DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[HCFA–6004–FC]

RIN 0938–AH19

Medicare Program; Additional Supplier Standards.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule establishes additional standards for an entity to qualify as a Medicare supplier for purposes of submitting claims and receiving payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). These regulations will ensure that suppliers of DMEPOS are qualified to provide the appropriate health care services and will help safeguard the Medicare program and its beneficiaries from any instances of fraudulent or abusive billing practices.

DATES: *Effective Date:* These regulations are effective on December 11, 2000.

Comment Date: We will accept comments on the policies discussed in section IV of the **SUPPLEMENTARY INFORMATION** section of this document. Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 11, 2000.

ADDRESSES: Mail an original and 3 copies of written comments to the following address only:

Health Care Financing Administration, Department of Health and Human Services, Attention: 6004–FC, P.O. Box 8013, Baltimore, MD 21244–8013

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–6004–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Charles Waldhauser, (410) 786–6140.

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I. Background

A. General

Medicare services are furnished by two types of entities, providers and suppliers. The term ''provider'', as defined in our regulations at 42 CFR 400.202, means a hospital, a critical access hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice, that has in effect an agreement to participate in Medicare. 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 with a similar agreement to furnish partial hospitalization services, is also considered a provider (see sections 1861(u) and 1866(e) of the Social Security Act (the Act) concerning definitions and provider agreements, respectively).

Generally, a Medicare ''supplier'' is an individual or entity that furnishes certain types of medical and other health items and services under Medicare Part B. There are different types of suppliers and thus, different definitions of the term ''supplier,'' as well as specific regulations governing the different types of suppliers. A supplier that furnishes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is one category of supplier known as a DMEPOS supplier.

In current regulations at § 424.57(a) concerning payment rules for items furnished by DMEPOS suppliers, we define the term ''supplier'' as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered items to Medicare beneficiaries, and that meets certain standards. The Part B covered items to which the definition refers are DMEPOS.

B. Legislative History

Section 131 of the Social Security Act Amendments of 1994 (Public Law 103–432, enacted on October 31, 1994) made changes to section 1834 of the Act, ''Special Payment Rules for Particular Items and Services.'' Specifically, it added a new subsection (j) to section 1834 of the Act that established additional requirements that a DMEPOS supplier must meet in order to obtain a supplier number. (A ''supplier number'' is the equivalent of a ''billing number'' that a supplier must have in order to submit claims and receive payment for items and services furnished under Medicare.) In section 1834(j)(1)(B)(ii)(IV) of the Act, the Congress also expressly delegated authority to the Secretary to specify any other requirements that a supplier must meet.

II. Provisions of the Proposed Regulations

On January 20, 1998, we published in the **Federal Register** (63 FR 2926) a proposed rule that would require DMEPOS suppliers to meet additional standards in order to submit claims and receive payment. We issued the proposal on the basis of section 1834(j)(1)(B)(ii)(IV) of the Act that authorizes the Secretary to specify additional requirements a DMEPOS supplier must meet. We note that we consulted with representatives of medical equipment and supply companies, carriers, and consumers before issuing the proposal.

As we stated in the proposed rule, we believe it was the Congress' intent in enacting section 131 of the Social Security Act Amendments of 1994 to

strengthen existing standards in order to protect the public interest. We also stated our belief that the additional standards we proposed would help safeguard the Medicare program and would serve to protect beneficiaries.

The major provisions of the proposed rule are as follows:

A. Specific Requirements for Supplier Standards

We proposed changes to clarify our current policy concerning certification and recertification for DMEPOS. Specifically, we proposed that in order to obtain a supplier number, a supplier must complete an application certifying that it meets the supplier standards found in § 424.57(c). Additionally, we proposed that when renewing an application for a DMEPOS supplier billing number, a supplier must recertify that it meets all of the supplier standards.

