ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–1198, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: angelbeck.richard@epa.gov.*

3. *Fax:* (312) 886–5824.

4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR 18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* At the previously listed EPA Region 5 address. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Richard Angelbeck, Environmental Scientist, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–9698, *angelbeck.richard@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's operating permits program revision submittal as a direct final rule without prior proposal, because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: January 15, 2008.

Margaret Guerriero,

Acting Regional Administrator, Region 5.

[FR Doc. E8–1319 Filed 1–24–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–6036–P]

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: Proposed rule.

SUMMARY: This proposed rule clarifies, expands, and adds 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 25, 2008.

ADDRESSES: In commenting, please refer to file code CMS–6036–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions under the ''Comment or Submission'' tab and enter the file code to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6036–P, P.O. Box 8012 Baltimore, MD 21244–8012.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6036–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–4696 or (410) 786–1161 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: August Nemec, (410) 786–0612.

SUPPLEMENTARY INFORMATION: *Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6036–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in

a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *https://www.cms.hhs.gov/eRulemaking*. Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

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

I. Background

Medicare services are furnished by two types of entities, providers and suppliers. At § 400.202, ''provider'' is defined as a hospital, a critical access hospital (CAH), a skilled nursing facility, a comprehensive outpatient rehabilitation facility, 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 proposed 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 suppliers (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 found at section 1834(j)(5) of the Act.

In FY 2007, the Medicare program spent more than $10 billion for DMEPOS supplies, and in April 2007, there were 116,471 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were 65,984 unique billing numbers. The largest concentration 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 30 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 DMEPOS is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DMEPOS, items furnished in skilled nursing facilities and hospitals. Also, the term DMEPOS is included in the definition of ''medical and other health services'' found at 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), 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, and (2) take the necessary actions to revoke enrolled suppliers who no longer meet supplier standards.

A. 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 proposed 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 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) 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(j)(1)(A) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended the Act to require the Secretary to establish a process for the enrollment of providers of services and suppliers.

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.

B. Historical Enrollment Initiatives

For many years, concern about easy entry into the Medicare program by unqualified or even fraudulent providers or suppliers has led us to increase our efforts to establish more stringent controls on provider and supplier entry into the Medicare program. The following is a summary of the regulations that we have published to ensure that only qualified providers and suppliers are participating in the Medicare program.

In the October 11, 2000 **Federal Register**, we published the Additional Supplier Standards final rule with comment period where we listed the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. In this rule, we established additional standards that a DMEPOS supplier must comply with in order to receive and maintain a Medicare billing number. This final rule with comment period outlined the supplier requirements to ensure that suppliers of DMEPOS are qualified to furnish DMEPOS items and to help safeguard the Medicare program and its beneficiaries from fraudulent or abusive billing practices.

In the April 21, 2006 **Federal Register**, we published the Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment final rule. This final rule implemented section 1866(j)(1)(A) of the Act. In this final rule, we required that all providers and suppliers (other than physicians or practitioners who have elected to ''opt-out'' of the Medicare program) must complete an enrollment form and submit specific information to CMS in order to obtain Medicare billing privileges. This final rule also required that all providers and suppliers must periodically update and certify the accuracy of their enrollment information to receive and maintain billing privileges in the Medicare program. These statutory provisions include requirements meant to protect beneficiaries and the Medicare Trust Funds by trying to prevent unqualified, fraudulent or excluded providers and suppliers from providing items or services to Medicare beneficiaries or billing the Medicare program or its beneficiaries.

In the April 10, 2007 **Federal Register** (72 FR 17992), we published Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) final rule implemented section 302 of the MMA and established DME competitive bidding. In addition, it created incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This final rule also incorporated provisions from section 5101 of the Deficit Reduction Act of 2005, which concerns beneficiary ownership of certain DMEs.

II. Provisions of the Proposed Rule

To ensure that DMEPOS suppliers understand how CMS interprets the DMEPOS supplier standards, we are revising certain supplier standards specified in § 424.57(c). We are also proposing several new DMEPOS supplier standards. We believe that these revisions and additions would help to ensure that legitimate DMEPOS suppliers are furnishing items of DMEPOS to Medicare beneficiaries.

