

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS-6036-F]

RIN 0938-AO90

Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards

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

ACTION: Final rule.

SUMMARY: This final rule will clarify, expand, and add to the existing enrollment requirements that Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers must meet to establish and maintain billing privileges in the Medicare program.

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

FOR FURTHER INFORMATION CONTACT:

Barry Bromberg, (410) 786-9953 for general issues, on-site inspections, maintaining ordering and referring documentation, and hours of operation.

Kimberly McPhillips, (410) 786-5374 for issues related to compliance with applicable laws, appropriate sites, direct solicitation, oxygen suppliers, and prohibition on sharing a practice location.

SUPPLEMENTARY INFORMATION:**I. Background**A. General Overview

Medicare services are furnished by two types of entities, providers, and suppliers. 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 "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 "supplier" is defined in §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 that meet the DMEPOS supplier standards. This final rule applies to all DMEPOS suppliers and amends the DMEPOS supplier standards set forth at §424.57(c). Those individuals or entities that do not furnish DMEPOS items but furnish other types of health care services only (for example, physician services or nurse practitioner services) would not be subject to this requirement. A supplier that furnishes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is one category of supplier. Other supplier categories may include, for example, physicians, nurse practitioners, and physical therapists. If a

supplier, such as a physician or physical therapist, also provides DMEPOS to a patient, then the supplier is also considered to be a DMEPOS supplier. The term "DMEPOS" encompasses the types of items included in the definition of medical equipment and supplies in section 1834(j)(5) of the Act.

In FY 2007, the Medicare program spent more than \$10 billion for DMEPOS supplies, and in March 2008, there were 113,154 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were 65,984 unique billing numbers. The largest concentrations of DMEPOS suppliers were located in five States: California (approximately 9 percent), Texas (approximately 7 percent), Florida (approximately 7 percent), New York (approximately 6 percent) and Pennsylvania (approximately 5 percent). We believe that approximately 20 percent of the DMEPOS suppliers are located in rural areas throughout the United States and that the vast majority of DMEPOS suppliers are small entities (based on Medicare reimbursement alone).

The term durable medical equipment is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DMEPOS, items furnished in SNFs and hospitals. Also, the term DMEPOS is included in the definition of "medical and other health services" in section 1861(s)(6) of the Act. Furthermore, the term is defined in §414.202 as equipment furnished by a supplier or a HHA that--

- Can withstand repeated use;
- 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.

Examples of DMEPOS supplies include items such as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs.

Prosthetic devices are included in the definition of "medical and other health services" under section 1861(s)(8) of the Act. Prosthetic devices are defined in this section of the Act 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 of 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, prosthetic devices do not include parenteral and enteral nutrition nutrients and implantable items payable under section 1833(t) of the Act."

Section 1861(s)(5) of the Act includes "surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocation" as one of the "medical and other health services" that is covered by Medicare. Other items that may be furnished by suppliers would include (among others):

- Prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title, and that are furnished within a certain time period after the date of the transplant procedure as noted at 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 listed at 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 at section 1861(s)(2)(F) of the Act.
- Oral drugs prescribed for use as an anticancer therapeutic 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.

The National Supplier Clearinghouse (NSC) is the Center for Medicare & Medicaid Services' (CMS) designated national enrollment contractor for DMEPOS suppliers. The primary functions of the NSC are to: (1) ensure that only qualified suppliers of DMEPOS are enrolled or remain enrolled in the Medicare program; (2)

process enrollment application in timely and accurate manner; and (3) take the necessary actions to revoke enrolled suppliers who no longer meet supplier standards.

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 Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program. Under this authority, this final rule will require the collection of information from providers and suppliers for the purpose of enrolling in the Medicare program and granting privileges to bill the program for health care services furnished to Medicare beneficiaries.
- Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due a provider or other person.
- 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.

- Section 1842(r) of the Act requires CMS to establish a system for furnishing a unique identifier for each physician who furnishes services for which payment may be made. To complete this, we need to collect information unique to that physician.

- Section 1862(e)(1) of the Act states that no payment may be made when an item or service was at the medical direction of an individual or entity that is excluded in accordance with sections 1128, 1128A, 1156, or 1842(j)(2) of the Act.

- Section 4312 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) amended section 1834 of the Act to require that certain Medicare supplies of durable medical equipment, prosthetics, and supplies (DMEPOS) to furnish CMS with a surety bond in an amount not less than \$50,000.

- Section 4313 of the BBA amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees including Directors and Board Members of corporations and non-profit organizations and charities. The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.

- Section 31001(i)(1) of the Debt Collection Improvement Act of 1996 (DCIA) (Pub. L. 104-134) amended section 7701 of 31 U.S.C. by adding paragraph (c) to require that any person or entity doing business with the Federal Government must provide their Tax Identification Number (TIN).

- Section 936(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended section 1866 of the Act by adding a new subsection (j)(1) to require the Secretary to establish a process for the enrollment of providers of services and suppliers.

- Section 302(a)(1) of MMA amended the Act to require the Secretary to develop quality standards for DMEPOS suppliers.

- Section 154(b) of the MIPPA amended the Act to establish a deadline for DMEPOS accreditation.

Section 6405(a) of the Affordable Care Act (ACA) requires that in order for payment for services to be made, a physician who orders DME for individuals must be a Medicare participating physician enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) of the Act that is enrolled under section 1866(j) of the Act.

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

In the January 25, 2008 **Federal Register** (73 FR 4503), we published a proposed rule that clarified, revised, and added to the DMEPOS supplier standards in §424.57.

In §424.57(c)(1), we proposed to revise this supplier standard by adding language to clarify that a DMEPOS supplier must be licensed to provide licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s).

The purpose of this standard is to ensure that DMEPOS suppliers obtain and maintain the necessary State licenses required to furnish the services provided to Medicare beneficiaries. In addition, we believe that each DMEPOS supplier is responsible for determining what licenses are required to operate a DMEPOS supplier's business. While the NSC maintains information regarding State licensure laws, we do not believe that the NSC is responsible for notifying any supplier of what licenses are required or that any changes have occurred in the State licensing requirements. We believe that we are enrolling DMEPOS suppliers, not third party agents that subcontract their operations to suppliers that are not enrolled or cannot enroll in the Medicare program. Therefore, to ensure that only qualified suppliers are enrolled or maintain enrollment in the Medicare program, we maintain that a DMEPOS supplier must be licensed to provide licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s).

In §424.57(c)(7), we proposed to clarify the supplier standard for maintaining a physical facility on an appropriate site. Specially, we proposed to clarify the term, "appropriate site." In addition, we stated that an "appropriate site" applies to "closed

door" businesses, (such as pharmacies/suppliers providing services only to beneficiaries residing in a nursing home). We also solicited comments on whether we should establish a minimum square footage requirement to the definition of an appropriate site and what, if any, appropriate exceptions would apply to a minimum square footage requirement.

The supplier location must be accessible during posted business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation. We believe that all DMEPOS suppliers must have a permanent, durable sign that is visible at the main entrance of the facility and positioned so that it is visible to the public, including customers using wheelchairs.

In §424.57(c)(8), we proposed to clarify this provision by revising (c)(8) to read as follows: "Permits CMS, the NSC, or agents of CMS or the NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section." If the NSC or its agents are unable to perform a site visit during a supplier's posted business hours, the NSC would deny billing privileges for prospective applicants or would revoke the billing privileges of DMEPOS suppliers enrolled in the Medicare program.

In §424.57(c)(9), we proposed to revise this supplier standard to exclude the use of cell phones and beepers/pagers as a method of receiving calls or using "call forwarding" to forward a call to a cell phone or beeper/pager from the public or beneficiaries during the supplier's posted hours of operation. We maintain that DMEPOS suppliers who are utilizing cell phones, call forwarding, beeper numbers, pagers, answering services or other methods to receive telephone calls in a location other than the place of business for business calls during their posted hours of operations are not in

compliance with this standard and that DMEPOS suppliers who exclusively use answering machines or answering services during their posted hours of operations are not in compliance with this standard. Therefore, we revised this standard to read, "Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries. The use of cellular phones, beeper numbers, and pagers as the primary business phone is prohibited. Additionally, DMEPOS suppliers are prohibited from forwarding calls from the primary business telephone listed under the name of the business to a cellular phone, or a beeper/pager. The exclusive use of answering machines, answering services or facsimile machine (or combination of these options) cannot be used as the primary business telephone during posted operating hours."

In §424.57(c)(10), we proposed to revise this provision to specify that the DMEPOS supplier has a comprehensive liability insurance policy in the amount of at least \$300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that insurance policy must remain in force at all times. In addition, we proposed that a DMEPOS supplier must list the NSC as a certificate holder on the policy and notify the NSC in writing within 30 days of any policy changes or cancellations.

In §424.57(c)(11), we proposed to revise this supplier standard to clarify that suppliers cannot directly solicit patients, which includes, but is not limited to, a prohibition on telephone, computer e-mail or instant messaging, coercive response internet advertising on sites unrelated to DMEPOS products, or in-person contacts. We

also proposed that DMEPOS supplier may only contact the Medicare beneficiary under the current provisions at §424.57(c)(11)(i) through (iii). We believe that if CMS or the NSC through on-site inspection obtains or develops evidence that a DMEPOS supplier has made prohibited contacts with Medicare beneficiaries in violation of the provisions found in this section that CMS or the NSC may revoke that supplier's billing privileges, and may determine if such billing may be for fraudulent or unnecessary supplies.

In §424.57(c)(12), we proposed to revise the provision to clarify its intent. Specifically, we proposed that a DMEPOS supplier: (1) is responsible for maintaining proof of the delivery in the beneficiary's file; (2) must furnish information to beneficiaries at the time of delivery of items as to how the beneficiary can contact the supplier by telephone; (3) must provide the beneficiary with instructions on how to safely and effectively use the equipment or contract this service to a qualified individual; (4) is responsible for providing instruction on the safe and effective use of the equipment that should be completed at the time of delivery; and (5) must document that this instruction has taken place. Our proposal was based on the belief that a DMEPOS supplier is solely responsible for delivery of Medicare-covered items and for instruction on the use of those items. While we believe that a DMEPOS supplier may choose to contract out the delivery of Medicare-covered items to another individual or entity, the DMEPOS supplier has ultimate responsibility for ensuring delivery in accordance with this standard and for maintaining all necessary documentation to demonstrate that the beneficiary received the Medicare-covered item and appropriate instructions for its use. We believe that our

revised interpretation of this section will help to ensure that instructions for the safe and appropriate use of products will be given to beneficiaries.

In §424.57(c)(27), we proposed a new standard that specified that the DMEPOS supplier must obtain oxygen from a State-licensed oxygen supplier. To ensure that DMEPOS suppliers meet and maintain this standard, we believe that DMEPOS suppliers who are supplying oxygen must contract with a supplier licensed by the State to provide them with oxygen. Obviously, this standard does not apply when the State does not license oxygen suppliers. We understand that in certain areas, DMEPOS suppliers may obtain oxygen from oxygen suppliers in other States. However, when a DMEPOS supplier is located in a State where licensure is required, then they must obtain their oxygen from a State-licensed oxygen supplier, regardless of which State the oxygen supplier obtained their licensure. We believe that this standard would help to protect Medicare beneficiaries and promote quality in the furnishing of oxygen.

In §424.57(c)(28), we proposed a new supplier standard that states that the supplier is required to maintain ordering and referring documentation, including the National Provider Identifier, received from a physician, nurse practitioner, physician assistant, clinical social worker, or certified nurse midwife, for 7 years after the claim has been paid. We maintain that a DMEPOS supplier should retain the necessary ordering and referring documentation received from physicians, nurse practitioners, physician assistants, clinical social workers, or certified nurse midwives to assure themselves that coverage criterion for an item has been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is

liable for the dollar amount involved unless a properly executed Advance Beneficiary Notice of possible denial has been obtained.

In §424.57(c)(29), we proposed a new standard that specifies that the supplier is prohibited from sharing a practice location with another Medicare supplier. In addition, we solicited comments on whether we should establish an exception to this space sharing proposal for physicians and nonphysician practitioners and the circumstances which warrant an exception since we are aware that physicians and other licensed nonphysician practitioners may obtain their own DMEPOS supplier number and furnish DMEPOS from their office. We believe that allowing a DMEPOS supplier to commingle its practice location with another DMEPOS supplier effectively limits the ability of CMS and the NSC to ensure that each DMEPOS supplier meets all of the supplier standards specified at §424.57. Since we are aware that physicians and other licensed nonphysician practitioners may obtain their own DMEPOS supplier number and furnish DMEPOS from their office, we solicited comments on whether we should establish an exception to this space sharing proposal for physicians and nonphysician practitioners and the circumstances which warrant an exception.