We proposed new standards and revisions to existing standards relating to the following subject areas:

- Compliance with Medicare statutory provisions and applicable regulations.
- Compliance with applicable Federal and State licensure and regulatory requirements.
- Misrepresentation of facts.
- Signature used on a supplier number application.
- Providing requested information and documentation.
- Scope of exclusions.
- Rental or purchase option.
- Warranties.
- Delivery.
- Reassignment of supplier numbers.
- Physical facility.
- Business telephone.
- Liability insurance.
- Telemarketing.
- Prescription drugs.

B. Additional Revisions

We also proposed to require that DMEPOS suppliers obtain a surety bond. We based this requirement on section 1834(a)(16) of the Act which requires DME suppliers to provide the Secretary, on a continuing basis, with a surety bond. We requested comments on the advisability of exercising this authority to impose a surety bond on all suppliers of prosthetics, orthotics, and supplies to the same extent as required for suppliers of durable medical equipment.

III. Analysis of and Responses to Public Comments

We received 120 comments on the proposed rule primarily from suppliers of DMEPOS and organizations representing various types of DMEPOS suppliers. A summary of the comments and our responses to them follow.

A. Payment Rules (Proposed § 424.57(b))

Comment: One commenter requested that an exception be granted to the effective date provision in a change of ownership situation. The commenter was referring to the statement in the proposed rule that Medicare will not pay for any Medicare covered items provided by a DMEPOS supplier prior to the date HCFA issues a DMEPOS supplier number. The commenter suggested that in the case of a change of ownership, Medicare should pay for covered services as of the date of acquisition.

Response: We are aware of the change of ownership issue. However, at this time we are not prepared to include a change of ownership provision in this final regulation. We plan to address change of ownership issues in a separate rulemaking.

Comment: One commenter stated that a supplier should not receive multiple billing numbers for the same physical location, regardless of how many tax ID numbers they possess.

Response: This suggestion is problematic, in that the Internal Revenue Service (IRS) Employer Identification Number (EIN) is the basic identification number that we use to distinguish between suppliers. Suppliers also may obtain multiple EINs for different lines of business.

We note that section 1834(j)(1)(D) of the Act states that ''The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.'' Therefore, we encourage suppliers to request only one supplier number per physical location. However, we are not prepared at this time to forbid multiple billing numbers based on multiple EINs if we can establish through a site visit or other means that clearly distinct lines of business are being conducted at a location. In this final rule, we are adding a new paragraph (b)(1) to § 424.57 to require suppliers to enroll separate physical locations, other than warehouses or repair facilities.

B. Supplier Standards (Proposed § 424.57(c))

1. General

Comment: One commenter suggested that we require immediate recertification of all suppliers based on the new standards.

Response: This would create a heavy administrative burden on both HCFA and the suppliers. As we stated in the proposed rule, we will not require all DMEPOS suppliers to submit new applications for billing numbers on the date this regulation becomes effective, but will require DMEPOS suppliers to submit new applications as the old numbers expire. Although we may not routinely check to determine the compliance of current suppliers with new standards, it is important to note that as of the effective date of this regulation, December 11, 2000, all DMEPOS suppliers must comply with these standards. We may perform random or focused reviews of previously enrolled suppliers to determine their compliance with the new standards. We may revoke a supplier number if we find evidence that the standards are not satisfied.

Comment: One commenter stated that physicians should be exempt from supplier standards because they have to meet similar standards in order to be licensed.

Response: While physicians are required to meet State licensing requirements, these may vary by State, and do not necessarily apply to physicians while they are functioning as suppliers. More importantly, standards are different for physicians than suppliers. Therefore, we decline to exempt physicians from the requirements.

2. Compliance With Medicare Statutory Provisions and Applicable Regulations (Proposed § 424.57(c)(1))

Comment: One commenter suggested that HCFA provide a list of the requirements that a supplier would need in order to comply with this standard.

Response: We have not accepted this suggestion. The intent of this standard is to ensure that the supplier meets all Medicare requirements that may apply. The standard is essentially a restatement of section 1834(j)(1)(B)(ii)(I) of the Act. We note that we do make extensive efforts to educate suppliers on the requirements they must meet through manuals, bulletins, seminars, and other means.