A. Proposed Clarifications and Revisions of Existing DMEPOS Supplier Standards

The supplier standard at § 424.57(c)(1) states, ''Operates its business and furnishes 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 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. Further, 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. If a State requires a specific license to furnish certain services, we believe that a DMEPOS supplier cannot contract with an individual or other entity to provide these licensed services, but rather, the DMEPOS supplier could hire the individual as a W–2 employee. The owner of the supplier, or full-time W–2 employee, must obtain and maintain this licensing requirement. We are proposing 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). 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 general, to ensure compliance, the NSC verifies that DMEPOS suppliers meet the supplier standards in § 424.57, comply with State business and product licensing requirements, and meet applicable local zoning requirements.

The supplier standard at § 424.57(c)(7) specifies that the DMEPOS supplier maintains a physical facility on an appropriate site and that the physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. We are proposing to revise this standard to require that DMEPOS suppliers maintain business records for 7 years after the claim has been paid and to clarify the term, ''appropriate site.'' An appropriate site includes, but is not limited to, the following features:

- 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.
- The supplier location must be accessible during posted hours of operation to beneficiaries and to CMS, and must maintain a permanent visible sign in plain view and posted hours of operation. We believe that DMEPOS suppliers must have its hours of operation posted and in plain view and that suppliers submit changes to their posted hours of operation in advance of any change by notifying the NSC via the Medicare enrollment application. 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 where the place of business is located.
- The supplier's place of business must be staffed during the supplier's posted hours of operation. The supplier's place of business must be accessible to the public, CMS, the NSC and any of its agents during the supplier's posted hours of operation regardless of whether beneficiaries routinely visit the facility.
- The supplier's place of business may be a ''closed door'' business, such as pharmacies or suppliers providing services only to beneficiaries residing in a nursing home, that complies with all applicable Federal, State, and local laws and regulations.

A supplier is not in compliance with this standard if no one is available during the posted hours of operation.

In addition, we believe that an ''appropriate site'' applies to ''closed door'' businesses, (such as pharmacies/suppliers providing services only to beneficiaries residing in a nursing home) and are responsible for being in compliance with all applicable Federal, State, and local laws and regulations. We believe that ''closed door'' businesses must comply with all the requirements of § 424.57(c)(7), and all DMEPOS supplier standards. Additionally, the facility has to be accessible to beneficiaries, CMS or its agents regardless of whether beneficiaries routinely visit the facility.

We are soliciting 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 standard at § 424.57(c)(8) states, ''Permits CMS, or its agents to conduct on-site inspections to ascertain supplier compliance with the requirements of this section. 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 are proposing to revise (c)(8) to limit the provision to on-site inspection. The proposed revision would 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.

The supplier standard at § 424.57(c)(9) states, ''Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine can not be used as the primary business telephone for purposes of this regulation.'' We are proposing 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. Therefore, we are proposing to revise 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 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.'' 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.

The supplier standard at § 424.57(c)(10) states, ''has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's

place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.'' We are proposing 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. The 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 the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed. DMEPOS suppliers are responsible for providing the contact information of an individual employed with the underwriter.'' While the NSC routinely verifies comprehensive insurance coverage with an insurance agent, it may be necessary to contact the underwriter to verify the policy's coverage. Specifically, the NSC may need to verify insurance coverage with an underwriter when: (1) Self-insurance is used; or (2) when the NSC believes that the insurance agent is misrepresenting the terms and conditions of coverage. This would not preclude the use of self-insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or the NSC can verify the policy and its coverage provisions with an independent underwriter. Therefore we are also proposing that to add a provision stating that self-insurance may be used to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or the NSC can verify the policy and its coverage provisions with an independent underwriter.

DMEPOS suppliers are responsible for providing the contact information of an individual employed with the underwriter, who can verify coverage. To ensure that coverage is actually issued and the policy is in effect, we believe that the NSC should be able to verify policy coverage with an insurance agent, or when necessary, the underwriter, since this is the company affording coverage. This proposed revision would not preclude the use of self-insurance to demonstrate compliance with the comprehensive liability insurance policy as long as CMS or its designated contractor can verify the policy and its coverage provisions with an independent underwriter.

