250		6,125		618,590

Although this burden would be incurred in the first year of our proposed requirement, we must average the totals in Table 8 over a 3-year period. This results in: (1) 4,083 affected physicians and practitioners; (2) 2,042 ICR burden hours; and (3) \$206,197 in ICR burden costs.

b. Newly Enrolling Physicians and Practitioners

When completing the CMS-855S initial enrollment application, physicians and practitioners would have to furnish accreditation information on the form. We estimate that this would take 30 minutes per application. Table 9 outlines the total annual hour and cost burdens.

TABLE 9: TOTAL ANNUAL HOUR AND COST BURDENS FOR NEWLY ENROLLING PHYSICIANS AND PRACTITIONERS REPORTING ACCREDITATION VIA CMS-855S

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	400	0.5	200	67.26	13,452
Physicians	250	0.5	125	194.66	24,333
Physical and Occupational Therapists	100	0.5	50	80.52	4,026
Ocularists	40	0.5	20	67.26	1,345
Orthotists	400	0.5	200	67.26	13,452
Pedorthists	100	0.5	50	67.26	4,026
Total	1,290		645		60,634

4. Requirements for Becoming a Qualified Practitioner

Under § 424.57(d)(3), all eligible professionals who wish to become qualified practitioners, to provide prosthetics or custom-fabricated orthotics, and who are not enrolled in Medicare as

DMEPOS suppliers (and therefore do not bill Medicare for these items) must--

- Be licensed in orthotics, pedorthics, or prosthetics in the state in which his or her practice is located if the state requires such licensure; or
- If the state does not require such licensure--
- Be specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, or orthotics; and
- Meet the certification requirements specified in § 424.57(d)(3)(i)(B)(2).

Specifically, this section discusses the hour and cost burdens for physicians and practitioners who are-- (1) not enrolled in Medicare as DMEPOS suppliers; (2) located in a state that does not require licensure in orthotics, pedorthics, and prosthetics; and (3) must obtain certification under § 424.57(d)(3).

Approximately 15 states require licensure to furnish prosthetics and custom-fabricated orthotics. However, we do not have concrete data regarding the number of unenrolled and unlicensed individuals in the 35 other states or the territories who provide these items, for these persons do not bill Medicare for them. For purposes of this burden estimate, and solely to establish a rough figure on which commenters can submit feedback to us, we project that approximately 5,000 physicians and practitioners would seek certification within the first year following the implementation of § 424.57(d)(3). We estimate that 500 physicians and practitioners would seek certification under § 424.57(d)(3) each year thereafter.

As we lack sufficient data regarding the number of qualified practitioners, who fall within the universe of 5,000 physicians and practitioners, we will use the figures in Table 3 as a baseline estimate. To illustrate, orthotists represented 18 percent of the 12,250 suppliers referenced in Table 3 (or 2,200 out of 12,250); we project that 18 percent of the 5,000-person

universe (or 900) would consist of orthotists. We also utilized the wage estimates and the 10-hour projection. This results in the following Year 1 hour and cost burdens associated with § 424.57(d)(3).

TABLE 10: HOUR AND COST BURDENS ASSOCIATED WITH § 424.57(d)(3) IN YEAR 1

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	2,040	10	20,400	67.26	1,372,104
Physicians	1,285	10	12,850	194.66	2,501,381
Physical and Occupational Therapists	365	10	3,650	80.52	293,898
Ocularists	125	10	1,250	67.26	84,075
Orthotists	900	10	9,000	67.26	605,340
Pedorthists	285	10	2,850	67.26	191,691
Total	5,000		50,000		5,048,489

Table 11 reflects the annual hour and cost burdens in Year 2 and each year thereafter.

The figures are based on the 500-individual universe.