In §424.57(c)(30), we proposed a new supplier standard that would require a DMEPOS supplier to be open to the public a minimum of 30 hours per week, except for those DMEPOS suppliers who are working with custom-made or fitted orthotics and prosthetics. We believe that most legitimate DMEPOS suppliers are open to the public for more than 40 hours per week and that all legitimate DMEPOS would need to be open a minimum of at least 30 hours per week in order to attract, retain, and serve Medicare

beneficiaries. Given that Medicare beneficiaries may not be able to find transportation during limited operating hours, the DMEPOS supplier must be open and available for periods long enough for beneficiaries to readily access their facility. We believe that most legitimate DMEPOS suppliers are open to the public for more than 40 hours per week and that all legitimate DMEPOS would need to be open a minimum of at least 30 hours per week in order to attract, retain, and serve Medicare beneficiaries. To ensure that DMEPOS suppliers are able to report any change in their posted business hours, we are proposing to revise the CMS-855S Medicare enrollment application to accommodate this proposed change.

In §424.57(c)(31), we proposed to add a new supplier standard that specified that a DMEPOS supplier could not have Internal Revenue Service (IRS) or a State taxing authority tax delinquency. We also proposed to define a "tax delinquency" as meaning an amount of money owed to the United States or a State: a conviction or civil judgment for tax evasion, a criminal or civil charge of tax evasion, or the filing of a tax lien.

In §424.57(d), we proposed to redesignate the current text as paragraph (d)(1) and proposed adding a new paragraph that specified that "CMS, the NSC, or CMS designated contractor establishes a Medicare overpayment from the date of a adverse legal action or felony conviction (including felony convictions within the 10 years preceding enrollment or revalidation of enrollment) that precludes payment. In addition, we proposed that any overpayment assessed by CMS or its designated contractor due to a lack of reporting would follow the existing rules governing Medicare overpayments set forth at §405.350 et. seq. We believe that §424.57(d)(2) is necessary because some DMEPOS suppliers fail

to report adverse legal actions and felony convictions to the NSC within the 30 days of the reportable event. Since it is essential that DMEPOS suppliers notify the NSC of all adverse legal actions and felony convictions within 30 days of the reportable event, we believe that it is essential to establish this new provision. This new provision would allow the CMS, the NSC, or a designated Medicare contractor the authority to assess and collect an overpayment from the time of the reportable event. In addition, the CMS, the NSC, or a designated CMS contractor would revoke the DMEPOS supplier's Medicare billing privileges, in accordance with §424.57(d)(1), if the legal adverse action or felony conviction precludes participation in or payment from the Medicare program.

III. Analysis of and Responses to Public Comments

In the January 25, 2008 **Federal Register** (73 FR 4503), we published a proposed rule that clarified, revised, and added to the DMEPOS supplier standards in §424.57.

We received 208 timely comments in response to the proposed rule. In this section of the final rule we present a summary of our proposals and address the comments received on these proposals.

A. Clarifications and Revisions of Existing DMEPOS Supplier Standards

1. Licensure Requirements

In §424.57(c)(1), we proposed to revise this supplier standard by adding language to clarify that a DMEPOS supplier must be licensed to provide licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s). These licensed services include but are not limited to supplying oxygen or a general DMEPOS license.

Comment: A commenter believes the NSC should maintain and make available, a list of each States' licensing requirements.

Response: The National Supplier Clearinghouse (NSC) does maintain information regarding State licensure laws for DMEPOS suppliers on its web site (see www.palmettogba.com/nsc). However, the DMEPOS supplier is ultimately responsible for determining what business, product and other applicable licenses are required for his or her business, regardless of the accuracy of the information provided on the NSC Web site. We also believe it is the business owner's responsibility to be aware of any changes in the State licensing requirements for his or her business. During the enrollment and reenrollment process the NSC verifies that the DMEPOS supplier is in compliance with all applicable State licensing requirements.

Comment: Several commenters supported requiring DMEPOS suppliers to be licensed for all services they provide and that DMEPOS suppliers should not be allowed to contract out for these services. In addition, one commenter stated that the changes proposed to the licensure requirement for Medicare suppliers are necessary and beneficial.

Response: We agree and are revising §424.57(c)(1)(ii)(C) to address the commenters concern regarding contracting out of services. In addition, this requirement applies to the competitive bidding program as governed by part 414, subpart F.

Comment: A commenter believes that because of the complexity of State licensing requirements, it is too severe to revoke all billing numbers when licensing requirements are not met in only one State.

Response: We do not believe that there are any exceptions to State licensing requirements, unless the State in which the DMEPOS supplier furnishes services provides for such an exception, and that exception does not conflict with Federal law. Moreover, while a DMEPOS supplier can enroll using a single tax identification number (TIN) for one or more practice locations, a DMEPOS supplier also may obtain different TINs for each practice location. If the DMEPOS supplier makes the business decision to enroll multiple practice locations under the same TIN, a revocation by the NSC of this TIN will necessitate the revocation of related businesses associated with that TIN.

Comment: One commenter stated that restricting licensed professionals to W-2 employees likely will increase overall operating expenses and requested that we clarify that licensed professionals may be hired as either part-time or full-time employees.

Response: We agree and have revised §424.57(c)(1)(ii) to clarify that the licensed professionals must be part-time or full-time employees.

Comment: A commenter stated that §424.57(c)(1)(ii) as written, would allow DMEPOS suppliers to contract with nonlicensed individuals to avoid contracting with licensed individuals. In addition, it would not be financially feasible for all DMEPOS suppliers to have licensed professionals on staff, and therefore, CMS should allow contracting for services as long as they are in compliance with State requirements.

Response: We do not believe that this provision is written in such a way as to allow DMEPOS suppliers to contract with nonlicensed individuals to avoid employing part-time or full-time W-2 employees. In addition, we believe that a DMEPOS supplier who does not have a licensed individual on staff (part-time or full-time) as a W-2

employee would be in violation of §424.57(c)(1). Moreover, while we are concerned with the financial burden placed on small businesses, we recognize that a certain amount of capital is required to establish and maintain a business. To this end, we believe that enrolled DMEPOS suppliers should be required to meet State licensing qualifications, rather than subcontracting to a third-party agent who may or may not be qualified. Moreover, since we cannot ensure with any degree of certainty, the qualifications of a subcontracted individual or his or her compliance with Federal, State, and local licensure requirements, we believe the Medicare program and its Medicare beneficiaries would be better served if we could verify that a DMEPOS supplier meets the applicable State licensing requirements for a DMEPOS supplier's chosen specialty.

Comment: One commenter questioned whether CMS considers a co-employment arrangement with a Professional Employment Organization to be compliant or noncompliant with this proposed rule.

Response: We would consider a co-employment arrangement with a professional employment organization to be compliant with this proposed rule provided any licensed services are performed by an individual who receives a W-2 with the DMEPOS supplier's legal business name on it. For situations of co-employment, the W-2 also may have the legal business name of the professional employment organization, but this must be in addition to the DMEPOS supplier's legal business name.

Comment: A commenter requested that physical therapy clinics be exempt from the requirement for State certification that applies to DMEPOS suppliers because it will affect patient access to necessary care if the physical therapy clinic in which an individual

was being treated was not certified as a DMEPOS supplier and that it is an unnecessary burden to apply the same rules to licensed health care professionals as supplier companies.

Response: We believe that enrolled DMEPOS suppliers should meet all applicable State licensing requirements. We do not believe it is an unnecessary burden to apply the same rules to licensed health care professionals as supplier companies; in fact, to do otherwise would allow different regulatory and compliance standards to emerge. Finally, many of the rules of licensed health care professionals and many of the rules of the supplier companies are not duplicative or consecutive; rather, they are cumulative.

Comment: Several commenters believe that the licensing requirement provision is too restrictive and should be revised to state that properly licensed personnel are available to furnish the offered services. In addition, these commenters stated that the current language is too broad and would include administrative staff.

Response: This final regulation states that a DMEPOS supplier must be in compliance with Federal, State, and local laws and requirements. It also states a DMEPOS supplier cannot contract with an individual or other entity to provide licensed services. This requirement only would apply to a DMEPOS supplier's administrative staff if the administrative staff member is also responsible for providing a licensed service for the DMEPOS supplier. Moreover, we are promoting a State's prerogatives on licensure by imposing this requirement only in States where there are no such rules for contracting for licensed services. Rather, we are hoping to diminish the chance of

fraudulent practices by requiring that a DMEPOS supplier directly furnish licensed services.

Comment: One commenter believes disallowing contracting with individuals or entities is unfair to the small supplier.

Response: While we are concerned with the potential financial burden that this change imposes on small businesses, and we will monitor the impact of this requirement on small businesses. We believe that small DMEPOS suppliers should meet the applicable State licensing requirements for the services they provide.

Comment: One commenter recommended that rather than restricting the practice of contracting with licensed personnel, CMS should require the supplier to purchase additional insurance to cover the licensed person.

Response: We believe that a DMEPOS supplier must meet the applicable State licensing requirements for the services they provide to Medicare beneficiaries. In addition, while we agree that additional insurance may provide additional protection for the supplier, it does not help to ensure that a Medicare beneficiary is receiving quality products and instruction from a licensed individual and we will allow contracting for licensed services only when the State where the item or service is supplied permits a DMEPOS supplier to contract for licensed services. Moreover, we believe that DMEPOS suppliers participating in competitive bidding must maintain all applicable State licenses for the products and services they are bidding on or furnishing in each competitive bidding area. In addition, we believe that it is the responsibility of DMEPOS suppliers participating in competitive bidding to ensure that any subcontractor obtains and

maintains all appropriate State licenses in the area where they are providing services. We maintain that DMEPOS suppliers awarded a competitive bidding contract and that are subcontracting will be allowed on a phase-in basis for licenses services and licensed professionals participating in competitive bidding.

Comment: One commenter believes that this regulation is in conflict with some State licensing requirements, as some States permit DMEPOS suppliers to comply with its State licensing requirements by contracting with an individual or other entity to provide the licensed service. In addition, the commenter states a Federal regulation cannot supersede the historic police powers of the State unless it was the clear and manifest purpose of the Congress (see Downhaur v. Somani).

Response: We agree with this commenter because, State licensing laws and regulations on the licensure of DMEPOS suppliers govern how DMEPOS suppliers furnish items within a particular State. Therefore, we maintain that a DMEPOS supplier can contract for licensed services only when the State where the licensed service is being provided allows for this sort of arrangement consistent with §424.57(c)(1)(ii)(C).

Comment: A commenter does not believe that CMS should be in the business of professional licensing.

Response: It is important to note that we require the DMEPOS supplier to be State licensed, not to obtain a license from CMS. This change will help to ensure that DMEPOS suppliers are meeting State licensing requirements.

Comment: Several commenters recommended that the provision of not contracting out licensed services and the W-2 employee provisions of this standard only apply when not addressed by State licensing requirements.

Response: We agree with these commenters. We believe that DMEPOS suppliers must meet all applicable State licensing requirements and that this standard will only apply when not addressed by State licensing requirements.

Comment: Several commenters do not believe it should matter if the service is furnished by a W-2 employee or a 1099 contractor so long as both are properly licensed with no adverse legal action current or pending.

Response: We agree with these commenters because a DMEPOS supplier is accountable for meeting the applicable State licensing requirements, and by requiring that W-2 employees or a 1099 contractor (when allowed by State law) of the supplier are appropriately licensed, the NSC can verify that a DMEPOS supplier is meeting all applicable State licensing requirements.

Comment: One commenter stated that they are opposed to the revisions in §424.57(c)(1) because it would prevent all but the largest DMEPOS suppliers from bidding on contracts under the DMEPOS competitive bidding program because smaller businesses would not be able to hire staff all the potential licensed professionals as W-2 employees.

Response: We want to clarify that the employment requirement will not apply to contract suppliers participating in the competitive bidding program and we have reflected this intention in §424.57(c)(1)(ii)(B).

Comment: Several commenters believe that the proposed rule conflicts with the rules for participation in the competitive bidding program, as the competitive bidding program itself allows items and services in a product category to be supplied directly or through a subcontractor and provides safeguards to allow subcontracting.

Response: We agree with these commenters, and have revised §424.57(c)(1)(ii)(B) to reflect that the employment requirement for the furnishing of licensed services does not apply to contract suppliers participating in the competitive bidding program.

Comment: One commenter stated that this regulation conflicts with CMS' accreditation standards which permit contracting for licensed services, so long as the DMEPOS supplier complies with State licensure laws and is ultimately responsible for the services provided by a contractor.