Moreover, we propose that a DMEPOS supplier obtain the appropriate liability coverage prior to submitting its Medicare enrollment application and supporting documentation to the NSC. (When a policy is issued, up to 90 days may pass before the underwriter receives notification that the policy has been issued by the insurance agent or broker.) In addition, we believe if the NSC is unable to verify the issuance and validity of liability insurance with an insurance agent, or when necessary, an underwriter at the time of filing, then the NSC should deny Medicare billing privileges without further action, including an onsite review. Accordingly, the NSC must be able to verify the issuance and validity of a DMEPOS liability insurance policy on the day a prospective DMEPOS supplier submits a Medicare enrollment application to the NSC for review. If the NSC is unable to verify the issuance and validity of a liability insurance policy with an insurance agent, or when necessary, the underwriter for a DMEPOS supplier enrolled in the Medicare program, then the NSC may revoke the billing privileges of that supplier.

In addition, we believe that it is the responsibility of the DMEPOS supplier to list the NSC as a certificate holder on the policy. By listing the NSC as a certificate holder on the policy, the NSC would be able to verify coverage with the underwriter. A DMEPOS supplier who fails to list the NSC as a certificate holder on the policy may have their enrollment application denied or billing privileges revoked because the NSC may not be able to verify the issuance and validity of the policy. Finally, we believe that it is the DMEPOS supplier's responsibility to: (1) Ensure that insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and (2) notify the NSC in writing within 30 days of any policy changes or cancellations.

The supplier standard at § 424.57(c)(11) states, ''Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies: (i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (ii) the supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item; and (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.'' We are proposing to revise this supplier standard to clarify that suppliers can not 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. The 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.

The supplier standard at § 424.57(c)(12) currently states that the supplier must be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery. The supplier must document that it or another qualified party has, at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively. We are proposing to revise paragraph (c)(12) provision to clarify its intent. A DMEPOS supplier—

- Is responsible for maintaining proof of the delivery in the beneficiary's file;
- The supplier must furnish information to beneficiaries at the time of delivery of items as to how the beneficiary can contact the supplier by telephone;
- Must provide the beneficiary with instructions on how to safely and effectively use the equipment or contract this service to a qualified individual;
- Is responsible for providing instruction on the safe and effective use of the equipment that should be completed at the time of delivery; and

• Must document that this instruction has taken place.

We believe 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.

B. Proposed New DMEPOS Supplier Standards

At § 424.57(c)(27), we are proposing a new standard that specifies 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. For example in State A, a license is required when supplying oxygen. If a DMEPOS supplier located in State A is supplying oxygen, they must get their oxygen from a state-licensed oxygen supplier. To extend this example, in State B, where no license is required for an oxygen supplier, a DMEPOS supplier may obtain their oxygen from a non-licensed supplier within State B, or a licensed supplier (in a State where you must have a State license to supply oxygen), or from a non-State-licensed supplier outside of State B (where there is no State license required for supplying oxygen). We believe that this standard would help to protect Medicare beneficiaries and promote quality in the furnishing of oxygen.

At § 424.57(c)(28), we are proposing 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. Since all DMEPOS supplies are ordered and referred by physicians, nurse practitioners, physician assistants, clinical social workers, or certified nurse midwives, we believe that it is essential that DMEPOS suppliers maintain documentation regarding the specific individual who ordered or referred a Medicare beneficiary for DMEPOS. In addition, we are codifying the requirement to maintain ordering and referring documentation for 7 years as required in Publication 100–08, Chapter 5, Section 8.

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.

At § 424.57(c)(29), we are proposing a new standard that specifies that the supplier is prohibited from sharing a practice location with another Medicare supplier. DMEPOS suppliers may not share a practice location with any other Medicare supplier, including a physician/physician group or another DMEPOS supplier. We believe that allowing DMEPOS suppliers to commingle practice locations, operations, staff, inventory and other aspects of supplier's operations constitutes a significant risk to the Medicare program. Moreover, to allow 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. Finally, we do not believe that legitimate DMEPOS suppliers routinely share practice locations with another Medicare supplier.

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 are soliciting 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.

At § 424.57(c)(30), we are proposing a new supplier standard that specifies, ''Is 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 are proposing this new standard because the NSC has found that a number of existing DMEPOS suppliers have posted restrictive or limited business hours, and in some cases, have posted business hours that are so restrictive that it makes it nearly impossible for a NSC to conduct on onsite visit or for a beneficiary or the public to obtain DMEPOS services. Since we question the legitimacy of any DMEPOS supplier with posted operating hours of less than 4 hours a day, we are proposing to establish a minimum number of operational hours for DMEPOS suppliers. Moreover, we believe that most legitimate DMEPOS suppliers are open to the public at least 30 hours per week. 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 (either 6 hours a day, 5 days a week or 5 hours a day, 6 days a week) in order to attract, retain and serve Medicare beneficiaries. We believe that a minimum number of operating hours will help to ensure that DMEPOS suppliers are open to the public and are able to serve the needs of 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. 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.