TABLE 11: ANNUAL HOUR AND COST BURDENS OF § 424.57(d)(3) IN YEAR 2 AND SUBSEQUENT YEARS

Category	Number of Physicians and Practitioners	Hour Burden Per Submission	Total Hour Burden	Hourly Wage (\$)	Total Cost Burden (\$)
Prosthetists	204	10	2,040	67.26	137,210
Physicians	128	10	1,280	194.66	249,165
Physical and Occupational Therapists	36	10	360	80.52	28,987
Ocularists	13	10	130	67.26	8,744
Orthotists	90	10	900	67.26	60,534
Pedorthists	29	10	290	67.26	19,505
Total	500		5,000		504,145

We averaged the totals in Tables 10 and 11 over a 3-year period. This results in the following annual figures of: (1) 2,000 affected physicians and practitioners; (2) 20,000 burden hours; and (3) \$2,018,926.

C. Final ICR Hour and Cost Burdens

We estimate the following total ICR burdens associated with our proposed provisions in each of the first 3 years of this rule.

TABLE 12: SUMMARY OF ANNUAL INFORMATION COLLECTION BURDENS

Regulation Section(s)	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost (\$)	Total Labor Cost (\$)	Total Cost (\$)
§424.57(c)(22) – Enrolled seeking accreditation	0938-New	12,250	12,250	10	122,250	†	4,123,930	4,123,930
§424.57(c)(22) – Newly enrolling seeking accreditation	0938-New	1,290	1,290	10	12,290	††	1,199,414	1,199,414
§424.57(c)(22) – Enrolled reporting accreditation via 855S	0938-1056	4,083	4,083	0.5	2,042	†††	206,197	206,197
§§424.57(c)(22) – Newly enrolling reporting accreditation via 855S	0938-1056	1,290	1,290	0.5	645	††††	60,634	60,634
§ 424.57(d)(3)***	0938-New	2,000	2,000	10	20,000	†††††	2,018,926	2,018,926
Total		12,746	12,746		75,807		7,609,101	7,609,101

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 1.

† See the values listed in Table 5.

†† See the values listed in Table 7.

††† See the values listed in Table 8.

†††† See the values listed in Table 9.

***The values are based on the 3-year average of the values listed in tables 10 and 11. Three years is the maximum length of an OMB approval.

††††† See the values listed in Tables 10 and 11.

We welcome comments on all burden estimates contained in the collection of information section of this notice of proposed rulemaking.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, (CMS-6012-P)

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IV. Regulatory Impact Statement

This proposed rule would implement a statutory mandate that only individuals and suppliers qualified to do so can furnish, fabricate or bill for prosthetics and custom fabricated orthotics. The statute was enacted to ensure quality of care and eliminate care or services furnished or fabricated by individuals who were not qualified to do so. The idea inherent in the statute is not to deny necessary services but to ensure that the individuals and suppliers furnishing or fabricating these items are qualified to do so. As with all program changes, whether undertaken by us or in response to statutory imperative—as is the case with this rule—we always consider the impact of the proposed changes on access to care. In the case of the statutory provisions being implemented via this rule, we do not believe beneficiary access to care will be significantly affected. This rule involves only a very small percentage of the overall universe of physician, non-physician practitioner, and organizational suppliers. Of those affected, we believe that many either already comply with our proposed requirements or would come into compliance. We acknowledge that there may be some discontinuity of care in instances where a beneficiary seeks or has been receiving items from an individual or supplier that does not meet the requirements of the statute. However, we believe it will be minimal, and the benefit in improved quality of care outweighs the possible discontinuity. In addition, the phased in effective dates for compliance will allow reasonable time for practitioners and suppliers to meet the statutory and regulatory requirements thus minimizing any disruption in access to needed services. We welcome comment on these assumptions.

In summary, we believe that our proposed rule would, as the Congress ostensibly intended in its enactment of section 1834(h)(1)(F) of the Act, protect Medicare beneficiaries and

the Medicare Trust Funds by ensuring that only qualified practitioners furnish prosthetics and custom fabricated orthotics.

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 USC 804(2)).