Response: We have amended §424.57(c)(1) to permit contracting for licensed services, so long as the State where the licensed services are being performed allow for such contracting and the DMEPOS supplier complies with State licensure laws and is ultimately responsible for the services provided by a contractor . The supplier standards in §424.57 are separate from the quality standards which are used by accrediting organizations. This regulation does not conflict with our accreditation standards listed at §424.57(c)(22) through (c)(25).

Comment: A commenter stated that the proposed rule is unnecessary because many of the DMEPOS suppliers must be accredited by September 30, 2009 on top of already having to meet the State licensure requirements. Moreover, supplier's ability to

use subcontractors for the purpose of assuring service throughout a competitive bidding area would be limited which could disadvantage the small suppliers compared to large suppliers.

Response: We disagree with these commenters because a DMEPOS supplier is accountable for meeting the applicable State licensing requirements, and by requiring DMEPOS suppliers to employ individuals who are appropriately licensed, the NSC can verify that a DMEPOS supplier is meeting all applicable State licensing requirements.

Comment: Several commenters stated that the standard to prohibit a DMEPOS supplier from contracting with an individual or other entity to provide the licensed service places an unfair burden on small suppliers who at times must contract with licensed personnel or provide specific services to the supplier's patients. Also, this requirement makes it seem like CMS is singling out DMEPOS suppliers by not allowing them the use of staffing agencies when demand is great. In addition, the commenter believes that this standard would restrict suppliers that have full time respiratory therapists from hiring temporary licensed respiratory therapists during times of vacation, illness or increased staffing needs, and have a detrimental effect on patient's access to care and restrict respiratory therapists from performing duties in the patient's home.

Response: We believe that a DMEPOS supplier must be licensed to provide licensed services, and therefore, we are not adopting any exceptions to this provision except where a State permits contracting for licensed services. In addition, many small businesses currently have an owner or W-2 employee who is licensed to provide a service that requires a State licensure. We believe that the changes we are adopting in this final

regulation will not have a detrimental effect on patient's access to care and do not restrict respiratory therapists from performing duties in the patient's home. Finally, as stated previously, we are clarifying that DMEPOS supplier may hire a licensed W-2 employee on a part-time or full-time basis and we will permit contracting for licensed services, so long as the State permits contracting for licensed services and the DMEPOS supplier complies with State licensure laws and is ultimately responsible for the services provided by a contractor.

Comment: One commenter asks how disallowing the contracting of licensed individuals could affect competitive bidding, given that a supplier is required to submit a bid for all of the oxygen modalities.

Response: When allowed under State law, we will permit contracting for licensed services, so long as the DMEPOS supplier complies with State licensure laws and is ultimately responsible for the services provided by a contractor. In order for a DMEPOS supplier to be able to participate in the DMEPOS competitive bidding program, the supplier must comply with all of the DMEPOS supplier standards and be enrolled in the Medicare program as a DMEPOS supplier.

Comment: One commenter asked if this rule is requiring all oxygen suppliers to directly provide liquid oxygen since CMS competitive bidding rules allow for contracting in certain areas.

Response: No, all oxygen suppliers do not need to directly provide liquid oxygen. A supplier can use a qualified subcontractor to deliver oxygen. If the supplier is not in a competitive bidding area and does not furnish liquid oxygen as part of their business

model and the prescription specifically indicates that the physician is ordering liquid oxygen, the supplier would either need to get approval from the ordering physician to furnish a different modality or refer the beneficiary to another supplier. If a physician orders liquid oxygen in areas that fall under competitive bidding, then the oxygen supplier must supply liquid oxygen.

Comment: A commenter stated that the proposed rule would result in different Federal requirements for hospital-based DMEPOS suppliers based solely on the location of the supplier and further disadvantage hospitals because hospitals generally use independent contractors to perform its services.

Response: We disagree with this commenter because all DMEPOS suppliers, including those based at hospitals or operated by other providers, are required to meet State licensing requirement for the services they provide. This change will enable CMS or our designated contractor to verify that the supplier is meeting the applicable State licensing requirements for the services that it furnishes.

2. Physical Facility--Appropriate Site

In §424.57(c)(7), we proposed to clarify the supplier standard for maintaining a physical facility on an appropriate site. Specially, we proposed to clarify the term, "appropriate site." In addition, we stated that an "appropriate site" applies to "closed door" businesses, (such as pharmacies/suppliers providing services only to beneficiaries residing in a nursing home). We also solicited comments on whether we should establish a minimum square footage requirement to the definition of an appropriate site and what, if any, appropriate exceptions would apply to a minimum square footage requirement.

Comment: One commenter recommended that a minimum square footage requirement be established so the suppliers cannot qualify for participation in the Medicare program with unsuitable locations. This commenter stated that square footage should be adequate to store the necessary inventory.

Response: We appreciate this comment and have adopted a minimum square footage requirement of 200 square feet in §424.57(c)(7). We agree with this commenter that a DMEPOS supplier must maintain a minimum area of space for inventory, storage, and including patient records.

Comment: Several commenters stated that the variability between suppliers and services provided are too great to set a minimum number of square feet required to attain a supplier number.

Response: We appreciate these comments and considered them in establishing minimum square footage requirements within §424.57(c)(7).

Comment: A number of commenters opposed the establishment of a specific square footage requirement for supplier' physical locations.

Response: Since many DMEPOS suppliers who do not have a minimum square footage have been determined in the past to be fraudulent suppliers or have provided less than sufficient services to Medicare beneficiaries, we believe that a minimum square footage requirement is necessary to ensure that DMEPOS suppliers are operating a legitimate business. However, based on public comments, we were concerned that establishing a minimum square footage requirement of 500 square feet may impose an undue burden for some suppliers. Accordingly, based on public comments and our

review of existing supplier operations, we are adopting a minimum square footage of 200 square feet per practice location. We believe that 200 square feet represents the smallest practice location that can be used to meet the supplier standards in §424.57. Specifically, we would expect that most practice locations have space for inventory, storage, including patient records, a desk and chairs, and in most cases a restroom for employees and customers.

Comment: One commenter recommended that we clarify that DMEPOS suppliers may continue to utilize centralized business centers to house beneficiary and other business records and centralized customer call centers are permissible under this revised standard.

Response: We believe that it is necessary to have prompt access to delivery, maintenance, and beneficiary records at the supplier's facility where the beneficiary receives services. This enables the beneficiary to promptly obtain necessary information and for CMS and our agents to perform a review of the records. We agree that the use of a centralized business center by a multisite supplier to house these records when the information in the records can be furnished to the beneficiary or CMS and our agents, or both. For example, the supplier location could use a computer terminal to access the records which are being stored off site. Then, it could express mail the documents requested.

Comment: A commenter stated that it is not economically feasible for a small supplier to maintain a storefront.

Response: We do not require that a DMEPOS supplier maintain a storefront, and if the DMEPOS supplier chooses to maintain a storefront, it may be coupled with its storage space for DMEPOS. However, if the supplier is in a commercial building, the sign can be posted at the entrance of the building. We believe that it is essential for our beneficiaries and site reviewers to be able to promptly locate the supplier. Therefore, the signage must be readily visible to the general public. We understand the concerns that additional costs may be incurred for small businesses. However we believe that the majority of our DMEPOS suppliers already meet this requirement. Additionally, those DMEPOS suppliers with less than the 200 square foot minimum space and who have entered into a long term lease before the publication of this final rule will have time to transition into a new location, as explained later in this rule.

Comment: Several commenters stated that they do not support CMS' proposal to micromanage a supplier' business operation by dictating size, hours, staffing, and access via a single standard without exception for the specific services being furnished.

Response: We believe that the provisions of §424.57(c)(7) are designed to ensure that DMEPOS suppliers conform to generally accepted business practices employed by quality suppliers.

Comment: Several commenters believe it would be in CMS's best interest to retain the current policy which allows for a central record storage location for multi-State DME suppliers.

Response: We agree that multistate DME suppliers can maintain central record storage locations and have amended the regulations text in §424.57(c)(7)(i) to reflect this concern.

Comment: One commenter stated that there can be a problem with the requirement of external signage when it conflicts with local zoning ordinances.

Response: We believe that prospective suppliers of DMEPOS and existing suppliers of DMEPOS must understand and comply with the supplier standards found in this section. Accordingly, prospective suppliers of DMEPOS should ensure that their practice location meets the requirements found in §424.57(c)(7) and the other supplier standards found in this section prior to buying or entering into a leasing arrangement for a given practice location. For example, if the owner of prospective supplier of DMEPOS knows or should have known that local zoning ordinances preclude the establishment of home-business in a residential neighborhood, then the prospective supplier of DMEPOS should make the business decision to: (1) obtain a waiver to the local zoning ordinance in advance of submitting their enrollment application to the NSC; or (2) select a different practice location that will ensure the supplier's compliance with the requirements specified in §424.57(c)(7).

Comment: One commenter stated that it may not be possible to fulfill the signage requirement because the owner of the building may not allow the posting of the sign, and that the patients that they see are by appointment only so posting a sign with office hours is not necessary.

Response: As previously stated, we believe that prospective suppliers of DMEPOS and existing suppliers of DMEPOS must understand and comply with the supplier standards found in this section. Accordingly, prospective suppliers of DMEPOS should ensure that their practice location meets the requirements found in §424.57(c)(7) and the other supplier standards found in this section prior to buying or entering into a leasing arrangement for a given practice location. Accordingly, we disagree with this commenter, and believe that it is essential that the beneficiaries and CMS agents can clearly see where the supplier is located and the supplier's hours of operation. If the building owner will not allow the posting of hours of operation, then the DMEPOS supplier should consider the supplier site to be inappropriate for a business that serves Medicare beneficiaries. Even for suppliers that take appointments, we believe that proper signage and posted hours are required for proper beneficiary information.

Comment: One commenter believes it is not always possible to give the NSC prior notice to a change in the hours of operation.

Response: While we understand that suppliers have 30 days to notify the NSC of change in posted business hours, we do not believe that legitimate suppliers routinely change their posted hours of operation frequently. Moreover, there is nothing in our current rules or within this final regulation which precludes a DMEPOS supplier from notifying the NSC prior to or at the time a change of posted business hours are implemented.

Comment: A commenter stated that size and space requirements are already established in the accreditation process, and therefore, are unnecessary as a separate supplier standard.

Response: Since the requirements included within accreditation standards set forth in §424.57(c)(21) through §424.57(c)(25) and quality standards are independent of the supplier standards in §424.57, we believe that it is appropriate to establish a minimum square footage requirement to assist us in determining whether a DMEPOS supplier is operating a legitimate business as neither of the aforementioned sets of standards include a provision for minimum square footage.

Comment: One commenter requested what defines a permanent, durable sign and noted that sometimes it may be necessary to have permanent signage attached to the glass panel of a facility.

Response: While we have not defined what constitutes a permanent durable sign, there is no requirement that a permanent sign be or not be attached to a glass panel.

Comment: Several commenters suggested that an exemption should be granted when it is necessary for the office to be temporarily closed during posted office hours to account for holidays, natural disasters, short-term closures, patient deliveries, emergencies, and other unforeseen occurrences.

Response: We note that we have always made exceptions concerning posted hours for disasters and emergencies and Federal and State holidays. However, while we recognize that personal emergencies do occur, we believe that suppliers should be

available during posted business hours. Moreover, we believe that a DMEPOS supplier should do its best to plan and staff for temporary absences.

Comment: 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.

Response: We agree with the concerns raised by this commenter and have adopted an exception to §424.57(c)(7) for State-licensed orthotic and prosthetic personnel in private practice as one of the exceptions to this provision.

Comment: One commenter suggests that rather than mandating a certain amount of square footage, an alternative could be a rule indicating that the office space must consist of an ADA accessible reception area, a minimum of one examination room and a restroom, unless there is a common area restroom.

Response: We believe that it would be very difficult for us to develop specifications for these items. Moreover, we believe that doing so would likely be more restrictive for some types of suppliers.

Comment: One commenter notes that in most leased spaces, especially in medical buildings, the signage locations are predetermined, and therefore, the commenters do not believe a quality standard should mandate signage on the exterior of the building.

Response: We believe that the sign must be visible at the main entrance of the facility and visible to the public. Therefore, in a public medical building, the sign could be posted in the main lobby entrance if access to the lobby is available to the general public.

Comment: One commenter recommended that if CMS does set minimum square footage requirements that we give suppliers time for the expiration of current leases and to obtain a new location or "grandfather" locations already in use.