3. Compliance With Applicable Federal and State Licensure and Regulatory Requirements (Proposed § 424.57(c)(2))

Comment: One commenter stated the standard requiring that a supplier must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements is vague and excessive. Additionally, one

commenter stated that when Medicaid requirements are stricter than Medicare's, we should use the Medicaid requirements. One commenter also suggested that we allow no exceptions to State licensing requirements. One commenter recommended that consideration be given to waiving Federal standards where applicable State safeguards exist. The commenter added that complying with layers of rules adds confusion, cost, and diverts resources from clinical functions to administrative functions.

Response: This requirement is merely a restatement of the law—see section 1834(j)(l)(B)(ii)(I) of the Act. While we agree with the philosophy of requiring suppliers to meet the highest possible standards, it would introduce an increased level of complexity and administrative burden on providers operating in more than one State to meet different requirements in different States in order for the supplier to bill Medicare. For this reason, we have declined to pursue this option. We will take under consideration the possibility of granting waivers, from parts of the National Supplier Clearinghouse (NSC) review process (for example, site visits), to suppliers who are certified or licensed by States with sufficiently stringent requirements. We intend to allow no exceptions to applicable State licensing requirements.

4. Misrepresentation of Facts (Proposed § 424.57(c)(3))

The proposed standard states that a supplier must not make, or cause to be made, any false statement or misrepresentation of a material fact on an application for a billing number. A supplier must provide complete and accurate information in response to questions on its application for a billing number. Any changes in information supplied on the application must be reported within 35 days of the change.

Comment: One commenter stated that this standard needs further clarification. One commenter requested a definition of ''false statement'' and ''misrepresentation''. Also, one commenter suggested that the application form use simple, clear terminology to provide unambiguous guidance as to the information required.

Response: This standard is now located at § 424.57(c)(2). We are not providing definitions of the terms ''false statement'' and ''misrepresentation''. These are not technical terms and carry the common meaning normally associated with them. We will continue to develop the application form to be as clear, simple and unambiguous as possible. We note that we are revising the time frame allowed to a supplier to report changes to the information supplied on the application form. We are changing the proposed ''35 days'' to ''30 days'' to be consistent with the standard established through the application form. In addition to revocation of the billing number, if the supplier knowingly fills out the application incorrectly (for example, misrepresentation of facts or failure to report critical information) the supplier may be subject to civil and criminal penalties for submitting a false statement in connection with a health care matter.

5. Signature Used on a Supplier Number Application (Proposed § 424.57(c)(4))

Comment: One commenter suggested that HCFA should clarify that the signature does not have to be that of an officer of the company, but of a responsible official with first hand knowledge of the requirements listed on the application.

Response: We have not changed the proposed language because we believe that the specificity suggested by the commenter is addressed in the instructions for the DMEPOS application form (Form HCFA–855S). This standard is now located at § 424.57(c)(3). Those instructions specify that the application must be signed by an authorized representative of the supplier. An authorized representative is defined as ''The appointed official (for example, officer, chief executive officer, general partner, etc.) who has the authority to enroll the entity in Medicare or other Federal health care programs as well as to make changes and/or updates to the applicant's status, and to commit the corporation to Medicare or other Federal health care program laws and regulations.'' We believe this requirement protects the integrity of the supplier's information and makes the supplier accountable for its dealings with the Medicare program.

6. Providing Requested Information and Documentation (Proposed § 424.57(c)(5)).

This section, as published in the January 20, 1998 proposed rule, stated that a supplier must agree to furnish to HCFA all information or documentation HCFA requires, including—

- Information or documentation needed to process or adjudicate Medicare claims;
- Upon request, copies of contracts with third parties for furnishing Medicare covered items to Medicare beneficiaries;
- Upon request, documentation that it has advised beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment and about the purchase option for capped rental equipment;
- Upon request, documentation that it has advised Medicare beneficiaries about Medicare covered items covered under warranty;
- Upon request, documentation demonstrating that it has delivered Medicare covered items to Medicare beneficiaries;
- Upon request, documentation that it maintains and repairs directly, or through a service contract with another company, Medicare covered items rented to beneficiaries;
- Upon request, proof of liability insurance; and
- Any other information required by this or other Medicare requirements.