Executive Order 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

As previously stated in section III. of this proposed rule, we estimate that 12,250 physicians and practitioners who are enrolled as DMEPOS suppliers and who have billed Medicare for prosthetics or custom-fabricated orthotics, but who are not accredited, would seek to obtain accreditation under § 424.57(c)(22) in order to continue billing for such items. Though accreditation figures vary by accreditation organization and by supplier type, we project (based on internal statistics and our review of the range of accreditation fees charged by various accreditation organizations) that the average annual cost for a physician or practitioner to obtain and remain accredited under § 424.57(c)(22) would be roughly \$1,500; this represents the fee charged by the applicable accreditation organization. (This is predicated on a triennial

accreditation cycle, with the accreditation costs being incurred incrementally over the 3-year period.) This results in an annual cost to these individuals of \$18,375,000 (12,250 x \$1,500). In combining this cost with the ICR costs of this proposed rule (as shown in section III. of this proposed rule), we determine that in no year would the total costs of this proposed rule exceed \$100 million. Therefore, this is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organization and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities for two reasons. First, the number of affected parties represents only an extremely small percentage of the universe of over 1.5 million individual and organizational medical providers nationwide. Second, we do not believe an annual cost of \$1,500 combined with the occasional submission of paperwork (as described in section III. of this proposed rule) would have a significant economic impact on these suppliers and practitioners. We believe these costs would be less than 3 percent of the supplier's or practitioner's revenue, as defined by HHS for significant impact.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside

of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation, as the anticipated annual spending is \$30 million. In 2016, that threshold is approximately \$146 million. This proposed rule would have no consequential effect on state, local or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement cost on state and local governments, preempts state law, or otherwise has Federalism implications. Since this rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

There were several uncertainties associated with our proposed projections. First, we could not determine precisely the number of DMEPOS suppliers who would choose not to pursue accreditation or be unable to become accredited. Second, we had no data on which to base our 5,000-person and 500-person estimates in Tables 10 and 11. As such, these estimates are merely designed to solicit comment on the number of individuals who would be affected by § 424.57(d)(3). Third, we welcome comment on our estimation of \$1,500 as the annual cost for a qualified supplier to obtain and remain accredited in accordance our proposals. Fourth, as we

lack sufficient data to estimate any potential burden on fabricating facilities, we request comments regarding the types of possible burden and, if there are any, the costs involved.

We note that by limiting payment to the circumstances described in this rule, our regulations would likely reduce the provision of and billing for these items to instances consistent with the statute. We believe, however, that this would enhance the quality of services and items by ensuring that unqualified entities and individuals are not furnishing such goods, while simultaneously having no real effect on how prices are set for them.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects for 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 424 as set forth below:

PART 424 – CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh).

2. Section 424.57 is amended as follows:

a. In paragraph (a) by adding the definition of "Custom-fabricated orthotics," "Fabrication facility", "Occupational therapist", "Ocularist", "Orthotist", "Podiatrist", "Physical therapist", "Physician", "Positive model of the patient", "Prosthetics", "Prosthetist", "Qualified practitioner", and "Qualified supplier" in alphabetical order and in the definition of "DMEPOS supplier" by removing the reference "paragraphs (c) and (d) of this section" and adding in its place the reference "paragraphs (c) and (h) of this section".

b. Revising paragraph (c)(22);

c. In paragraph (c)(26) removing the reference "paragraph (d) of this section" and adding in its place the reference "paragraph (h) of this section";

d. Redesignating paragraph (d) as paragraph (h) and adding a new paragraph (d);

e. In newly designated paragraph (h)(1)(i) and (ii), removing the reference "paragraph (d)(15) of this section" and adding in its place the reference "paragraph (h)(15) of this section".

f. In newly designated paragraphs (h)(1)(i), (ii), (h)(4)(ii)(B), (h)(5)(iii) introductory text, (h)(12), and (h)(15)(ii), removing the reference "paragraph (d)" of this section and adding in its place the reference "paragraph (h)" of this section.

