



CMS-6036-F2

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6036-F2]

RIN 0938-AQ57

Medicare Program; Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Safeguards

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

ACTION: Final rule.

SUMMARY: This final rule removes the definition of "direct solicitation" and allows DMEPOS suppliers, including DMEPOS competitive bidding program contract suppliers, to contract with licensed agents to provide DMEPOS supplies, unless prohibited by State law. It also removes the requirement for compliance with local zoning laws and modifies certain State licensure requirement exceptions.

EFFECTIVE DATE: These regulations are effective on [insert date 30 days after the date of publication in the **Federal Register**.]

FOR FURTHER INFORMATION, CONTACT: Katie Mucklow Lehman, (410) 786-0537; Frank Whelan, (410) 786-1302.

SUPPLEMENTARY INFORMATION:**I. Background****A. General Overview****1. Providers and Suppliers**

Medicare services are furnished by providers and suppliers. The term "provider" is defined at 42 CFR 400.202 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.

Provider is also defined in sections 1861(u) and 1866(e) of the Social Security Act (the Act).

For purposes of the DMEPOS supplier standards, the term "DMEPOS supplier" is defined in 42 CFR 424.57(a) as an entity or individual, including a physician or Part A provider that sells or rents Part B covered DMEPOS items to Medicare beneficiaries and which meets the DMEPOS supplier standards. A supplier that furnishes DMEPOS is one category of supplier. Other supplier categories include, for example, physicians, nurse practitioners, and physical therapists. If a supplier, such as a physician or physical therapist, also furnishes DMEPOS to a patient, the supplier is also considered to be a DMEPOS supplier.

2. DMEPOS

The term "durable medical equipment" is defined in section 1861(n) of the Act. It is also included in the definition of "medical and other health services" in section 1861(s)(6) of the Act. Furthermore, the term is defined in 42 CFR 414.202 as equipment furnished by a supplier or an HHA that--

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, 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 appropriate for use in the home.

Examples of durable medical equipment include blood glucose monitors, hospital beds, oxygen tents, and wheelchairs. Prosthetic devices are included in the definition of "medical and other health services" in section 1861(s)(8) of the Act. Prosthetic devices are defined as devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. Other examples of prosthetic devices include cardiac pacemakers, cochlear implants, electrical continence aids, electrical nerve stimulators, and tracheostomy speaking valves.

Section 1861(s)(9) of the Act provides for the coverage of leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacement if required because of a change in the patient's physical condition. As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as "orthotics and prosthetics." Under section 1834(h)(4)(B) of the Act, the term "prosthetic devices" does not include parenteral and enteral nutrition nutrients, supplies and equipment, and implantable items payable under section 1833(t) of the Act.

Section 1861(s)(5) of the Act includes "surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations" as one of the "medical and other health services" that are covered by Medicare. Other items that may be furnished by suppliers include, but are not limited to:

- Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title, as noted in section 1861(s)(2)(J) of the Act.
- Extra-depth shoes with inserts or custom-molded shoes with inserts for an individual with diabetes, as described in section 1861(s)(12) of the Act.
- Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies included in section 1861(s)(2)(F) of the Act.
- Oral drugs prescribed for use as an anticancer chemotherapeutic agent, as specified in section 1861(s)(2)(Q) of the Act.

- Self-administered erythropoietin, as described in section 1861(s)(2)(O) of the Act.

B. Statutory Authority

Various sections of the Act and the regulations require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made. The following is an overview of the sections that grant this authority:

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of the Department of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program.
- Section 1834(j)(1)(A) of the Act states that no payment may be made for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number. In order to obtain a supplier billing number, a supplier must comply with certain supplier standards as identified by the Secretary.

We are authorized to collect information on the Medicare enrollment application (that is, the CMS-855 (Office of Management and Budget (OMB) approval number 0938-0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program, as established by Title XVIII of the Act.

II. Provisions of the Proposed Rule and Responses to Public Comments

In the April 4, 2011 **Federal Register** (76 FR 18472), we issued a proposed rule that removed the definition of and modified the requirements regarding "direct

solicitation;" allowed DMEPOS suppliers, including DMEPOS competitive bidding program contract suppliers, to contract with licensed agents to provide DMEPOS supplies unless prohibited by State law; removed the requirement for compliance with local zoning laws; and modified certain State licensing requirement exceptions. We received 14 timely pieces of correspondence on the April 4, 2011 proposed rule. In this section of the final rule, we will present our proposals and summarize and respond to the public comments that we received.