Response: We agree with this commenter and will establish a 3-year phase-in period for those existing suppliers of DMEPOS who have signed leases, including long-term leases, on or before the publication date of this final rule. We believe that this phase-in period will provide small businesses with sufficient time to identify a practice location that meets the minimum square footage requirement. We will make this requirement effective for existing DMEPOS suppliers 3 years from the effective date of this regulation. However, we do not believe that it is appropriate to establish a similar requirement for prospective suppliers of DMEPOS, including those suppliers who have a pending enrollment application with the NSC. Consequently, we expect prospective DMEPOS suppliers to comply with this requirement as of the effective date of this regulation. As prospective DMEPOS suppliers seek billing privileges after the effective date of this regulation, we expect them to comply with this requirement in order to be enrolled in Medicare.

Comment: One commenter is concerned that the minimum square footage requirement may be over interpreted as a means to shut down legitimate suppliers (for

example, a legitimate supplier being 25 feet short after the rule becomes effective but having a 5-year lease to fulfill).

Response: We proposed the minimum square footage as a basis for ensuring that legitimate suppliers are meeting the supplier standards in §424.57 and that these suppliers are providing quality products and services to Medicare beneficiaries. As stated previously, we will impose this requirement on those suppliers who have entered into leases, including long-term leases, on or before the date of publication of this final rule. Accordingly, we maintain that DMEPOS suppliers who had entered into lease arrangements of 1 year or less must come into compliance with this provision at the end of their current lease. Similarly, DMEPOS suppliers who have entered into leasing arrangements of more than 1 year but less than 3 years must come into compliance with this standard at the end of their current lease; and that all existing DMEPOS suppliers must come into compliance with this standard within 3 years of the effective date of this final rule.

Finally, while we are establishing a transition period for implementation of this requirement for DMEPOS suppliers already enrolled in the Medicare program, we are not adopting a transition period for DMEPOS suppliers enrolling a new practice location, reactivating the billing privileges for a DMEPOS supplier previously enrolled in the Medicare program or for DMEPOS suppliers changing their existing practice location or selling their existing practice location.

Comment: One commenter notes that licensing and accrediting bodies inspect suppliers' facilities to assure the supplier has a legally defined means of providing care.

The commenter believes that Medicare should have no role in determining the appropriateness of a supplier's facility.

Response: While we agree that licensing and accreditation are essential elements for ensuring quality of care, we disagree with the commenter that CMS or our designated contractor should have no role in determining the appropriateness of a supplier's facility. Since the implementation of the DMEPOS supplier standards in October of 2000, we have played an important role in determining the appropriateness of a supplier's facility via regulation at §424.57.

Comment: One commenter questioned why the square footage matters if a supplier meets all requirements and has Medicare beneficiaries coming to the supplier's physical location where products are stocked and provided.

Response: We maintain that an appropriate amount of square footage is generally necessary to ensure that the facility can meet its obligations to a beneficiary which include an area for the beneficiary to sit, or room for a wheelchair and room for it to turn/move around, as well as room for stock and for the equipment necessary for running a business. In addition, in the past many suppliers with very minimal square footage have been determined to be fraudulent or have provided inferior service to Medicare beneficiaries.

Comment: One commenter questioned whether it is CMS' intent to require suppliers to be a retail-type business by mandating minimum square footage which needlessly drives up the cost of doing business for nonretail suppliers.

Response: While "closed door" businesses are eligible to participate in the Medicare program, we believe that it is necessary to include a minimum square footage into what is considered an appropriate site. We understand there may be concern that this requirement may cause a change in business practices for smaller suppliers and could possibly result in increased costs. However, we believe that most DMEPOS suppliers are already meeting this standard.

Comment: A commenter stated that the minimum square footage requirement is not appropriate because the Federal rule would preempt State or local land use or supplier laws already in place and will not take into account the supplier's operations or the needs of the beneficiaries being serviced.

Response: We disagree with this commenter. While we are not preempting State and local land use laws, we are establishing criteria to enroll in the Medicare program as a DMEPOS supplier. We believe that this revised criterion will help to ensure that Medicare beneficiaries receive quality services from quality suppliers.

Comment: A commenter stated that the minimum square footage requirement is unnecessary for suppliers' facilities that are not intended for beneficiary access and that this proposed standard blurs the distinction between a classic retail establishment and a service facility dedicated to the provision of supplies and equipment to patients in their homes. In addition, the commenter requests that CMS consider different business models for supplier standards, including suppliers that provide quality items and services to beneficiaries, but do not operate facilities intended to be stores for in-person access.

Response: We disagree with this commenter. Since most DMEPOS suppliers are not solely service facilities, we believe that these enrolled suppliers must provide reasonable access for Medicare beneficiaries in the event that a beneficiary has a problem or requires prompt service. It is also essential that CMS or our agents have access during posted hours of operations to ensure that the supplier continues to meet the supplier standards in §424.57.

Comment: A commenter suggests that CMS consider that the appropriate size of a facility is based on the services provided, the size of the organization and the status of the location.

Response: We appreciate this comment and have considered these factors in adopting a minimum square footage requirement for DMEPOS suppliers. As noted previously, we maintain that an appropriate amount of square footage is generally necessary to ensure that the facility can meet its obligations to a beneficiary which include an area for the beneficiary to sit, or room for a wheelchair and room for it to turn/move around, as well as space for inventory, patient records and equipment necessary for running a business.

3. On-site Inspections

In §424.57(c)(8), we proposed to clarify this provision by revising (c)(8) to read as follows: "Permits CMS, the NSC, or agents of CMS or the NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section."

Comment: One commenter recommended that instead of revoking a supplier's billing privileges when a site visit cannot be conducted, the NSC should "suspend" the

billing privileges pending further investigation to determine if the entity is a legitimate supplier.

Response: We do not have statutory or regulatory authority to suspend billing privileges under those circumstances. However, we note that DMEPOS suppliers are afforded appeal rights if their billing privileges are revoked.

Comment: A commenter believes routine on-site visits should be by appointment to ensure proper person(s) are available.

Response: We disagree with this commenter. While we understand that proper staff may not always be on-site when unannounced site visits occur, it is necessary for all DMEPOS suppliers to be open during posted hours of operations. The revised language only clarifies who is authorized to conduct the on-site visit. Moreover, we believe that unannounced site visits are necessary to ensure that a DMEPOS supplier is continually meeting the supplier standards in §424.57.

Comment: Several commenters believed that it would be unjust to deny or revoke based on one site visit during posted hours because the business could be closed for a legitimate reason on the day of the visit, the mandated staff may be on call, or that another emergency situation may occur that would prevent a DMEPOS supplier from being open during posted hours of operation.

Response: While we understand that unexpected or emergency business closings can occur, we believe that it is essential that DMEPOS suppliers establish practices and procedures to address unexpected or emergency situations. In addition, we understand

the nature of unforeseen emergencies and when warranted, the NSC will conduct an unannounced follow-up visit prior to denying or revoking billing privileges.

Comment: One commenter believes this requirement constitutes over regulating by the government.

Response: We disagree with the commenter. We have found unannounced on-site visits to be a very effective tool in combating fraud and abuse and to protect the Medicare Trust Fund from unscrupulous suppliers. Moreover, CMS and our designated contractor, the NSC, have conducted unannounced on-site visits since 2000 to ensure compliance with those standards which only can be verified by visual inspection.

4. Business Telephone Operations

In §424.57(c)(9), we proposed a revision of this standard so that it would read, "Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries. The use of cellular phones, beeper numbers, and pagers is prohibited. Additionally, DMEPOS suppliers are prohibited from forwarding calls from the primary business telephone listed under the name of the business to a cellular phone, or a beeper/pager. The exclusive use of answering machines, answering services or facsimile machine (or combination of these options) cannot be used as the primary business telephone during posted operating hours."

Comment: One commenter requested that we clarify that all call forwarding to a main business office number when multiple office locations exist would be permitted.

Response: While we appreciate this comment, we do not believe that it is appropriate for a DMEPOS supplier to forward calls from one practice location to a main business office number when multiple practice locations exists.

Comment: One commenter stated that preventing the use of alternative technologies during business hours would have an adverse effect on the quality of services that suppliers are able to furnish to Medicare beneficiaries.

Response: While we appreciate this comment, we believe that the supplier standards in §424.57(c)(9) are not overly prescriptive and help to ensure that the DMEPOS supplier is operational during posted hours of operations.

5. Comprehensive Liability Insurance

In §424.57(c)(10), we proposed a revision to this provision to specify that the DMEPOS supplier has a comprehensive liability insurance policy in the amount of at least \$300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier and ensures that insurance policy must remain in force at all times. In addition, we proposed that a DMEPOS supplier must list the NSC as a certificate holder on the policy and notify the NSC in writing within 30 days of any policy changes or cancellations. Although we are not finalizing the proposed revision in this final rule, we will consider this provision in a future rulemaking.

6. Solicitation of Beneficiaries

In §424.57(c)(11), we proposed to revise this supplier standard to clarify that suppliers and their agents cannot make a direct solicitation of Medicare beneficiaries,

which includes, but is not limited to, telephone, computer, e-mail, instant messaging, or in-person contacts, except under the current provisions at §424.57(c)(11)(i) through (iii).

Comment: One commenter recommended that we retract the proposed provision and allow the current telephone standard to remain unchanged. This commenter also stated that a supplier is not "cold calling" the beneficiary when the supplier has received a verbal order from a physician and requested that we clarify that a supplier is not violating this standard if the supplier contacts a beneficiary via telephone after it has received a verbal order from the beneficiary's treating physician.

Response: We do not agree. We believe that it is inappropriate for a DMEPOS supplier to contact a beneficiary based solely on a physician order. In the situation described by the commenter, the contact is without the beneficiary's knowledge that the physician would be contacting a supplier on the beneficiaries behalf and would be prohibited unless one of the current provisions in §424.57(c)(11) (i) through (iii) applied. However, if a physician contacts the supplier on behalf of the beneficiary's 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 by that physician.

Comment: One commenter stated that CMS lacks the statutory authority to expand on the longstanding statutory and regulatory prohibition on unsolicited telephone contacts to further types of speech.

Response: We disagree with the commenter's assertion that we are trying to expand on the statutory authority which prohibits unsolicited telephone contacts set forth in section 1834(a)(17) of the Act. We believe that we have the statutory authority to clarify and revise the supplier standard in §424.57(c)(11). Specifically, section 1834(j)(1)(B) of the Act gives the Secretary the authority to establish additional supplier standards. In addition, section 1871 of the Act provides the Secretary the right to prescribe regulations as may be necessary to carry out the administration of the Medicare program. Moreover, we believe that it is necessary to review, clarify, and, if necessary, revise existing regulatory standards to address changes in practice by DMEPOS suppliers in order to protect Medicare beneficiaries and the Medicare Trust Funds.

Comment: Several commenters stated that our proposal to clarify and revise §424.57(c)(11) violated First Amendment protections by unconstitutionally restricting commercial speech. In addition, this commenter stated that, "Business solicitation by DME suppliers is clearly a form of commercial speech as any business has the right to market its products to potential customers. Advertising by suppliers of medical equipment is not inherently misleading and can be an important method of informing beneficiaries of products and services that are covered or accessible under their Medicare coverage."

Response: We disagree that the revisions that we are adopting in §424.57(c)(11) of this final rule deny or abridge First Amendment rights. Specifically, this revised standard does not change or alter a DMEPOS supplier's ability to advertise its products and services to the general public or Medicare beneficiaries generally. As such, television, radio, and Internet advertisements are permitted. In addition, DMEPOS suppliers may advertise their products or services at health fairs, community events, or the DMEPOS supplier's web site. This provision seeks to prohibit a supplier from making direct solicitations with Medicare beneficiaries without their consent.

Comment: One commenter stated that the proposed change to §424.57(c)(11) would harm Medicare beneficiaries and all healthcare consumers. This commenter also stated that this proposal would have the effect of limiting consumer education, price comparison, and overall choice.

Response: We disagree with this commenter that the changes we are adopting in this final rule will limit consumer education, price comparison or overall choice because suppliers can continue to educate the public about the advantages of their products or services through marketing practices that help to educate and inform the public and Medicare beneficiaries about their healthcare choices.

Comment: One commenter stated that if a beneficiary visited a retail store, on their own volition, to seek information on DMEPOS products, that the proposed change would prohibit the supplier from providing information or education that the beneficiary requested.

Response: We disagree that a DMEPOS supplier could not provide information or education when the beneficiary contacts the DMEPOS supplier for information. The revised supplier standard in §424.57(c)(11) states that DMEPOS suppliers must agree not to directly solicit patients, except as permitted under the current provisions in §424.57(c)(11)(i) through (iii). Accordingly, if the Medicare beneficiary initially contacts the DMEPOS supplier, then the supplier's contact with the beneficiary would not be a direct solicitation and the supplier may, therefore, discuss, educate, and inform the Medicare beneficiary about the various products and alternatives available to that beneficiary.