g. In newly designated paragraphs (h)(2)(i), (ii), and (iii) removing the reference "paragraph (d)(3) of this section" and adding in its place the reference "paragraph (h)(3) of this section".

h. In newly designated paragraphs (h)(3)(i), removing the references "paragraph (d)(2) of this section" and adding in its place the reference "paragraph (h)(2)" and removing the reference "paragraph (d)(3)(ii) of this section" and adding in its place the reference "paragraph (h)(3)(ii) of this section".

i. In newly designated paragraph (h)(15)(ii), removing the reference “paragraph (d)(15)(i) of this section” and adding in its place “paragraph (h)(15)(i) of this section”.

The revisions and additions read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

(a) * * *

Custom-fabricated orthotic means an item as listed in section 1861(s)(9) of the Act that meets all of the following:

(i) Is individually made for a specific patient.

(ii) Is constructed using one of the positive model techniques (as defined in this paragraph).

(iii) Is made based on clinically derived and rectified castings, tracings, measurements, and other images (such as x-rays) of the body part and may involve the use of calculations, templates, and components.

(iv) Is made using basic materials including, but not limited to the following:

(A) Plastic.

(B) Metal.

(C) Leather or cloth in the form of uncut or unshaped sheets or bars.

(D) Other basic forms and involves substantial work such as the following:

(1) Vacuum forming.

(2) Cutting.

(3) Bending.

(4) Molding.

(5) Sewing.

(6) Drilling.

(7) Laminating.

* * * * *

Fabrication facility means the physical structure that--

(1) Meets the requirements in paragraph (d)(4) of this section; and

(2) Must be used by a qualified practitioner or a qualified supplier to fabricate prosthetics or custom-fabricated orthotics that are billed to and paid for by Medicare.

* * * * *

Occupational therapist means an individual who meets the personnel qualifications for an occupational therapist as specified in § 484.4 of this chapter.

Ocularist means a trained technician skilled in the arts of fitting, shaping, and painting ocular prostheses who is certified by the National Examining Board of Ocularist.

Orthotist means an individual who meets the personnel qualifications for an orthotist as specified in § 485.70(d) of this chapter.

Pedorthist means an individual with specific training in footwear which includes other pedorthic devices to solve problems in, or related to, the foot.

* * * * *

Physical therapist means an individual who meets the personnel qualifications for a physical therapist as specified in § 484.4 of this chapter.

Physician means an individual who meets the personnel qualifications for a physician as specified in § 484.4 of this chapter.

Positive model of the patient means a particular type of custom fabrication in which one of the following modeling techniques is used:

(i) Molded to the patient model as a negative impression of the patient's body part and a positive model rectification are constructed.

(ii) Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) system.

(iii) Direct formed model.

Prosthetics means an item as described in section 1861(s)(9) of the Act.

Prosthetist means an individual who meets the personnel qualifications for a prosthetist as specified in § 485.70(f) of this chapter.

Qualified practitioner means one of the following eligible professionals or other persons defined in paragraph (a) of this section who meets the prosthetic and custom-fabricated orthotic requirements specified in paragraph (d)(3) of this section:

(i) Occupational therapist.

(ii) Ocularist.

(iii) Orthotist.

(iv) Pedorthist.

(v) Physical therapist.

(vi) Physician.

(vii) Prosthetist.

Qualified supplier means a DMEPOS supplier as defined in paragraph (a) of this section that is accredited by a CMS-approved accreditation organization to fabricate prosthetics and custom-fabricated orthotics as described in §424.58(c).

* * * * *

(c) * * *

(22)(i) DMEPOS supplier requirements. A DMEPOS supplier must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number and to enroll in Medicare. The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the DMEPOS supplier to receive payment for those specific products and services.