A. Direct Solicitation

In the August 27, 2010 **Federal Register** (75 FR 52629), we published a final rule that addressed several matters related to the DMEPOS supplier standards in 42 CFR 424.57(c). One involved the prohibition in §424.57(c)(11) against the direct solicitation of Medicare beneficiaries by DMEPOS suppliers. Previously, the definition of direct solicitation was generally limited to telephonic contact. The August 27, 2010 final rule expanded the scope of this provision to include in-person contacts, e-mail, and instant messaging. Since publication of the August 27, 2010 final rule, we discovered that implementation of the expanded portions of this provision as written was unfeasible. The definition of "direct solicitation" was criticized as being overly broad as it covered some types of marketing activity outside the bounds of what we intended to prohibit under our regulations.

Therefore, in the April 4, 2011 proposed rule, we proposed to remove the definition of "direct solicitation" from §424.57(a), revise §424.57(c)(11) to remove all

references to "direct solicitation," and clarify that the prohibition was limited to telephonic contact.

The proposed revision to §424.57(c)(11) thus read as follows:

- Must agree not to contact a beneficiary by telephone when supplying a

Medicare-covered item unless one of the following applies:

++ The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

++ The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

++ If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

We received the following comments on this proposal:

Comment: A commenter expressed support for CMS's proposal to remove e-mail, instant messaging, and in-person contacts from the definition of "direct solicitation." However, the commenter requested a further revision to §424.57(c)(11) that would allow suppliers to contact Medicare beneficiaries upon receipt of a written or verbal prescription or prescriber order as long as the beneficiary has been made aware (for example, through the prescribing physician) that he or she will be contacted by a supplier. The commenter believed that requiring written consent from the beneficiary

would severely limit his or her access to care by delaying the provision of needed services and items. It would also impose a large administrative burden on physicians and physician offices, as they would have to obtain the beneficiary's written permission to be contacted by the DMEPOS supplier.

The commenter added that the policy stated in CMS's February 2010 frequently asked question (FAQ) #3 regarding what constitutes "unsolicited contact" with a beneficiary is appropriate. CMS's response to that question was:

"If a physician contacts a supplier on behalf of a beneficiary with the beneficiary's knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact would not be considered "unsolicited."

Please note that the beneficiary need only be aware that a supplier will be contacting him/her regarding the prescribed covered item, recognizing that the appropriate supplier may not have been identified at the time of consultation."

Response: We appreciate the commenter's support. We note that we did not specifically solicit comments on our proposed change to §424.57(c)(11). As such, we are not in a position to incorporate the commenter's requested revision of §424.57(c)(11) into this final rule. However, we have addressed these concerns in our Frequently Asked Questions (FAQ) section (available at <http://www.cms.gov/MedicareProviderSupEnroll/> by clicking on "DME Supplier Telemarketing Frequently Asked Questions" under the "Downloads" section) and may update that information in the future.

Comment: A commenter supported CMS's proposed revisions regarding §424.57(c)(11), believing that the current standard prohibiting "direct solicitation" of beneficiaries is too broad, thus making it difficult for compliant suppliers to operate their businesses and respond to the care expectations of beneficiaries. The commenter posed

several scenarios, asking whether any of them violated the DMEPOS supplier standards.

Response: We appreciate the commenter's support. For the scenarios that the commenter posed, we will be conducting significant outreach to the DMEPOS supplier and beneficiary communities before and after the implementation of this final rule. This will include the issuance of updated frequently asked questions (FAQs). We will address the general tenets of the commenter's scenarios in our FAQ updates.

Comment: One commenter stated that the proposal to remove the definition of "direct solicitation" from §424.57(c)(11) will continue to unnecessarily restrain DMEPOS suppliers. In order to reduce annoying or abusive marketing practices while also granting suppliers more freedom to legitimately contact beneficiaries, the commenter recommended that §424.57(c)(11) be revised to allow beneficiaries to give verbal permission for a supplier to contact them, and/or allow DMEPOS suppliers to contact beneficiaries when they have received a written order or prescription for a Medicare-covered item to be furnished from the patient's physician prior to contact with the beneficiary.