Comment: One commenter stated that we did not adequately define, "directly solicit" or "coercive internet advertising."

Response: We appreciate the request for clarification. We believe that "direct solicitation" occurs when a DMEPOS supplier or its agents directly contacts an individual Medicare beneficiary by telephone, e-mail, instant messaging, or in-person contact without his or her consent for the purpose of marketing the DMEPOS supplier's health care products or services or both. In addition, we removed the reference to "coercive response internet advertising" from this rule in order to ensure that this standard is clear and understandable.

Comment: One commenter asked if internet advertising such as internet "yellow pages," the use of Google AdWords, appearance in search engine results or other "keyword" advertisements informing the public of products and services provided by a supplier would constitute coercive response internet advertising.

Response: As noted previously, we removed the reference to “coercive response Internet advertising” from this final rule in order to ensure that this standard is clear and understandable. We believe that advertising techniques such as internet yellow pages, Google AdWords, and search engine keyword result-driven advertising are techniques used by businesses to educate and inform the public about a company and its products. In addition, these practices are normally considered mass advertising. Accordingly, web site advertisements that are intended to market a DMEPOS supplier to the general public are permissible and are not considered direct solicitation for the purpose of this standard.

Comment: Several commenters would like CMS to clarify the restrictions on a supplier who may contact a Medicare recipient about noncovered items because it appears to limit a supplier's legitimate marketing activities such as web pages describing various products, services and inserts to periodical publications dealing with various products and services.

Response: We do not agree that this standard limits a supplier's legitimate marketing activities. We believe that DMEPOS suppliers can continue to conduct mass advertising. For the purposes of this final rule, we believe direct solicitation targets Medicare beneficiaries without their consent. Accordingly, we believe that direct solicitation is significantly different in scope than general advertising. Again, these solicitations are one on one in nature and not the same as general advertising to the public and also apply to noncovered items if they are being solicited by a Medicare enrolled DMEPOS supplier.

Comment: One commenter asks if a web site dedicated to short-term cash rentals of not readily-accessible portable oxygen concentrators for travel use (using an Advance Beneficiary Notices (ABN) if the customer is a Medicare beneficiary) violates the provisions outlined in the proposed rule.

Response: We believe, for the purpose of this standard, a web site dedicated to short-term cash rentals of not-readily accessible portable oxygen concentrators for travel use to be of use to the general public. Using ABNs if the customer is a Medicare beneficiary would be required for the supplier to not be held liable for the charge under section 1879 of the Act. Using ABNs assists the beneficiaries in making informed decisions about the product. A dedicated web site that can be freely accessed by the general public, at the consumer's choice, is not considered direct solicitation for the purpose of this standard.

Comment: Several commenters suggested that the standard is satisfactory as it exists and that changing it as proposed would be overly restrictive, burdensome, and could prevent patients from receiving important information.

Response: We believe the revision of this standard was necessary to include current trends and technological advances, such as door-to-door solicitation, electronic mail, and instant messaging. However, we do not believe this provision would prohibit DMEPOS suppliers from contacting Medicare beneficiaries in the situations described in the current provisions in §424.57(c)(11)(i) through (iii). For example, a supplier could contact a beneficiary with whom they already have an established business relationship or

for legitimate reasons, such as annual fitting reminders, updating or verifying information from previously serviced beneficiaries.

Comment: Several commenters recommended that we add another reason for the DMEPOS supplier to contact the patient, namely when the physician places the DMEPOS order (written or verbal) on behalf of the patient.

Response: As noted previously, a DMEPOS supplier may not contact a beneficiary based solely on a physician order. However, a supplier may contact a beneficiary if a physician contacts a DMEPOS 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). In that instance, the contact would not be considered a direct solicitation and therefore, would not implicate the standard set forth at §424.57(c)(11). Please note that the beneficiary need only be aware that a DMEPOS 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 the consultation.

Comment: A commenter stated that prohibiting a supplier from directly soliciting patients, including "in-person contacts" improperly restrains free speech and disadvantages a small supplier by limiting a supplier to mass media advertising, which is only financially feasible to large suppliers. The commenter also stated that the beneficiary will be adversely affected because, under the proposed rule, a member of the hospital staff would need to obtain written permission from the beneficiary and transmit

that permission to the supplier before the supplier could initiate the service causing unnecessary waiting periods.

Response: We believe that a "direct solicitation" occurs when a DMEPOS supplier or their agent contacts an individual Medicare beneficiary without their consent for the purpose of marketing the DMEPOS supplier's health care products or services or both; therefore we are clarifying our regulations by adding the definition of "direct solicitation" to §424.57(a). These types of direct solicitations are one on one in nature and not the same as advertising to the public in a general marketing campaign. Finally, we do not believe Medicare beneficiaries will be adversely affected by this provision's contact restrictions causing unnecessary waiting periods prior to a DMEPOS supplier's initiation of services. As long as the beneficiary has completed a consent form giving the hospital staff member permission to share the beneficiary's information with the DMEPOS supplier for the purpose of initiating service, the hospital staff person can order the service on the beneficiary's behalf. Hospitals or other entities use consent forms for the purpose of ordering medical supplies or services on behalf of patients as standard operating procedure to ensure compliance with the Privacy Act and its implementing regulations.

7. Product Delivery and Beneficiary Instructions

In §424.57, we proposed to revise paragraph (c)(12) provision to clarify its intent. Specifically, we proposed that a DMEPOS supplier: (1) is responsible for maintaining proof of the delivery in the beneficiary's file; (2) must furnish information to beneficiaries at the time of delivery of items as to how the beneficiary can contact the supplier by

telephone; (3) must provide the beneficiary with instructions on how to safely and effectively use the equipment or contract this service to a qualified individual; (4) is responsible for providing instruction on the safe and effective use of the equipment that should be completed at the time of delivery; and (5) must document that this instruction has taken place. We are continuing to review the public comments received on this provision and we will consider finalizing this provision in a future rulemaking effort.

B. New DMEPOS Supplier Standards

1. Obtaining Oxygen

In §424.57(c)(27), we proposed a new standard that specified that the DMEPOS supplier must obtain oxygen from a State-licensed oxygen supplier. In addition, we stated that the proposed new standard would not apply when the State does not license oxygen suppliers.

Comment: One commenter stated that they generally agree that DMEPOS suppliers should obtain oxygen from appropriately licensed oxygen supply companies, but requested that we clarify that the supplier standard in §424.57(c)(27) does not preclude suppliers from subcontracting the pick-up and delivery of liquid and gaseous oxygen cylinders.

Response: It is our intention to ensure that oxygen suppliers promote quality in the furnishing of oxygen or oxygen-related equipment, and, in doing so, protect Medicare beneficiaries against substandard product(s) or poor service. The pick-up and delivery of liquid and gaseous oxygen cylinders does not interfere with our intentions for this

provision. Therefore, oxygen suppliers may continue to subcontract the pick-up and delivery of oxygen and oxygen-related products.

Comment: A commenter stated that there is confusion regarding who needs to be licensed for specific services and believes the provisions in §424.57(c)(27) needs greater specificity and detail.

Response: We appreciate this comment and have revised §424.57(c)(27) to address this concern. We have clarified in this section that DMEPOS suppliers are responsible for knowing which licenses are required for the DMEPOS that they supply.

Comment: One commenter interpreted the proposed rule as requiring an oxygen supplier to get their oxygen from an in-State licensed oxygen supplier.

Response: This final rule will require licensed oxygen suppliers to get their oxygen and oxygen-related equipment from other licensed or State-certified oxygen suppliers. However, if an oxygen supplier's physical location is in a State that does not require oxygen licensure or certification, then the oxygen supplier is not required to get its oxygen or oxygen-related equipment from other licensed oxygen suppliers. It is not our intention to restrict Medicare beneficiaries' oxygen supplier choices.

Comment: One commenter interpreted this standard as requiring an in-State oxygen license for out-of-State suppliers and believes this limits access for Medicare beneficiaries.

Response: We do not require oxygen licensure or certification for oxygen suppliers whose physical locations are in States that do not require oxygen licensure or certification. However, this provision does restrict unlicensed oxygen suppliers from

supplying oxygen and oxygen-related equipment to oxygen suppliers whose physical locations are in States that require oxygen licensure or certification.

Comment: A commenter suggested adding "if applicable" to this provision because not all States license oxygen suppliers.

Response: We agree and will revise §424.57(c)(27) to incorporate language regarding applicability to States that license oxygen suppliers.

Comment: One commenter recommended that we incorporate the proposed standard in §424.57(c)(27) into the revised supplier standard in §424.57(c)(1).

Response: We disagree with this commenter and have adopted a new supplier standard in §424.57(c)(27).

2. Ordering and Referring Documentation

In §424.57(c)(28), we proposed a new supplier standard that states that the supplier is required to maintain ordering and referring documentation, including the National Provider Identifier, received from a physician, nurse practitioner, physician assistant, clinical social worker, or certified nurse midwife, for 7 years after the claim has been paid.

Comment: One commenter stated that it would be more practical and reasonable to base any records retention policy on the date of service and lengthen the retention period to 10 years, which is the guideline used by many in the industry. This commenter stated that this change would capture CMS' concerns about availability of records and cause fewer disruptions to the supplier recordkeeping practices. Another commenter

believes that record retention should mirror that of industry or State standards such as the State Board of Pharmacy which is typically 3 years.

Response: We appreciate the commenter' suggestions. However with the enactment of section of 6406(a) of the ACA, we published an interim final rule with comment in the May 5, 2010 **Federal Register** (75 FR 24437), which established 7 year retention period based on the date of service in §424.516(f). Moreover, we believe that this retention policy is consistent with the policy established at §424.516(f) in the November 19, 2008 final rule (73 FR 69726) entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions: and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)". Finally, in §424.57(c)(28), we establish that suppliers are required to maintain ordering and referring documentation consistent with the provisions found in §424.516(f).

Comment: One commenter stated that it would be more practical and reasonable to base any records retention policy on the date of service.

Response: We concur with this commenter and have revised this supplier standard to reflect that records should be based on the date of service and not the date of payment.

Comment: One commenter is concerned about why CMS would develop a supplier safeguard mandating records retention based upon the date the claim was paid when all business transactions are based upon the date of service or date equipment was

provided. The addition of a new date would require systems modification just for managing records and the purge process.

Response: As stated previously, we have revised this standard to base any records retention policy on the date of service.

Comment: Some commenters stated that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191) and State laws govern the manner in which medical records need to be kept and urged CMS to retract the new standard in §424.57(c)(28).

Response: The HIPAA record retention policy codified at 45 CFR 164.530 relates to a covered entities privacy policies and procedures (for example, administrative records of complaints, notices, and other administrative actions or procedures); and therefore, does not preclude us from establishing a documentation retention standard. In addition, since Medicare is a Federal program, it is not subject to State law. We note that section 6406(a) of the ACA (Pub. L. 111-148) amends section 1842(h) of the Act by adding a new paragraph (9) which states the following:

The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

We also note that section 6406(d) of ACA specifies that "[t]he effective date of this provision shall apply to orders, certifications and referrals made on or after January 1, 2010." Therefore, we believe that finalization of our proposed record

retention requirements at §424.57(c)(28) is consistent with the section 6406(a) of ACA requirement.

3. Prohibition on Sharing of a Practice Location

In §424.57(c)(29), we proposed a new standard that specifies that the supplier is prohibited from sharing a practice location with another Medicare supplier. In addition, we solicited comments on whether we should establish an exception to this space sharing proposal for physicians and nonphysician practitioners and the circumstances which warrant an exception since we are aware that physicians and other licensed nonphysician practitioners may obtain their own DMEPOS supplier number and furnish DMEPOS from their office.

Comment: One commenter stated that the proposed standard is too restrictive and could discourage suppliers from forming networks under the competitive rules and urged CMS to retract the new standard in §424.57(c)(29).

Response: We do not believe that the new standard will restrict the ability of suppliers to form networks for the purpose of competitive bidding.

Comment: Several commenters requested that we clarify whether a "practice location" is limited to physical space or whether it also encompasses equipment or staff and requests clarification of the definition of the terms "sharing" and "practice location."

Response: DMEPOS suppliers list the practice location in Section 4 of the Medicare enrollment application (CMS-855S). For the purposes of this standard, sharing a practice location refers to sharing of the physical location as described on the

CMS-855S. In general, the practice location is the physical space where a DMEPOS supplier operates his or her business and meets with customers and potential customers.