(ii) Requirements for DMEPOS suppliers fabricating or billing prosthetics and custom-fabricated orthotics. Effective 1 year after the posting of the final revised quality standards or the next revalidation, whichever is later, a DMEPOS supplier fabricating or billing for prosthetics or any of the custom-fabricated orthotics identified on the list described in paragraph (d)(2) of this section must do all of the following:

(A) Meet the requirements specified in paragraph (c)(22)(i) of this section.

(B) Be accredited by a CMS-approved accreditation organization for orthotics and prosthetics as described in § 424.58(c). The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the qualified supplier (as defined in §424.57(a)) to receive payment for the prosthetics and specific custom-fabricated orthotics.

(C) Notify the AO of any change in conditions, practices, or operations that were relied upon by the AO at the time of accreditation. This would include, but not be limited to, a requirement for notifying the AO of any changes in personnel, including changes in status or qualifications of employees of the qualified supplier or of any personnel utilized by the qualified supplier via contract or other business relationship. This requirement is included to ensure that qualified suppliers, once accredited, continue to meet all of the accreditation and other supplier standards.

* * * * *

(d) Additional standards for qualified suppliers fabricating or billing for prosthetics or custom-fabricated orthotics, or qualified practitioners furnishing or fabricating prosthetics and custom-fabricated orthotics.

(1) General rule. CMS makes payment for a bill or claim for a prosthetic or custom-fabricated orthotic identified on the list in paragraph (d)(2) of this section and meets all of the following:

(i) Furnished by a qualified practitioner.

(ii) Fabricated by a qualified practitioner or qualified supplier at a fabrication facility as defined in paragraph (a) of this section.

(iii)(A) Billed by a qualified supplier; or

(B) Submitted as a claim by a Medicare beneficiary.

(2) List of prosthetics and custom-fabricated orthotics subject to the additional standards.

CMS maintains a list of prosthetics and custom-fabricated orthotics subject to the requirements in this section. The list is--

(i) Updated as necessary; and

(ii) Posted on the CMS website.

(3) Training, licensure, and certification requirements for qualified practitioners. (i) A qualified practitioner who is not enrolled in Medicare as a DMEPOS supplier must meet either of the following licensure and certification requirements:

(A) Licensed in orthotics, pedorthics or prosthetics by all States in which they practice.

(B) In States that do not provide licenses for orthotics, pedorthics or prosthetics a qualified practitioner must be--

(1) Specifically trained and educated to provide and manage the provision of pedorthics, prosthetics, and orthotics; and

(2) Certified by any of the following:

(i) ABC.

(ii) BOC.

(iii) A Secretary-approved organization that has standards equivalent to the ABC or BOC.

(ii) Qualified practitioners must meet the licensure, training, education and certification requirements specified in this section within 1 year of publication of the final rule.

(4) Fabrication facility requirements. A fabrication facility at which qualified suppliers and qualified practitioners fabricate prosthetics and custom-fabricated orthotics, as defined in § 424.57(a), must meet all of the following requirements:

(i) Be located within the United States or one of its territories.

(ii) Be a business that is organized, established and licensed under applicable state and federal laws

(iii) Have a process for maintenance and production of fabrication records including the following:

(A) Job/work orders.

(B) Record tracking systems.

(C) Real time recordkeeping, for example, ensuring that records are updated as the fabrication takes place.

(iv) Have a quality assurance process to identify non-standard production outcomes, and improve fabrication outcomes.

(v) Have a periodic review and employee demonstration of fabrication/safety/communication/operations competencies with corrective action plans for staff that do not meet the minimal standards.

(vi) Have full time appropriately credentialed staff member(s) who are (qualified practitioners or qualified suppliers) onsite to fabricate and to supervise fabrication.

(vii) Have a laboratory area with appropriate safety equipment (for example, flammable material storage, gloves, safety glasses, proper ventilation).

(viii) Have a separate waiting area and chairs with armrests, as necessary.

(ix) Have a patient care and fitting rooms with appropriate levels of privacy and sanitation. Patient fitting and care areas should be separate from the fabrication area.