Response: We disagree with the commenter's first recommendation as it pertains to §424.57(c)(11)(i) regarding verbal consent. Due to the potential for abuse, we believe it is important that there be a documented record of the beneficiary's approval of the contact. Concerning this recommendation and as previously explained, we are not in a position to adopt this suggestion for this final rule. However, we may consider addressing the issue through future rulemaking.

Comment: A commenter noted that the April 4, 2011 proposed rule stated: "In

the interim, we intend to instruct Medicare contractors to continue applying the restrictions on telephone solicitation that were in effect before publication of the August 27, 2010 final rule, instead of implementing the final rule's requirements regarding direct solicitation." The commenter requested that CMS explain its legal authority to instruct Medicare contractors not to enforce the regulatory modification to the "direct solicitation" requirement made in the August 27, 2010 final rule. The commenter stated that Federal regulations have the effect of law and that CMS instructions cannot trump them.

Response: We understand the commenter's concerns. However, due to the concerns that we ourselves had regarding the implementation of the August 27, 2010 final rule, we decided not to enforce it while working on the April 4, 2011 proposed rule. Indeed, we believed that the direct solicitation restrictions in the August 27, 2010 rule created an exigent situation, such that enforcement of the rule as written would have been problematic. Nor would it have benefitted the DMEPOS supplier community, Medicare beneficiaries, or CMS for the August 27, 2010 rule to have been enforced while waiting for the restrictions in question to be removed via a subsequent regulation.

Comment: A commenter recommended that CMS retain the "direct solicitation" provisions established in the August 27, 2010 final rule, and modify the definition of "direct solicitation" found in §424.57(a) by deleting the phrase, "which includes, but is not limited to." The commenter believes by deleting this phrase it would make the "direct solicitation" definition less ambiguous.

Response: For reasons previously stated, we believe that the definition of "direct

solicitation" should be deleted from the regulations.

Comment: A commenter requested that CMS explain, using actual examples: (1) why it believed a problem existed in unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries; (2) whether those problems have abated or increased; and (3) why it is not taking the necessary steps to reduce or eliminate unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries.

Response: We disagree with the commenter's assertion that we have not taken steps to resolve these problems. We have not conducted formal studies in a way that would enable us to quantify whether those issues have abated or increased. Although we are modifying the supplier standard on direct solicitation at §424.57(c)(11), we will continue to actively monitor the issue of unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries. We will also be working with law enforcement agencies to determine if further agency intervention is required. In the event we believe that we need to take action to limit these types of communications, we will engage in further rulemaking to address this concern.

Comment: A commenter recommended that CMS add a subparagraph (iv) to §424.57(c)(11) that will allow suppliers, after receipt of a prescription or prescriber order, to contact individuals to coordinate the delivery of a covered item. The commenter stated that it can be extremely difficult, and sometimes impossible, for suppliers to coordinate timely delivery of an item without first contacting the beneficiary. The commenter also noted that the proposed language in §424.57(c)(11)(ii) is ambiguous

because it states that the supplier may contact the beneficiary to arrange delivery only after the item has already been furnished. In short, the commenter contends that the supplier must contact the beneficiary in order to furnish the item; waiting for written permission from the beneficiary before contacting him or her is neither practical nor efficient. Another commenter agreed that contact with the beneficiary is necessary so that the item can be furnished. Another commenter contended that contacting beneficiaries about the delivery of a prescribed item is, in actuality, "care coordination," not telemarketing, and is not an "unsolicited communication."

Response: As previously explained, we are not able to adopt the commenter's recommendation. However, we may consider addressing the issue through future rulemaking.

Comment: A commenter stated that the August 27, 2010 final rule contained a CMS response to a public comment in that rule that stated:

However, if a physician contacts the supplier on behalf of the beneficiary's [sic] with the beneficiary's knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including the delivery and billing information), then that contact would not be considered a direct solicitation for the purpose of this standard. This is the case even if the physician has not specified the precise DMEPOS supplier that will be contacting the beneficiary regarding the item referred to by that physician.

The commenter stated that the April 4, 2011 proposed rule removing the prohibition against "direct solicitation" did not address this specific issue. The commenter sought confirmation that the quoted verbiage remains CMS policy notwithstanding the removal of the "direct solicitation" reference.

Response: For reasons previously stated, we are finalizing the version of §424.57(c)(11) that was in the April 4, 2011 proposed rule by removing the definition of "direct solicitation." The language in this final rule reflects our policy on this particular issue. The quoted verbiage still reflects our policy with regard to this provision.