At § 424.57(c)(31), we propose adding a new supplier standard that specifies, ''Does not have an Internal Revenue Service (IRS) or a State taxing authority tax delinquency.'' Currently, we do not consider whether a DMEPOS supplier that is seeking enrollment or one that is currently enrolled in the Medicare program has an IRS or a State taxing authority tax delinquency. To ensure that Medicare payments are only being made to organizations and individuals who have satisfied existing tax debts, we will have a basis to revoke the billing privileges of a DMEPOS supplier, including physicians and nonphysician

practitioners who are also enrolled as a DMEPOS supplier, that has failed to comply with this standard.

The Government Accountability Office (GAO) found that over 21,000 of the physicians, health professionals, and suppliers paid under Medicare Part B during the first 9 months of calendar year 2005 had tax debts totaling over $1 billion. The GAO report titled, ''Medicare, Thousands of Medicare Part B Providers Abuse the Federal Tax System (GAO–07–587T)'' found abusive and potentially criminal activity, including failure to remit to IRS individual income taxes or payroll taxes or both withheld from their employees.

Moreover, we are proposing to revise the Medicare enrollment application (that is, CMS–855S) to require that DMEPOS suppliers: (1) Certify that the supplier does not have an IRS or a State taxing authority tax delinquency; and (2) consent to having CMS or its designated contractor verify that the information submitted by a DMEPOS supplier regarding a tax delinquency is correct and accurate as determined by the IRS or State taxing authority. We believe that this change will allow CMS and its designated contractors to verify that the information submitted by a DMEPOS supplier is accurate.

We would propose 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 would redesignate the current text as paragraph (d)(1). We would add a new paragraph (d)(2) specifying 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 are proposing 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 proposed § 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 adverse legal action or felony conviction precludes participation in or payment from the Medicare program.

III. Collection of Information Requirements

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

We are soliciting public comment on each of the following issues pertaining to the information collection requirements contained in this proposed rule.

Section II.A. of this proposed rule provides proposed clarifications and revisions of the existing DMEPOS supplier standards. The following is a discussion of the information collection requirements contained in the § 424.57(c) that are clarified and revised by this proposed rule.

Section II.A. of this proposed rule provides proposed clarifications of the information collection requirements contained in § 424.57(c)(1). The standard 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. As stated in section II.A. of this proposed rule, 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.

In § 424.57(c)(12)(ii) we propose to specify 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 is subject to the PRA, we believe it 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.

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 estimate 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.

Section 424.57(c)(10)(iii) states that with respect to liability insurance, it is the responsibility of the DMEPOS supplier to, ''promptly notify the NSC in writing of any policy changes or cancellations.'' The burden associated with this requirement is the time and effort associated with drafting and submitting notification to the NSC of any policy changes or cancellations. While this burden is subject to the PRA, we believe it is exempt under 5 CFR 1320.3(h)(6). Facts or opinions collected from a single person or entity are not

subject to the PRA. The aforementioned information collection request will be reviewed on a case by case basis, as they submitted individual DMEPOS suppliers.

Section 424.57(c)(12) states that a supplier, ''Must be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery.'' In addition, the supplier must, ''Document 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.'' This standard imposes reporting and recordkeeping requirements.

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. The burden associated with these requirements is subject to the PRA. However, we believe it 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.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group Attn.: William Parham, CMS–6036–P Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn.: Carolyn Lovett, CMS Desk Officer, CMS–6036–P, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

IV. Response to Comments

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

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, 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.