Comment: One commenter requested that we clarify that the enrolled practice location does not include a warehouse, storage facility, or repair facility.

Response: As stated previously, a DMEPOS supplier identifies the practice location in Section 4 of the CMS-855 and is a place where a DMEPOS supplier operates his or her business and meets with customers and potential customers.

Comment: Several commenters requested that we clarify that the space sharing provision in §424.57(c)(29) is not intended to preclude a physician or licensed health professional (who is also recognized as a DMEPOS supplier by Medicare) from furnishing both DMEPOS products and professional services to his or her patients in the same practice location.

Response: We appreciate this comment and have established an exception to this standard for physicians and NPPs as defined in the statute. Under section 1842(b)(18)(C) of the Act, physical and occupational therapists may operate as a DMEPOS supplier, as well as a licensed professional at the same practice location if these suppliers are furnishing DMEPOS to their own patients as part of professional service.

Comment: One commenter stated that if any limitation on sharing practice locations is put in place that we should, at most, formalize the NSC's practice of prohibiting multiple NSC supplier numbers at a single address.

Response: While we have established a limited number of exceptions to the prohibition of sharing a practice location, we agree that the NSC should not convey

billing privileges to suppliers who are not in compliance with the provisions of this final rule. Moreover, with the implementation of the National Provider Identifier (NPI), a DMEPOS supplier must obtain a NPI for each practice location, unless the supplier is a sole proprietorship. Accordingly, we believe that this policy is consistent with current National Supplier Clearinghouse operational policy and the provisions for issuing an NPI.

Comment: One commenter agreed with the statement in the preamble of the proposed rule that stated, “We do not believe that legitimate DMEPOS suppliers routinely share practice locations with another Medicare supplier.”

Response: We appreciate this comment and continue to believe that legitimate businesses do not share practice locations with competitors.

Comment: One commenter stated that if a space sharing agreement passes under both the Anti-kickback statute and the Stark statute and regulations, then they do not believe such arrangements should be automatically prohibited by a supplier standard.

Response: We disagree with this commenter. While the statutory and regulatory provisions referenced previously are intended to prohibit specific practices, these provisions do not address the full range of problems that occur when DMEPOS suppliers are commingling practice locations. The Anti-kickback statute, the Stark statute, and our regulations are separate authorities and do not preclude us from establishing additional DMEPOS supplier standards. In addition, we do not believe that legitimate DMEPOS suppliers share inventory, staffing or a practice location with a competing DMEPOS supplier.

Comment: Several commenters recommended that physical therapists (PTs) be exempt from this provision because it would place an undue burden on the patient to purchase the limited DME items offered in the PT office at another location – especially for pediatric PTs or those located in rural areas.

Response: As stated previously, we are establishing an exception for physical and occupational therapists from the provision in §424.57(c)(29).

Comment: Several commenters stated that there should be an exception to this provision when both businesses are owned by the same person or entity or the DME supplier is a separate unit located within or owned by a larger health care facility such as a hospital. Other commenters stated there should be an exception to this provision when a pharmacy is operating within a State-licensed health center because of the burden separate locations would put on the patients.

Response: We disagree with commenters who stated that we should establish an exception based solely on ownership. Moreover, unless the owner of DMEPOS supplier is a sole proprietorship, DMEPOS suppliers are required to obtain a unique National Provider Identifier for each practice location. Accordingly, unless a DMEPOS supplier has satisfied an exception under §424.57(c)(29), we do not believe that an owner should be permitted to establish a sole proprietorship and an organizational entity at the same practice location. Similarly, we do not believe that the same owner should be able to obtain separate Medicare billing privileges for DMEPOS suppliers at the same practice location found on the Medicare enrollment application. As stated previously, we do not believe that legitimate businesses share practice locations with competitors. However,

we agree with the commenters who stated that there should be an exemption when the entity or DME supplier is a separate unit located within or owned by a larger facility. Therefore, we have established exceptions to the sharing of space limitation found in §424.57(c)(29). In §424.57(c)(29)(ii)(C), we have established an exception for DMEPOS suppliers that have a practice location within a Medicare provider that is subject to the requirements specified in 42 CFR 489.2(b). This exception will allow a hospital, home health agency (HHA), skilled-nursing facility (SNF), or other Part A provider that is enrolled in Medicare to co-locate with a DMEPOS supplier that is owned by that Part A provider and is a separate unit. It is important to note that these DMEPOS suppliers while owned by the Part A provider must still meet all of the other DMEPOS supplier standards in §424.57 to obtain and maintain Medicare billing privileges.

Comment: One commenter asked if two entities, with two different "Doing Business As" (DBA) names are owned by the same parent company would they be prohibited from having a common location under §424.57(c)(29).

Response: As stated previously, we have established certain exceptions to this provision. However, we do not believe that it is a common practice to establish multiple DBAs at the same practice location. Accordingly, we believe that two different DBAs that are owned by the same parent company would be prohibited from sharing a practice location under this provision.

Comment: One commenter believes the regulation text does not properly convey the intent of the language in the preamble and will result in additional micromanagement of DMEPOS suppliers by CMS.

Response: We believe that the provisions of this final rule and the regulation text are consistent. In addition, we believe that the provisions as adopted allow CMS or the NSC to ensure that DMEPOS suppliers are operating in accordance with established business practices used by legitimate companies. As stated previously, we do not believe that legitimate DMEPOS suppliers share inventory, staffing or operational space with their competitors.

Comment: One commenter believes that an orthotic and prosthetic facility should be allowed to share space with complementary, but not competing businesses that may already have a Medicare supplier number, specifically physicians and physical therapy offices.

Response: We disagree with this commenter. While we have established an exception to §424.57(c)(29) for physicians, NPPs, and physical and occupational therapists who are furnishing items to their own patients as part of their professional service, we do not believe that a similar exception should be established for orthotic and prosthetic facilities or personnel because they are not individual practitioners who are furnishing items to their own patients as part of their professional service. The facilities in question would be sharing space with another supplier whereas the exceptions noted are supplying their own patients as part of their service.

Comment: Several commenters questioned whether the supplier can have an office in the same building where other hospital-owned Medicare suppliers (outpatient pharmacy, physician groups) are located is if it is hospital-owned.

Response: We agree that a DMEPOS supplier may be enrolled within the same building owned by a hospital.

Comment: One commenter does not believe co-existing in an office space jeopardizes quality supplier standards.

Response: We disagree because we have found that unrelated business entities that share the same practice location often provide poor quality care or, in some case, are associated with fraudulent businesses or do not exist.

Comment: One commenter agrees with CMS' proposal that nonphysician DMEPOS suppliers should not share a practice location with another Medicare supplier, especially if that other Medicare supplier is a possible referral source.

Response: We appreciate the support for our provision regarding the sharing of space and further clarify that the Anti-kickback statute, the Stark Statute, and our regulations are separate authorities apart from the sharing of space provisions adopted within this final rule.

Comment: Several commenters requested that we not create exceptions to this provision for physicians and other licensed providers to share space as it is a bad idea that creates inconsistent application of the regulations. In addition, making physicians discontinue distributing DME from their offices is good and the physician, orthotist/prosthetist, and physical therapist should have no financial relationship to ensure true medical necessity.

Response: We believe that we can consistently apply the regulations and allow for reasonable exceptions. Moreover, we believe that physicians can furnish DMEPOS to

their own patients as part of professional service. In addition, in many cases, a physician furnishing DMEPOS to their own patients can benefit those patients in terms of convenience and continuity of care.

Comment: One commenter asks if this standard would apply in the circumstance where the business owner owns a pharmacy and a separate DMEPOS company with 2 different supplier Medicare numbers sharing the same location for retail sales (note – both businesses have the same stock holders and are held by a separate holding company).

Response: We believe that the scenario described is prohibited under the provisions of this final regulation.

Comment: One commenter suggested that an exception to this provision be made for those physicians/NPPs that supply blood glucose monitoring devices to their patients.

Response: We appreciate this comment and as stated previously, we are adopting an exception to the prohibition on space sharing for physician, NPPs, and physical and occupational therapists.

4. Hours of Operation

In §424.57(c)(30), we proposed a new supplier standard that would require a DMEPOS supplier to be open to the public a minimum of 30 hours per week, except for those DMEPOS suppliers who are working with custom-made orthotics and prosthetics.

Comment: Several commenters requested that physical therapy practices be exempt from posting office hours because this would limit the services available to the Medicare patients.

Response: We believe that all DMEPOS suppliers should have posted hours of operation.

Comment: A commenter stated that it would be burdensome for hospitals or health systems that owned or controlled DMEPOS suppliers to display hours of operation and that the proposed standard is unnecessary since the implementation of mandatory accreditation.

Response: In §424.57(c)(8), we already require that DMEPOS suppliers, including those owned or controlled by hospitals and health systems, to maintain a visible sign and post their hours of operation. Accordingly, we believe that we are clarifying an existing NSC practice by adopting this revised standard. Moreover, since accreditation primarily focuses on patient care, it does not directly address the verification of this existing supplier standard.

Comment: One commenter believes the requirement that suppliers maintain a physical facility that is staffed at all times with posted working hours is most beneficial.

Response: We appreciate this comment and have adopted a minimum number of posted hours of operation for DMEPOS suppliers in §424.57(c)(30).

Comment: Several commenters stated that it is a widespread practice among DMEPOS suppliers –large and small – to have part-time or "by appointment only" hours for some locations, especially in rural areas, and asked that we reconsider the new supplier standard in §424.57(c)(30) which requires suppliers to remain open to the public for a minimum of 30 hours a week. Some commenters believe remaining at the facility for 30 hours per week would leave no time for item delivery and proposed that CMS

consider the requirement met as long as the hours are posted and the supplier is open during those hours.

Response: We believe that DMEPOS suppliers must be open to the public a minimum number of hours to ensure patient access to services. After a careful review of these comments, we continue to believe that DMEPOS suppliers must be open and available to the public a minimum of 30 hours per week. We believe that establishing a minimum number of hours is in the best interest of the Medicare program and Medicare patients, especially for those who are disabled or with limited means of transportation.

Comment: Several commenters stated that they do not believe that CMS has the authority or business expertise to dictate the number of hours a DMEPOS supplier should operate to be considered legitimate when this would be determined based on the needs of the customer base.

Response: We believe that section 1834(j)(1)(B) of the Act gives the Secretary the authority to implement additional supplier standards. We maintain that the requirement that a DMEPOS supplier is open a minimum number of hours help to ensure that it is engaged in furnishing DMEPOS to Medicare beneficiaries. In addition, we believe that this requirement also may help increase access to care for Medicare beneficiaries.

Comment: One commenter recommended that we consider permitting flexibility in the hours of operation so long as they are clearly posted and deviations to the posted hours are noted with a specific return time.

Response: We disagree with this commenter. It is essential for our Medicare beneficiaries to have access to suppliers during regularly scheduled hours. Medicare beneficiaries should not be advised that the supplier has temporarily changed their hours once they have made the effort to visit the supplier. Moreover, allowing DMEPOS suppliers to constantly change their posted hours of operation would make it virtually impossible for us to determine if a supplier is actually in operation. While we recognize that emergencies do occur, it is the responsibility of the DMEPOS supplier to establish staff contingencies to ensure that their business remains open to the public in spite of a personal emergency.

Comment: Several commenters recommended that we establish an exception to the supplier standard in §424.57(c)(30) for physicians, physical therapists, and other licensed health professionals holding DMEPOS suppliers numbers, especially when DMEPOS supplies makes up such a small portion of the practice.

Response: We appreciate these comments and have added an exception to this supplier standard for physicians and licensed non-physician practitioners, including physical and occupational therapists, that only furnish DMEPOS supplies to their own patients to §424.57(c)(30).

Comment: Several commenters stated that it is not economically feasible for a small one person supplier to be staff during all posted hours of operations because they often make house calls.

Response: While we understand the concerns of small suppliers, we believe that Medicare beneficiaries and the NSC should be able to have access to the supplier at

regularly posted hours. Also, as previously noted, we have established exceptions for physicians, NPPs, and certain other suppliers.

Comment: One commenter stated that this requirement does not allow a sole proprietor, being the only certified fitter as well as the owner, to be sick, go on vacation, or have a personal emergency without violating Medicare standards.

Response: We agree and have adopted an exception to this provision for suppliers working with custom-made orthotics and prosthetics.

Comment: Several commenters stated that there may be episodic instances where DMEPOS suppliers may legitimately not be able to be open for 30 hours per week including inclement weather conditions, staffing shortages as the result of labor disputes, staff illnesses or holiday periods, and various other unusual occurrences or natural disasters that would prohibit a supplier from being open 30 hours in a particular week.