Comment: One commenter stated that direct solicitation creates an opportunity for businesses to solicit the purchase of products that recipients may not need, and that this opens the door for fraud and waste.

Response: We appreciate the commenter's concern. As previously stated, we will continue to actively monitor the issue of unwanted and unsolicited communications between DMEPOS suppliers and beneficiaries. We will also be working with law enforcement agencies to determine if further agency intervention is required. In the event we believe that we need to take action to limit these types of communications, we will engage in further rulemaking to address this concern.

After review of the public comments received, we are finalizing our proposals to remove the definition of "direct solicitation" from §424.57(a), to revise §424.57(c)(11) to remove all references to "direct solicitation," and to clarify that the prohibition is limited to telephonic contact.

B. Contractual Arrangement Issues

In the August 27, 2010 final rule, we finalized an additional layer of oversight of DMEPOS suppliers via State law. Specifically, we added a new paragraph (c)(1)(ii) to §424.57. It read--

- State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier--
 - ++ Must be licensed to provide the item or service;
 - ++ Must employ the licensed professional on a full-time or part-time basis, except for DMEPOS suppliers who are--
 - Awarded competitive bid contracts using subcontractors to meet this standard; or
 - Allowed by the State to contract licensed services as described in paragraph (c)(1)(ii)(C) of this section;
 - Must not contract with an individual or other entity to provide the licensed services, unless allowed by the State where the licensed services are being performed.

After the implementation of §424.57(c)(1)(ii), the absence of specific State laws regarding certain areas of DMEPOS supplier oversight caused confusion among suppliers regarding who they could contract with. This was especially true regarding paragraphs (ii)(B)(2) and (ii)(C), which use the term "allowed by the State." Therefore in the April 4, 2011 proposed rule, we stated that we would revise §424.57(c)(1)(ii) to read--

- State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier--
 - ++ Must be licensed to provide the item or service; and
 - ++ May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

We believed that this change would clarify our expectations with regard to State licensure and contracts. We received the following comment on this proposal:

Comment: A commenter expressed support for our proposed revision to §424.57(c)(1)(ii), stating that it is straightforward compared to the current standard. The commenter also posed several factual scenarios and asked whether said situations would constitute violations of the DMEPOS supplier standards.

Response: We appreciate the commenter's support concerning this provision. As previously mentioned, we will be conducting outreach to the DMEPOS supplier community before and after the implementation of this final rule. This will include the issuance of updated FAQs. We will address the general tenets of the commenter's scenarios during this process. We also remind suppliers that they must always comply with any applicable Federal and State laws, including, without limitation, those related to fraud and abuse.

After review of the public comments received, we are finalizing our proposed revision to §424.57(c)(1)(ii) without modification.

C. Local Zoning Requirements

In the August 27, 2010 final rule, we stated in the new §424.57(c)(1)(iii) that the DMEPOS supplier must operate its business and furnish Medicare covered supplies in compliance with local zoning requirements. We believe that this would help ensure that DMEPOS suppliers were providing goods and services to Medicare beneficiaries in a physical location, rather than out of a residence; indeed, the latter practice is often prohibited by municipal code zoning requirements. However, the wide variances in State and municipal laws and the potential difficulty our contractors could have in verifying compliance with municipal codes, led us to propose the elimination of §424.57(c)(1)(iii) in the April 4, 2011 proposed rule. In hindsight, we believe that the task of ensuring that DMEPOS suppliers comply with local zoning requirements is best left to the States. The State's verification of the supplier's compliance will generally be reflected in the supplier's business license status, which the National Supplier Clearinghouse (NSC) validates. Thus, ensuring the supplier's adherence to all State and local laws is, in part, accomplished through the verification of the supplier's licensure status. We received the following comments on this proposal:

Comment: A commenter requested that CMS explain the following:

- Whether the NSC verified that suppliers met local zoning requirements before the publication of the January 25, 2008 proposed rule entitled "Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Supplier Enrollment Standards."
- Whether the NSC verified that DMEPOS suppliers met local zoning requirements between January 2008 and the publication of the August 27, 2010 final rule.

- How this proposed change (that is, no longer verifying local zoning requirements) will impact CMS's efforts to reduce fraud, waste and abuse in the Medicare program.

- Whether it believes that more unscrupulous DMEPOS suppliers will try and obtain Medicare billing privileges in residential neighborhoods as a result of limiting the NSC from denying or revoking Medicare billing privileges based on local zoning requirements.