Comment: Several commenters stated that the intent of the requirement to furnish copies of contracts (proposed § 424.57(c)(5)(ii)) is unclear. Several commenters also objected to requiring Health Maintenance Organizations (HMO) and Managed Care Organizations (MCO) contracts. Many commenters stated that Medicare has no right to ''Most Favored Nation'' treatment. One commenter requested clarification of the requirement pertaining to contracts for the delivery of items.

Response: Regarding the comments concerning copies of contracts with third parties for furnishing Medicare covered items to Medicare beneficiaries, we never intended to require information that would lead to ''Most Favored Nation'' treatment. (By ''Most Favored Nation'' treatment we believe the commenter is referring to a situation in which the seller gives the purchaser a better price than he or she gives any of the seller's other customers.) We think the commenter believes that we intend to gain special privileges for the Medicare program. We only expect assurance of the supplier's compliance with the provisions currently shown in § 424.57(c)(6). Medicare pays based on the lower of the supplier's actual change or the fee schedule. We also do not require copies of HMO/MCO contracts. We have clarified this standard to require only copies of contracts that a supplier has with other entities that deliver supplies to Medicare beneficiaries on the supplier's behalf or that provide supplies to the supplier for use in providing items to Medicare beneficiaries. This would include arrangements for providing componentry. Note, however, that the standard in proposed § 424.57(c)(3), requires a contract if the supplier has no

inventory of its own. This standard is now located at § 424.57(c)(4).

Comment: Several commenters questioned the type of documentation required by HCFA and whether beneficiaries would have to sign the documents. A number of commenters suggested that we remove redundancy by including the documentation requirements in the specific standards to which they apply.

Response: Neither the proposal nor this final rule specifies that the beneficiary has to sign documents under this requirement. As suggested by the commenters, we have moved most of the documentation requirements to the specific standards to which they apply, for clarity and to eliminate redundancy.

Comment: With respect to the standard requiring documentation advising beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment, one commenter objected to additional documentation requirements and paperwork because most beneficiaries prefer to purchase inexpensive and routinely purchased equipment. The commenter believed that HCFA would increase the cost of processing claims if patients rented equipment up to the purchase price, when by physician order, other medical documentation, or expected length of need, one would anticipate usage beyond the months required to reach the purchase price. In addition, the standard would require that the purchase option for capped rental equipment must be given to the beneficiary and documented. The commenter stated that a conversation is usually held with the beneficiary at the time they receive a capped rental item, in order to ensure that they understand the equipment is owned by the supplier until such time as the purchase option is offered in the tenth month. At the tenth month, the purchase option letter is forwarded to the beneficiary, and suppliers customarily make every effort to communicate with the beneficiary with regard to the purchase or continued rental option. The commenter believed that this section of the standards is unnecessary because the purchase option letter should fulfill the need for this documentation.

Response: We have not specified any additional documentation requirements and paperwork. A purchase option letter is one way to document compliance with this requirement. The requirements for the purchase option are spelled out in § 414.229(d) of this part and in section 1834(a)(7)(A) of the Act. It is not the intent of this regulation to address the purchase option requirement other than to state that it must be met and documented.

Comment: With respect to the standard requiring documentation advising beneficiaries about Medicare covered items covered under warranty, one commenter questioned whether the supplier has to obtain a signed statement to this effect from the beneficiary, pointing out that it would add to the cost of providing services to Medicare patients.

Response: A signed statement by the beneficiary is not necessary to comply with this requirement. We will also consider other documentation, such as delivery logs and copies of warranty information provided to beneficiaries.

Comment: With respect to the standard requiring documentation that the supplier has delivered Medicare covered items to Medicare beneficiaries, several commenters asked what is considered reasonable documentation for orthotic and prosthetic devices and services because there are no delivery slips as there are in DME.