We began implementation of the statutorily mandated competitive bidding program (72 FR 17992) for DMEPOS suppliers on April 10, 2007. Competitive bidding changes the way that Medicare pays for certain DMEPOS categories under Part B of the Medicare program by using bids submitted by DMEPOS suppliers to establish payment amounts. Beginning in 2007, we initiated and began implementation of the program which initially involves ten product categories in the first Metropolitan Statistical Areas. We have received bids and anticipate contract awards in 2008. In addition, DMEPOS suppliers will be required to submit bids for all items within a product category for which they are bidding. The product categories and bid items may vary by competitive bidding area (CBAs). For 2007, using 2005 data and the item selection criteria in the competitive bidding regulation, we selected the following items for competitive bidding: (1) Oxygen supplies and equipment; (2) standard power wheelchairs, scooters, and related accessories; (3) complex rehabilitative power wheelchairs and related accessories; (4) mail-order diabetic supplies; (5) enteral nutrients, equipment, and supplies; (6) continuous positive airway pressure (CPAP) devices, respiratory assist devices (RADs), and related accessories; (7) hospital beds and related accessories; (8) negative pressure wound therapy (NPWT) pumps and related accessories; (9) walkers and related accessories; and (10) support surfaces (group 2 and 3 mattresses and overlays).

The statute requires that competition under the program begin in 10 of the largest Metropolitan Statistical Areas (MSAs) and then expand to 70 additional MSAs during the second phase of implementation. Additional competitive bidding areas will then be phased in over time. The final rule requires a formula-driven methodology for selecting the 80 MSAs for the first two phases of implementation and it will be sometime after 2008 before DMEPOS suppliers will participate in the competitive bidding initiative in these 80 MSAs and only for the product categories that are included in the first two phases of implementation.

It is important to note while competitive bidding will reduce the number of DMEPOS suppliers eligible for payment of selected product categories, competitive bidding will not totally prevent unscrupulous DMEPOS suppliers from gaining entry into the program and fraudulently billing for any of those products. 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 site visits to ensure that DMEPOS suppliers are in compliance with the provisions found at § 424.57. We are also expanding the funding for NSC operations to support the increased number of sites 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 will focus 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, and CMS is currently reviewing these comments.

Accordingly, while the activities described above will promote compliance with the existing supplier standards and reduce payments for suppliers selected under competitive bidding, 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 proposed 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 $6.5 to $31.5 million in any one year. Individuals and States are not included in the definition of a small entity.

We are not preparing an analysis for the RFA because we 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 proposed rule are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs. We also believe that the regulatory impact of this proposed rule is negligible and not calculable. We maintain that this proposed 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 proposed standards. Since we believe that a significant number of small entities currently meet each of the revised or new proposed 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 proposed rule would merely clarify, expand, and update our current policy found in the DMEPOS supplier standards currently covered under § 424.57. Therefore, we anticipate a minimal economic impact, if any, on small entities. We are soliciting public comment regarding any specific impacts that these proposed provisions will have on suppliers. To encourage such comments we are providing the public with the relevant data that we possess on DMEPOS suppliers.

The following table examines the allowed charges to the unique billing numbers (a DMEPOS supplier may have multiple locations, for example, a chain organization, but use only one unique billing number), the vast majority of DMEPOS suppliers are small entities (based on Medicare reimbursement alone).

TABLE 1.—TOTAL NUMBER OF SUPPLIERS ARRANGED BY ALLOWED CHARGES FOR DATES OF SERVICE

[January through December 2005 based on Unique Billing Numbers]

Allowed charge	Number of suppliers reimbursed for DME	Number of DMEPOS suppliers reimbursed for non-DME only
$0	2,016	4,655
$0.01–$999	2,544	6,624
$1,000–$2,499	2,099	4,993
$2,500–$4,999	2,285	4,459
$5,000–$9,999	2,964	4,153
$10,000–$24,999	4,568	4,328
$25,000–$49,999	3,378	2,100
$50,000–$99,999	2,780	1,245
$100,000–$499,999	5,955	1,191
$500,000–$999,999	1,762	220
$1,000,000–$4,999,999	1,345	105
$5,000,000 or more	208	7
Total	31,904	34,080

In reviewing the table above, the term, durable medical equipment (DME) is defined at section 1861(n) of the Act. This definition, in part, excludes from coverage as DME, items furnished in skilled nursing facilities and hospitals (equipment furnished in those facilities is paid for as part of their routine or ancillary costs). Also, the term DME is included in the definition of ''medical and other health services'' at 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 appropriate for use in the home.

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

Conversely, suppliers of non-DME only refers to items or services furnished by prosthetics, orthotist, and supplies found in section 1861(s)(5) of the Act.