Response: The NSC did not routinely verify, either before or after the publication of the January 25, 2008 proposed rule, whether DMEPOS suppliers met local zoning requirements. Therefore, we believe that our proposed change will not impact our ability to combat fraud, waste, and abuse, as it simply codifies existing practices. As explained previously, the State's verification of the supplier's compliance with local laws will often be reflected in the supplier's State business license status, which the NSC verifies. We note that DMEPOS suppliers would still be required to comply with all applicable Federal and State laws to comply with the supplier standards. Furthermore, suppliers are still required to comply with all applicable local zoning requirements. However, we believe that allowing local municipalities to enforce their zoning requirements is most appropriate, as they are most familiar with their respective requirements and have jurisdiction over these matters.

Comment: One commenter stated that in the April 4, 2011 proposed rule, CMS stated: "In the August 27, 2010 final rule, we finalized regulations at §424.57(c)(1)(iii) that required DMEPOS suppliers to comply with all local zoning requirements." This

statement, the commenter contended, made it appear that CMS established the requirement that DMEPOS suppliers adhere to local zoning requirements in August 2010. The commenter disagreed with this statement, noting that the March 2009 version of the CMS-855S showed that CMS required DMEPOS suppliers to submit "local (city/county) business licenses" in March 2009, if not before. The commenter recommended that CMS withdraw its proposal to remove the provision found at §424.57(c)(1)(iii) until it provides more facts and data to the public about why this change should be made. Another commenter opposed the proposal to remove §424.57(c)(1)(iii), believing that it would increase Medicare's exposure to fraud, waste, and abuse.

Response: The previously quoted statement in the August 27, 2010 final rule was not meant to imply that §424.57(c)(1)(iii) was a new requirement. It was merely a restatement of the fact that we had finalized §424.57(c)(1)(iii) in the August 27, 2010 rule. However, we decline to accept the suggestion to withdraw our proposal to remove §424.57(c)(1)(iii) for the reasons outlined in the April 4, 2011 proposed rule and in the summary of this provision outlined earlier in this final rule.

After review of the public comments received, we are finalizing the proposed changes to §424.57(c)(1) without modification.

D. State Licensure Requirement Exception

Per §424.57(c)(7), a DMEPOS supplier must maintain a physical facility on an appropriate site. The August 27, 2010 final rule added several paragraphs to §424.57(c)(7), of which paragraph (c)(7)(i)(A) stated that an appropriate site must,

among other things, meet the following size requirement:

Except for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, (the DMEPOS supplier) maintains a practice location that is at least 200 square feet. (Parentheses added.)

In the April 4, 2011 rule, we proposed to modify §424.57(c)(7)(i)(A) to allow orthotic and prosthetic professionals to qualify for the minimum square footage exception if the State does not offer licensure. We believed that due to variations in State licensing procedures, comparable practitioners should not be excluded from this exception. Of course, if a State does offer licensure for orthotic and prosthetic professionals, the supplier must obtain licensure in order to qualify for the minimum square footage exception. We received the following comments on this proposal:

Comment: For the square footage requirements, a commenter stated that DMEPOS suppliers furnishing orthotic and prosthetic items and services should have a facility large enough to perform all activities associated with orthotic and prosthetic activities, including a laboratory. The commenter expressed concern about orthotic and prosthetic offices that are very small, have little overhead, and spend time serving patients at nursing homes and other provider facilities. The commenter stated that this makes it difficult for larger facilities to compete.

Response: As we stated in the August 27, 2010 final rule (75 FR 52636), we received the following comment to the January 25, 2008 proposed rule, which proposed a minimum square footage requirement in §424.57(c)(7):

One commenter believes the minimum square footage requirement causes potential issues for orthotic and prosthetic suppliers, since the lab area is separate from the patient area and is often located off-site. The patient interaction area is

most important, but since this area can be as small as 80 square feet, the size requirement should not be imposed as to orthotic and prosthetic suppliers.

We agreed with this comment and, as a result, established an exception to the proposed requirement for certain orthotic and prosthetic suppliers. While we understand the April 4, 2011, proposed rule commenter's concerns, we continue to believe that this exception is necessary.

After review of the public comments received, we are finalizing the proposed changes to §424.57(c)(7)(i)(A) without modification.