Response: We believe it is reasonable to require a receipt for delivery of an orthotic or prosthetic device if they are not routinely provided items.

Comment: With respect to the standard requesting any other information required by this or other Medicare requirements, several commenters stated that this requirement needs limits, otherwise it will generate meaningless paper. Several commenters stated that we should follow the rules in 42 CFR 300 *et. seq.* concerning access to records and contracts between suppliers and subcontractors. One commenter stated that we cannot argue that we are entitled to greater access to information and documentation from Part B suppliers than from Part A suppliers' subcontractors. One commenter suggested that we add a requirement for telephone logs showing contacts with physicians, regarding physicians orders, and with beneficiaries and that we should require a list of delivery charges billed to Medicare or the beneficiary. One commenter stated that they had no objection to this requirement as long as the information required is referenced in the Medicare Carriers Manual and the DMERC supplier manual.

Response: We concur with much of the comment and are clarifying this requirement. Specifically, we are requiring that a supplier must agree to furnish to HCFA any information required by this or other applicable Medicare statute and regulations. We believe the references to 42 CFR 300ff should have been to 42 CFR 420.304, which contain the procedures that the Department of Health and Human Services follows in obtaining access to books, documents, and records in order to verify the costs of subcontractor services to a Medicare supplier. Although the procedures are reasonable for the purposes to which they are addressed, we believe that the changes we have made are a reasonable accommodation to purposes addressed in this regulation.

We disagree with the comment that we are not entitled to greater access to information from suppliers than from suppliers' subcontractors. The Congress specifically gave us authority with respect to DMEPOS suppliers in section 1834(j) of the Act.

Although we consider the maintenance of telephone logs for physician and beneficiary contacts good business practice, we are not prepared at this time to mandate their use because there may be other means to satisfy the requirements. We also are not prepared to require information on delivery charges. We will consider referencing the information required in the suggested manuals.

7. Scope of exclusions (Proposed § 424.57(c)(6))

Comment: With regard to the standard prohibiting a supplier from contracting with entities excluded from the Medicare program, one commenter stated that it may be necessary to contract with excluded entities in some situations—for example, if there is limited availability. Several commenters stated that it is unreasonable to expect that health care suppliers be able to accurately avoid such entities. They have no source to obtain this information and would, therefore, have to rely solely on the word of the subcontractor, which might not be accurate. Therefore, such policing activity should be the responsibility of HCFA. One commenter questioned the impact this requirement would have on inventory on-hand and servicing items under warranty.

Response: Information on excluded entities is available from the Government Printing Office and from the HHS Office of Inspector General (OIG). The OIG web site shows sanctioned entities. The web site address is: http//www.hhs.gov/progorg/oig/cumsan/index.htm. Allowing an excluded entity to contract with a Medicare supplier and indirectly receive Medicare funds because they are a source of items of limited availability would place the entity above the law because of this scarcity. We believe that the marketplace would soon adapt to fill this need, or that suppliers can be resourceful enough to find other

accommodations. We would also expect suppliers to take reasonable steps to determine if an entity with which they have a contractual arrangement is excluded or debarred. The standard is now located at § 424.57(c)(4).

8. Rental or Purchase Option (Proposed § 424.57(c)(7))

Comment: One commenter suggested that we revise the standard stating that a supplier must advise beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment and of the purchase option for capped rentals. The commenter suggested that the standard give suppliers the discretion of making the decision on whether to rent or purchase based on the length of need estimated by the ordering physician. A related issue is that warranty information should be provided to beneficiaries at the time the title to an item transfers. Including warranty information in the explanation of capped rental may serve to further confuse beneficiaries. Additionally, several commenters suggested that we clarify that this standard applies only to the inexpensive or routinely purchased and capped rental DME categories—and not other items, such as home dialysis supplies and equipment.