Response: We recognize that unforeseen emergencies do occur that would require a supplier to make temporary changes to scheduled hours. The NSC will take these circumstances into account. However, we believe that DMEPOS suppliers should adhere to its posted hours and should develop contingencies to remain open when personal emergencies or when staffing issues occur.

Comment: One commenter recommended that CMS implement an exception for physical therapists for the posting of office hours.

Response: We disagree with this commenter. We believe a physical therapist enrolled as a DMEPOS supplier must post its hours of operation for beneficiaries so that CMS or its agents can perform site visits. However, as discussed previously, we note that

we have established an exception for physical therapists in certain circumstances to the supplier standard of the 30 hours minimum requirement.

Comment: One commenter suggested the language describing the proposed change at §424.57(c)(8) be changed from "would deny" to "may deny" to allow for situations where the NSC or its agents are unable to perform a site visit during a supplier's posted business hours.

Response: While we understand this comment, we do not believe that the change is needed.

Comment: One commenter asked for clarification of what constitutes custom fabricated orthotics and prosthetics. The commenter questioned whether it is the definition from the competitive bidding document or the explanation of each product in the HCPCS codes.

Response: For purposes of the regulatory provision, orthotics and prosthetics is defined in the HCPCS codes related to each product and as described in the DMEPOS quality standards.

Comment: One commenter suggested an alternative to the proposed provision could be for the entire practice (all office locations collectively), to be open a minimum number of hours which would allow for satellite offices in remote areas, as well as accommodating those therapists in private practice for the purpose of limiting their work hours. The commenter considers 20 hours a week to be reasonable.

Response: Each DMEPOS supplier location is separately enrolled, and therefore, each location must meet all the required supplier standards in §424.57.

Comment: A commenter stated that requiring DMEPOS suppliers, except suppliers of prosthetics and orthotics, to be open to the public for at least 30 hours a week is unnecessary for supplier's facilities that are not intended for beneficiary access and that this proposed standard blurs the distinction between a classic retail establishment and a service facility dedicated to the provision of supplies and equipment to patients in their homes. In addition, the commenter requests that CMS consider different business models for supplier standards, and let the beneficiaries and their physicians decide what model may work best for them.

Response: We do not believe these arrangements are always in the best interest of the patient. We believe that all enrolled DMEPOS suppliers, except suppliers of prosthetics and orthotics, should maintain a minimum number of hours open to the public. This will ensure that the DMEPOS supplier is operational and allows CMS, the NSC or agents of CMS or the NSC to conduct unannounced site visits to ensure compliance with the standards set forth at §424.57.

Comment: One commenter believes the weekly hourly requirement severely limits the ability to provide services in small towns, because it does not allow for the use of "limited business hour" satellite facilities.

Response: After careful review of this standard, we have determined that requiring a DME supplier to be open and available to the public no less than 30 hours per week is in the best interest of the patient, especially for those who are disabled or with limited means of transportation.

5. Tax Delinquency

In §424.57(c)(31), we proposed adding a new supplier standard that specified that a DMEPOS supplier could not have Internal Revenue Service (IRS) or a State taxing authority tax delinquency. We also proposed to define a "tax delinquency" as meaning an amount of money owed to the United States or a State: a conviction or civil judgment for tax evasion, a criminal or civil charge of tax evasion, or the filing of a tax lien.

With the enactment of section 189 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110-275) on July 15, 2008, we are deferring the implementation of this proposal while we continue to review the public comments received on this provision and we will consider finalizing this provision in a future rulemaking effort if we deem it necessary. Accordingly, we are not adopting this proposed supplier standard in this rule and have removed the paperwork burden associated with this provision.

6. Medicare Overpayment

In §424.57(d), we proposed to redesignate the current text as paragraph (d)(1) and proposed adding a new paragraph that specified that "CMS, the NSC, or CMS designated contractor establishes a Medicare overpayment from the date of an adverse legal action or felony conviction (including felony convictions within the 10 years preceding enrollment or revalidation of enrollment) that precludes payment." In addition, we proposed that any overpayment assessed by CMS or its designated contractor due to a failure to report this information would follow the existing rules governing Medicare overpayments set forth at §405.350 et. seq. The underlying basis to report "adverse legal actions" to the NSC are

found in §424.530 and §424.535, which state the provisions for denial of enrollment and the revocation of billing privileges.

Comment: One commenter stated that the term "adverse legal action" was vague and requested that we clarify or eliminate the authority regarding overpayments resulting from adverse legal actions in §424.57(d). The commenter stated that no notice was provided regarding the types of events that would trigger an overpayment collection. This commenter further stated that before this regulatory provision could be finalized, more fulsome notice must be given so that stakeholders can submit meaningful comments.

Response: We agree and have revised §424.57(a) to add a definition for the term "final adverse action" as meaning one or more of the following actions: (1) a Medicare-imposed revocation of any Medicare billing number; (2) suspension or revocation of a license to provide health care by any State licensing authority; (3) revocation or suspension of accreditation; (4) a conviction of a Federal or State felony offense (as defined in §424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or (5) an exclusion or debarment from participation in a Federal or State health care program. This definition is narrower than the list of final adverse actions contained in Section 3 of the CMS-855S which was published on March 23, 2009. In fact, we limited the definition of "final adverse action" in this rule to those actions that currently serve as a basis for CMS to revoke a supplier's Medicare billing privileges under §424.535(a). If a final adverse action has been imposed upon a supplier, then that supplier would not be eligible to maintain Medicare billing privileges from the date of a

final adverse action. This provision provides CMS or its contractors with the discretion to establish an overpayment determination (as defined in §405.350) for all Medicare items and services furnished from the date of the final adverse action. CMS or our contractors may reopen all claims paid to the supplier on or after the date of the final adverse action that had been imposed upon that supplier. Moreover, suppliers who are assessed overpayments under this provision may appeal these determinations in accordance with the Medicare claims appeal procedures set forth in §405.900 through §405.1140.

Comment: One commenter believes the requirement to notify the NSC of changes is too burdensome.

Response: We appreciate the commenters' concerns. However, we maintain that it is necessary to require DMEPOS suppliers to notify the NSC of a final adverse action or other reportable change, including change of location, change of ownership (including authorized and delegated officials) within 30 days to mitigate the possible impacts associated with these types of changes.

7. Notification of Change in Hours Operation

In §424.57(c)(32), we are proposing that each supplier must report changes in hours of operation to the NSC 15 calendar days prior to the proposed change. The burden associated with this requirement is the time and effort associated with notifying the NSC of the change in hours of operation.

We are not finalizing this provision. In section V. of this final rule, we respond to the comment received on the information collection requirement associated with this provision.

8. Other Issues

The following is our response to a comment that was not on a proposal included in this proposed rule:

Comment: One commenter requested that we clarify that §424.57(c)(26) was reserved for the proposed DME surety bond standard.

Response: We note that §424.57(c)(26) was reserved for the proposed DME surety bond standard. We also note that the proposed provision at §424.57(c)(26) was finalized in the January 2, 2009 final rule (74 FR 166) entitled "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)."

IV. Provisions of the Final Regulations

This final rule finalizes the provisions of the proposed rule with the following exceptions:

- In §424.57(a), we modified our proposal as follows:

++ Added the definition for the term "direct solicitation."

++ Revised the definition for the term "final adverse action". We note that the definition for this term was added by a January 2, 2009 final rule (74 FR 166). We revised this term by--(1) replacing the semicolons at the end of paragraphs (i) through (iv) with periods; (2) revising paragraph (iii) by adding the phrase " as stated §424.58" to

the end of the paragraph; and (3) revising paragraph (iv) by removing the word "or" from end of the paragraph.

- In §424.57(c)(1), we made the following modifications to our proposal:

- ++ Added language to clarify that a DMEPOS supplier must be licensed to provide the licensed service(s) and cannot contract with an individual or entity to provide the licensed service(s).

- ++ Added language to clarify that a licensed professional can be a part-time or full-time employee.

- In §424.57(c)(7), we modified our proposal as follows:

- ++ Revised the proposed introductory text of paragraph (c)(7). The language regarding the space for storing records and retaining ordering and referring documentation was modified and redesignated as paragraphs (c)(7)(i)(E) and (F), respectively.

- ++ Added a new paragraph (c)(7)(i)(A) that specifies a minimum square footage requirement and an exception to the minimum square footage requirement for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice.

- ++ Modified and redesignated proposed paragraphs (c)(7)(i) through (c)(7)(iii) as paragraphs (c)(7)(i)(B) through (c)(7)(i)(D).

- ++ Redesignated paragraph (c)(7)(iv) as paragraph (c)(7)(ii).

++ Added a new paragraph (c)(7)(iii) that specifies that an appropriate site may be the centralized location for all of the business records and ordering and referring documentation of a multisite supplier.

- In §424.57(c)(9), we made technical and clarifying changes.
- In §424.57(c)(10), we are not finalizing this proposed provision in this final regulation.
- In §424.57(c)(11), we added a definition of direct solicitation in §424.57(a).
- In §424.57(c)(12), we are not finalizing this proposed provision in this final rule.
- In §424.57(c)(27), we are adopting this provision as proposed.
- In §424.57(c)(28), we adopting the provision established in §424.516(f).
- In §424.57(c)(29), we added an exception to our requirements on the prohibition of sharing a practice location in paragraph (c)(29)(ii).
- In §424.57(c)(30), we added exceptions for DMEPOS suppliers who are working with custom-made orthotics and prosthetics and physicians, nonphysician practitioners, and physical and occupational therapists.
- In §424.57(c)(31), we are not finalizing this proposed provision in this final rule.
- In §424.57(c)(32), we are not finalizing this proposed revision in this final rule.

Accordingly, we have withdrawn the information collection requirement request associated with this provision.

- In §424.57(e) (which was proposed as §424.57(d)), we are modifying our proposal with a change to the effective date of date of revocation. (See the Surety Bond final rule in the March 27, 2009 **Federal Register** (74 FR 13345)). In order to be consistent with our regulations at §424.535(g), we are extending the effective date of revocation from 15 to 30 days after notification of the revocation.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-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 PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following is a discussion of the provisions, as stated in section III. of this final rule, that contains information collection requirements.

The provision at §424.57(c)(1) states that a supplier must operate its own business and furnish Medicare-covered items in compliance with all applicable Federal and State

licensure and regulatory requirements. The purpose of this standard is to ensure that DMEPOS suppliers obtain and maintain the necessary State licenses required to furnish services provided to Medicare beneficiaries. While there is burden associated with complying with this standard, we believe it is exempt from the PRA as stated in 5 CFR 1320.3(b)(3). A collection of information conducted or sponsored by a Federal agency that is also conducted or sponsored by a unit of State, local, or tribal government is presumed to impose a Federal burden except to the extent that the agency shows that such State, local, or tribal requirement would be imposed even in the absence of a Federal requirement. In addition, we believe the burden associated with the maintenance of the required documentation is exempt from the PRA as stated in 5 CFR 1320.3(b)(2), to the extent that the time, effort, and financial resources necessary to comply with collection of information that would be incurred by persons in the normal course of their activities. Maintaining State license documentation is part of usual and customary business practices.

Proposed §424.57(c)(10)(iii) stated that with respect to liability insurance, it was the responsibility of the DMEPOS supplier to, "promptly notify the NSC in writing of any policy changes or cancellations." The burden associated with this proposed requirement was the time and effort associated with drafting and submitting notification to the NSC of any policy changes or cancellations. However, we have decided not to finalize this requirement in this final rule and therefore will not be submitting an information collection request to OMB for its review and approval.

Proposed §424.57(c)(12) stated that a supplier, "[m]ust be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery." In addition, the supplier must, "[d]ocument that it or another qualified party has at an appropriate time, provided beneficiaries with information and instructions on how to use the Medicare-covered items safely and effectively." The burden associated with this section is the time and effort required to: document the delivery of the Medicare-covered item; document the provision of information or instructions to the beneficiary by the supplier itself or another qualified party; maintain the documentation of delivery of the Medicare-covered items and the necessary information and instructions. While the burden associated with the aforementioned proposed requirements is subject to the PRA, we have decided not to finalize these requirements in this final rule and therefore will not be submitting an information collection request to OMB for its review and approval.

Proposed §424.57(c)(12)(ii) specified that a supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The burden associated with complying with the standard is the time and effort required for the supplier to provide its contact information to beneficiary at the time of delivery of the Medicare-covered item(s). While the burden associated with the aforementioned proposed requirement is subject to the PRA, CMS has decided not to finalize this requirement in this final rule and therefore will not be submitting an information collection request to OMB for its review and approval.