E. Open Hours Exception

Section 424.57(c)(30)(i), in the August 27, 2010 final rule, states that suppliers must be open to the public a minimum of 30 hours per week. Section (c)(30)(ii)(B) of this section prescribes an exception to this requirement for "licensed non-physician practitioners whose services are defined in sections 1861(p) and 1861(g) of the Act (and) furnishes items to his or her own patients as part of his or her professional service." (Parentheses added.) Sections 1861(p) and (g) of the Act define certain outpatient physical therapy services and certain outpatient occupational therapy services, respectively. In the April 4, 2011 proposed rule to clarify which non-physician practitioners fall under §424.57(c)(30)(ii)(B), we proposed to remove the phrase "licensed non-physician practitioners" from §424.57(c)(30)(ii)(B) and simply refer to physical and occupational therapists.

We did not receive any comments on this provision. Therefore, we are finalizing proposed changes to §424.57(c)(30)(ii)(B) without modification.

F. Out of Scope Comments

We received several other comments that were outside of the scope of the proposed rule. Therefore, we are not addressing these comments in this final rule.

III. Provisions of Final Rule

This final rule finalizes the provisions of the proposed rule without modification.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Regulatory Impact Statement

We have examined the impacts 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 (February 2, 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 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct 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). This final rule does not reach the economic threshold and thus is not considered 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 organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 million to \$34.5 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 the Secretary has determined that this rule will not have a significant economic impact on a substantial number of small entities. The provisions contained in this final rule are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs. They merely clarify several provisions in the DMEPOS supplier standards covered in §424.57. We anticipate a minimal economic impact, if any, on small entities.

As of March 2008, there were 113,154 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were only approximately 65,984 unique billing numbers. We believe that approximately 20 percent of the DMEPOS suppliers are located in rural areas.

Comment: A commenter suggested that we use current data (for example, June 2011) rather than data from 2008 to update the number of DMEPOS suppliers found in the Regulatory Impact Analysis (RIA) and the percentage of DMEPOS suppliers that are located in rural areas.

Response: The percentage of DMEPOS suppliers located in rural areas remains largely unchanged from 2008. As of June 2011, there were approximately 102,000 individual DMEPOS suppliers enrolled in Medicare. We believe that approximately 20 percent of Medicare-enrolled DMEPOS suppliers are located in rural areas.

Comment: A commenter recommended that CMS more fully explain how this proposed change will impact Medicare beneficiaries.

Response: We believe that Medicare beneficiaries will be well-served by the provisions of this final rule, as the protections afforded by §424.57(c)(11) will remain largely intact.

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 604 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 and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this final rule will 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 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule does not mandate

expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of \$136 million; therefore, no analysis is required.

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 costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professionals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 424--CONDITIONS FOR MEDICARE PAYMENT

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

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

Subpart D--To Whom Payment Is Ordinarily Made

§424.57 [Amended]

2. Section 424.57 is amended by—
 - A. Removing the definition of "Direct solicitation" in paragraph (a).

B. Revising paragraph (c)(1)(ii).

C. Removing paragraph (c)(1)(iii).

D. Revising paragraphs (c)(7)(i)(A) and (c)(11).

E. In paragraph (c)(30)(ii)(B), removing the phrase "Licensed non-physician practitioners" and adding the phrase "A physical or occupational therapist" in its place.

The additions and revisions read as follows:

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

(c) * * *

(1) * * *

(ii) State licensure and regulatory requirements. If a State requires licensure to furnish certain items or services, a DMEPOS supplier--

(A) Must be licensed to provide the item or service; and

(B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

* * * * *

(7) * * *

(i) * * *

(A)(1) Except for orthotic and prosthetic personnel described in paragraph (c)(7)(i)(A)(2) of this section, maintains a practice location that is at least 200 square feet beginning--

(i) September 27, 2010 for a prospective DMEPOS supplier;

(ii) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after September 27, 2010 and before September 27, 2013; or

(iii) September 27, 2013, for an existing DMEPOS supplier with a lease that expires on or after September 27, 2013.

(2) Orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice do not have to meet the practice location requirements in paragraph (c)(7)(i)(A)(1) of this section if the orthotic and prosthetic personnel are--

(i) State-licensed; or

(ii) Practicing in a State that does not offer State licensure for orthotic and prosthetic personnel.

* * * * *

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one

covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: January 11, 2012

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Approved: February 21, 2012

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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