As of April 2007, there were 116,471 individual DMEPOS suppliers. However, due to the affiliation of some DMEPOS suppliers with chains, there were only approximately 65,984 unique billing numbers (31,904 + 34,080). We believe that approximately 30 percent of the 116,000 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area 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 proposed 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 proposed 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 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 $120 million. That threshold is currently approximately $127 million. This rule does not mandate expenditures by State, local, or tribal governments, in the aggregate, or by the private sector of $127 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 proposed 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 businesses are open to the public for a minimum of 40 hours each week.

To reduce the burden associated with this provision, but also 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.

As a result of not having quantifiable data, we cannot effectively derive an estimate for the monetary impacts of these provisions. Accordingly, we are seeking public comment so that the public may provide any data available that provides a calculable impact or any alternative to the proposed provisions.

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 would amend 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 ''tax delinquency'' in alphabetical order.

B. Revising paragraph (c) introductory text and (c)(1).

C. Revising paragraphs (c)(7) through (c)(12) and (c)(15).

D. Adding new paragraphs (c)(26) through (c)(31).

E. Revising paragraph (d).

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.

* * * * *

Tax delinquency means an amount of money owed to the United States taxing authority from any individual, entity organization, association, partnership or corporation and it can be evidenced through the following measures brought by either 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.

* * * * *

(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 must be licensed to provide the item or service and cannot contract with an individual or other entity to provide the licensed services.

(iii) Local zoning requirements.

* * * * *

(7) Maintains a physical facility on an appropriate site that contains space for storing business records (including the supplier's delivery, maintenance, and beneficiary communication records) and 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, to facilitate an on site inspection by CMS or the NSC of the supplier's business records or ordering and referring documentation. An appropriate site

includes, but is not limited to, the following:

(i) 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.)

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

(iii) 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.

(iv) May be a ''closed door'' business, such as pharmacies or suppliers 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 § 424.57(c)(7).

(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. 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.

(10) Has a comprehensive liability insurance policy and meets the following insurance-related requirements:

(i) The comprehensive liability insurance is at least $300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, the insurance must also cover product liability and completed operations. Self insurance may be used to demonstrate compliance with the comprehensive liability insurance as long as CMS or the NSC can verify the policy and its coverage provisions with an independent underwriter. Failure to maintain required insurance at all times beginning with the date of filing will result in denial or revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

DMEPOS suppliers are responsible for providing the contact information of an individual employed with the underwriter.

(ii) List the NSC as a certificate holder on the policy.

(iii) Notify the NSC in writing within 30 days of any policy changes or cancellations.

(11) Agree not to 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. The DMEPOS supplier may only contact the Medicare beneficiary when supplying a Medicare-covered item and only when one or more of the following applies:

(i) The individual has given written permission to the supplier 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.

(12) Has met the following delivering and beneficiary instruction requirements:

(i) Maintains proof of the delivery in the beneficiary's file.

(ii) Furnishes information to the beneficiary at the time of delivery of items on how the beneficiary can contact the supplier by telephone.

(iii) Provides the beneficiary with instructions on how to safely and effectively use the equipment or contract this service to a qualified individual.

(iv) Completes and documents beneficiary instruction on the safe and effective use of the equipment at the time of delivery or other appropriate time.

* * * * *

(26) [Reserved]

(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, 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.

(29) Is prohibited from sharing a practice location with any other Medicare supplier.

(30) Is 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.

(31) Does not have an Internal Revenue Service (IRS) or a State taxing authority tax delinquency.

(d) *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. The revocation is effective 15 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter.

(2) *Overpayments associated with adverse legal action and felony convictions.* CMS, the NSC or a CMS-designated contractor establishes a Medicare overpayment from the date an adverse legal action or felony conviction (including felony convictions within the 10 years preceding enrollment or revalidation of enrollment) that precludes payment.

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

Dated: May 31, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 21, 2007.

Michael O. Leavitt,

Secretary.

Editor's note: This document was received by the Office of the Federal Register on January 22, 2008.

[FR Doc. E8–1346 Filed 1–24–08; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–27; MB Docket No. 08–3; RM–11407]

Radio Broadcasting Services; Wheatland, WY

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: Appaloosa Broadcasting Company, Inc. (''Petitioner''), the licensee of Station KIMX(FM), Channel 244C2, Laramie, Wyoming, has filed a