(x) Have disinfecting supplies, gloves, masks, and plastic for containing contaminated materials.

(xi) Have a fabrication facility information system, paper or digital, that can track the production, list component part number (and serial number if available), quantity, that is linked to patient information and be Health Insurance Portability and Accountability Act compliant. Such a system must allow facility staff and management, including those fabricating, to identify any parts that could be recalled at a later date.

(xii) Have parallel bars, a full-length mirror, and other appropriate assessment tools.

(xiii) Have a process using precautions to handle used patient devices that are contaminated.

(xiv) Have repair and disinfecting areas clearly labeled.

(xv) Have the ability to handle all potentially hazardous materials in facility properly.

(xvi) Have an emergency management plan and a safety management plan.

(xvii) Have policy for detecting/reporting counterfeit supplies.

(xviii) Have the proper tools, equipment, and computers commonly used in the fabrication of particular items and typically associated with the particular technical approach (negative impression/positive model, CAD-CAM, or direct formed), as applicable: These tools and equipment would include, but are not limited to the following

(A) Computers with appropriate graphics/modeling capacity and technology.

(B) Band saw.

(C) Disc sander.

(D) Sanding paper.

(E) Flexible shaft sander.

(F) Lathe.

(G) Drill press.

(H) Sewing machine.

(I) Grinding equipment.

(J) Paint-spraying equipment.

(K) Welding equipment.

(L) Alignment jig.

(M) Ovens capable of heating plastics for molding.

(N) Computer controlled milling machine.

(O) Lockable storage areas for raw materials and finished devices.

(P) Air compressor.

* * * * *

3. Section 424.58 is amended as follows:

- a. Revising the section heading.
- b. Redesignating paragraphs (c) through (e) as paragraphs (d) through (f) respectively.
- c. Adding a new paragraph (c).

The revision and addition read as follows:

§ 424.58 Requirements for DMEPOS accreditation organizations.

* * * * *

(c) Additional requirements for accrediting qualified suppliers. To accredit qualified suppliers that fabricate or bill Medicare for prosthetics and custom-fabricated orthotics as specified in § 424.57(c)(22)(ii), an independent accreditation organization must be one of the following:

- (1) American Board for Certification in Orthotics and Prosthetics, Incorporated (ABC).
- (2) Board for Orthotist/Prosthetist Certification International, Incorporated (BOC).
- (3) An organization that--

(i) Employs or contracts with an orthotist, prosthetist, occupational therapist or physical therapist who--

- (A) Meets the definition of qualified practitioner specified in § 424.57(a); and
- (B) Is utilized for the purpose of surveying the supplier or practitioner for compliance;

and

(ii) Has the authority granted by CMS to approve or deny the accreditation of qualified suppliers as defined in §424.57(a) based on a determination that the organization has standards equivalent to the ABC or BOC.

* * * * *

4. Section §424.535 is amended as follows:

- a. Revising the section heading.
- b. In paragraph (a)(2) introductory text by removing the phrase "the provider or supplier is--" and adding in its place "the provider or supplier is any of the following:".
- c. In paragraph (a)(2)(ii) by removing the phrase "Is debarred, suspended, or" and adding in its place the phrase "Debarred, suspended or".
- d. Adding paragraph (a)(2)(iii).

The revision and addition reads as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) * * *

(2) * * *

(iii) A qualified supplier as defined in § 424.57(a) that submitted a claim for payment for a prosthetic or custom-fabricated orthotic that was not--

(A) Furnished by a qualified practitioner; and

(B) Fabricated by a qualified practitioner or qualified supplier as defined in §424.57(a) at a fabrication facility as defined in §424.57(a).

* * * * *

Dated: December 9, 2016.

Andrew M. Slavitt,
Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: December 22, 2016.

Sylvia M. Burwell

Secretary,

Department of Health and Human Services

BILLING CODE 4120-01-P

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