The provision at §424.57(c)(28) discusses a recordkeeping requirement. This provision states that suppliers are required to maintain ordering and referring

documentation, including NPI, received from a physician or eligible professional for 7 years from the date of service. Based on public comment and the provisions established in prior rulemaking documents, we revised this provision for record retention requirement from 7 years after a claim is reimbursed to 7 years from the date of service.

The burden associated with this requirement is the time and effort necessary for a supplier to file and maintain ordering and referring documentation from the previously stated list of providers. While this requirement is subject to the PRA, the associated burden is exempt under 5 CFR 1320.3(b)(2), to the extent that the time, effort, and financial resources necessary to comply with collection of information that would be incurred by persons in the normal course of their activities. Maintaining ordering and referring documentation is a usual and customary business practice.

Proposed §424.57(c)(32), stated that each supplier must report changes in hours of operation to the NSC 15 calendar days prior to the proposed change. The burden associated with this requirement is the time and effort associated with notifying the NSC of the change in hours of operation. We estimated that 1,000 suppliers will be subject to this requirement. The estimated time required to report the information to the NSC is 10 minutes. The estimated total annual burden associated with this requirement is 167 hours. We received a public comment regarding the burden assessment for the information collection requirement contained in §424.57(c)(32).

Comment: One commenter stated that there is little gained by imposing such a rigid notification and requests that the requirement be modified to permit the supplies to

notify the NSC of changes in operation within 30 calendar days after the proposed change and that we should revise the burden estimate associated with this provision.

Response: We appreciate this comment and agree that this provision would increase the paperwork burden imposed on DMEPOS suppliers. Accordingly, we are not adopting this new supplier standard and have removed the paperwork burden associated with this provision. Consistent with supplier standard in §424.57(c)(2), we will continue to require that DMEPOS suppliers report changes in operation within 30 calendar days.

We have submitted a copy of this final rule to OMB for its review and approval of the aforementioned information collection requirements.

VI. 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), 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 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 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). This rule does not reach the economic threshold and thus is not considered a major rule.

To ensure that Medicare is making correct payments to only legitimate DMEPOS suppliers, we implemented a comprehensive payment and enrollment strategy. This strategy includes developing and implementing the statutorily-mandated competitive bidding program, making revisions to the National Supplier Clearinghouse contract, implementing a DMEPOS demonstration project, and publishing a proposed rule that would require DMEPOS suppliers to obtain a surety bond.

Accordingly, it is essential that we further develop and implement administrative and regulatory changes which prevent unscrupulous DMEPOS suppliers from enrolling or maintaining their enrollment in the Medicare program. To this end, we have implemented the following administrative changes and are seeking comments on mandated DMEPOS surety bonding requirements.

As part of our administrative change, we revised the contract with the National Supplier Clearinghouse (NSC) in FY 2008 and are currently recompeting this contract through full and open competition. The revised contract requires that the NSC conduct and increase the number of on-site visits to ensure that DMEPOS suppliers are in compliance with the provisions in §424.57. We are also expanding the funding for NSC operations to support the increased number of site visits. These expanded measures will help to ensure that only legitimate DMEPOS suppliers are enrolled or maintain enrollment in the Medicare program. In addition, we announced plans on June 28, 2007, to implement a 2-year demonstration involving DMEPOS suppliers. The goal of this

initiative is to strengthen our ability to detect and prevent fraudulent activity and has focused specifically on DMEPOS suppliers in South Florida and the Los Angeles metropolitan area. Based on the findings of this initiative, we will determine if the administrative processes and procedures used in this demonstration should be expanded to other parts of the country.

On August 1, 2007, we published a proposed rule (72 FR 42001) which would implement section 4312(a) of the Balanced Budget Act of 1997 (BBA) by requiring all Medicare DMEPOS suppliers to furnish CMS with a surety bond. The public comment period for this proposed rule closed on October 1, 2007. As noted previously, we finalized the surety bond provisions in a final rule entitled "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" on January 2, 2009.

Accordingly, while the activities described previously will promote compliance with the existing supplier standards, these activities do not supply CMS and the NSC with the needed authority to deny or revoke billing privileges to those DMEPOS suppliers that pose a significant risk to the program. Therefore, we believe that the provisions of this final rule are essential in expanding upon and strengthening the supplier standards in order to ensure that only legitimate suppliers are enrolled or maintain enrollment in the Medicare program.

The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and

suppliers are small entities, either by nonprofit status or by having revenues of \$7.0 to \$34.5 million in any 1 year. (For details, see the Small Business Administration's Web site at http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf (refer to the 620000 series. There are four categories of provider revenues listed, \$7.0, \$10.0, \$13.5, and \$34.5 million or less). Individuals and States are not included in the definition of a small entity.

We are not preparing an analysis for the RFA because we are certifying that this rule will not have a significant economic impact on a substantial number of small entities. We have determined that the RFA is reasonable given that the provisions contained in this final rule are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs. We also believe that the regulatory impact of this final rule is negligible and not calculable. We understand that there may be some additional concerns about costs associated with a minimum square footage requirement, however, we maintain that this final rule would not have an adverse impact on a significant number of small entities because we believe that these suppliers are operating on standard business practices and therefore are already in compliance with these standards. Additionally, we established a limited time exception for those entities that do not meet the minimum square footage requirement and have entered into a long term lease on or before the publication date of this final rule. Since we believe that a significant number of small entities currently meet each of the revised or new standard, we do not have information available to calculate the economic impact of any individual or combination of proposals would have on small entities. This final rule would merely clarify, expand, and update

our current policy in the DMEPOS supplier standards currently covered in §424.57.

Therefore, 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.

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 we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. We understand that a large number of DMEPOS suppliers fall into this category, however these provisions are procedural in nature and we expect that legitimate DMEPOS suppliers are already meeting these provisions.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. That threshold is currently approximately \$130 million. This rule does not mandate expenditures by State, local, or

tribal governments, in the aggregate, or by the private sector of \$130 million and 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.

We anticipate that this rule would codify certain procedural policies contained in the Program Integrity Manual (PIM) that DMEPOS suppliers already are supposed to adhere to, and that legitimate DMEPOS suppliers should already be meeting. By establishing the standards in this rule, we are establishing our authority to deny or revoke the Medicare billing privileges of DMEPOS suppliers that have failed to comply with one or more of these supplier standards.

We have considered alternatives to all of the provisions; however, only one of the provisions considered lends itself to other options. Initially, we considered establishing a 40 hour requirement for a DMEPOS supplier's hours of operation since most business are open to the public for a minimum of 40 hours each week.

To reduce the burden associated with this provision, but also to establish a minimum requirement for the hours of operation, we relaxed the initial 40-hour requirement to 30 hours per week because we believe that this is the minimum amount of time that a DMEPOS supplier is required to be open and legitimately operate as a business. We did not consider the alternative of not proceeding with the proposed

provisions because we believe that they are necessary to ensure that only legitimate DMEPOS suppliers are enrolling and maintaining enrollment in the Medicare program.

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

2. Section 424.57 is amended by--

A. Adding in paragraph (a) the definition of "direct solicitation" in alphabetical order.

B. In paragraph (a) revising the definition of "final adverse action".

C. Revising the introductory text of paragraph (c).

D. Revising paragraphs (c)(1), (c)(7) through (c)(9), (c)(11), and (e).

E. Adding new paragraphs (c)(27) through (c)(30).

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.

(a) * * *

Direct solicitation means direct contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, by a DMEPOS supplier or its agents to a Medicare beneficiary without his or her consent for the purpose of marketing the DMEPOS supplier's health care products or services or both.

* * * * *

Final adverse action means one or more of the following actions:

- (i) A Medicare-imposed revocation of any Medicare billing privileges.
- (ii) Suspension or revocation of a license to provide health care by any State licensing authority.

(iii) Revocation for failure to meet DMEPOS quality standards.

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation, or re-enrollment.

(v) An exclusion or debarment from participation in a Federal or State health care program.

* * * * *

(c) Application certification standards. The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

(i) Federal regulatory requirements that specify requirements for the provision of DMEPOS and ensure accessibility for the disabled.

(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;

(B) Must employ the licensed professional on a full-time or part-time basis, except for DMEPOS suppliers who are--

(1) Awarded competitive bid contracts using subcontractors to meet this standard; or

(2) Allowed by the State to contract licensed services as described in paragraph (c)(1)(ii)(C) of this section.

(C) 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; and

(iii) Local zoning requirements.

* * * * *

(7) Maintains a physical facility on an appropriate site. An appropriate site must meet all of the following:

(i) Must meet the following criteria:

(A) Except for State-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, maintains a practice location that is at least 200 square feet beginning--

(1) [OFR: Please insert 30 days from the date of publication] for a prospective DMEPOS supplier;

(2) The first day after termination of an expiring lease for an existing DMEPOS supplier with a lease that expires on or after [OFR: Please insert 30 days after the date of publication] and before September 27, 2013; or

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

(B) Is in a location that is accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents. (The location must not be in a gated community or other area where access is restricted.)

(C) Is accessible and staffed during posted hours of operation.

(D) Maintains a permanent visible sign in plain view and posts hours of operation. If the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier.

(E) Except for business records that are stored in centralized location as described in paragraph (c)(7)(ii) of this section, is in a location that contains space for storing business records (including the supplier's delivery, maintenance, and beneficiary communication records).

(F) Is in a location that contains space for retaining the necessary ordering and referring documentation specified in §424.516(f).

(ii) May be the centralized location for all of the business records and the ordering and referring documentation of a multisite supplier.

(iii) May be a "closed door" business, such as a pharmacy or supplier providing services only to beneficiaries residing in a nursing home, that complies with all applicable Federal, State, and local laws and regulations. "Closed door" businesses must comply with all the requirements in this paragraph.

(8) Permits CMS, the NSC, or agents of CMS or the NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section.

(9) Maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.

(i) Cellular phones, beepers, or pagers must not be used as the primary business telephone.

(ii) Calls must not be exclusively forwarded from the primary business telephone listed under the name of the business to a cellular phone, beeper, or pager.

(iii) Answering machines, answering services, facsimile machines or combination of these options must not be used exclusively as the primary business telephone during posted operating hours.

* * * * *

(11) Agree not to make a direct solicitation (as defined in §424.57(a)) of a Medicare beneficiary unless one or more of the following applies:

(i) The individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them 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.

* * * * *

(27) Must obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure.)

(28) Is required to maintain ordering and referring documentation consistent with the provisions found in §424.516(f)

(29)(i) Except as specified in paragraph (c)(29)(ii) of this section, is prohibited from sharing a practice location with any other Medicare supplier or provider.

(ii) The prohibition specified in paragraph (c)(29)(i) of this section is not applicable at a practice location that meets one of the following:

(A) Where a physician whose services are defined in section 1848(j)(3) of the Act or a nonphysician practitioner, as described in section 1842(b)(18)(C) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(B) Where a physical or occupational therapist whose services are defined in sections 1861(p) and 1861(g) of the Act, furnishes items to his or her own patient as part of his or her professional service.

(C) Where a DMEPOS supplier is co-located with and owned by an enrolled Medicare provider (as described in §489.2(b) of this chapter). The DMEPOS supplier--

(1) Must operate as a separate unit; and

(2) Meet all other DMEPOS supplier standards.

(30)(i) Except as specified in paragraph (c)(30)(ii) of this section, is open to the public a minimum of 30 hours per week.

(ii) The provision of paragraph (c)(30)(i) of this section is not applicable at a practice location where a--

(A) Physician whose services are defined in section 1848(j)(3) of the Act furnishes items to his or her own patient(s) as part of his or her professional service;

(B) Licensed non-physician practitioners whose services are defined in sections 1861(p) and 1861(g) of the Act furnishes items to his or her own patient(s) as part of his or her professional service; or

(C) DMEPOS supplier is working with custom made orthotics and prosthetics.

* * * * *

(e) Failure to meet standards -- (1) Revocation. CMS revokes a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation is effective 30 days after the entity is sent notice of the revocation, as specified in §405.874 of this subchapter.

(2) Overpayments associated with final adverse actions. CMS or a CMS contractor may reopen (in accordance with §405.980 of this chapter) all Medicare claims paid on or after the date of a final adverse action (as defined in paragraph (a) of this section) in order to establish an overpayment determination.

* * * * *

CMS-6036-F

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

Dated: August 19, 2010

Donald M. Berwick,
Administrator,
Centers for Medicare & Medicaid Services.

Approved: August 24, 2010

Kathleen Sebelius,
Secretary.

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