Response: This standard is merely a reinforcement of our regulations at § 414.229(d) which refer to the purchase option on capped rental items, and the statute, at section 1834(a)(7) of the Act referring to payment for other items of DME. Since it is the beneficiary's decision whether to rent or purchase items, the supplier must explain the ramifications of this decision to the beneficiary at the required points in time to help the beneficiary make an informed decision. We are clarifying the standard in this final rule to state that it applies only when DME items are provided. This standard is now located at § 424.57(c)(5).

9. Warranties (Proposed § 424.57(c)(8))

This proposed standard states that a supplier must honor all warranties, expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty.

Comment: One commenter suggested that the supplier be required to give the beneficiary a list of the warranty periods for all products sold by that supplier. This provides the beneficiary with full disclosure and ensures basic supplier compliance with the standard. One commenter suggested that warranty information be provided to beneficiaries at the time the title to an item transfers. Another commenter requested that this documentation be provided as part of the delivery document, rather than a separate notice.

Response: With regard to the suggestion about providing a complete list of warranties, we think that this requirement is too onerous for larger suppliers. We do not specify at what point in time the warranty information is to be provided—at the time of delivery or at time of transfer of title both seem to be reasonable points of time. This standard is located at § 424.57(c)(6).

Comment: One commenter suggested that this standard covers equipment components only. The commenter noted that the cost of repair or replacement not only includes the cost of the actual component(s), but also the extensive labor to remove the old units, install the new, refit and possibly realign the device. In addition, the commenter stated that the warranty from the manufacturer covers only the component costs. A related comment stated that, while the warranty provisions that were set forth in the proposed rule may make sense for off-the-shelf items, they create anomalies for customized devices. Medicare fees for orthotics and prosthetics devices include evaluation, fitting, costs of components, and repairs due to normal wear and tear for 90 days when not necessitated by changes in the residual limb or the patient's functional capabilities. Medicare fees do not include professional service charges for repairs beyond 90 days even though the manufacturer's warranty for parts may exceed 90 days. The commenter suggested that it is in the best interest of the Medicare program to pay the labor cost to replace a component part of a device rather than replace the entire device; therefore, the rules should clarify that the professional service costs to evaluate, fit, disassemble and reassemble an orthotic or prosthetic component covered under a manufacturer's warranty is a covered service.

Response: Medicare does not cover maintenance and servicing of equipment when such services are covered under warranty. Medicare does not make separate payment for ''fees'' charged to process warranty items, paperwork, etc. These fees have been built into the reimbursement rate. We do make payments for maintenance and servicing of equipment after the warranty has expired.

10. Delivery (Proposed § 424.57(c)(9))

This proposed standard stated that a supplier must be responsible for the delivery of Medicare covered items to beneficiaries. A supplier must provide beneficiaries with necessary information and instructions on how to use Medicare covered items safely and effectively.

Comment: One commenter stated that the capability of providing proof of delivery exists only when someone is at a beneficiary's home to sign for each delivery. They recommended, instead, that proof of delivery may be maintained by drivers in their individual daily ''log worksheets,'' as well as in the bills of lading for the supplies and equipment that are delivered. One commenter suggested that we include persons who are hearing impaired or have other disabilities. One commenter stated that, in some situations, instructions on how to use Medicare covered items are provided by physicians or other facilities (an ESRD facility, for example), so that the supplier is not directly responsible. One commenter urged that we coordinate any further developments of these standards with the Food and Drug Administration (FDA), insofar as they involve product information that is made available to the public. One commenter stated that instructions often are verbal rather than written, so that documentation in the medical record should suffice.

Response: It is our intention that all beneficiaries, including beneficiaries who are hearing impaired, or have other disabilities, always receive the necessary information to safely and effectively use the items they receive. We recognize that this may be accomplished through different means. This requirement can be satisfied as long as the supplier can establish that the necessary training/instructions have been delivered at an appropriate time and in an appropriate manner. We are modifying the language of this standard to clarify that a supplier must document that it, or other qualified parties, has provided the beneficiaries with necessary information and instructions at an appropriate time. This standard is now located at § 424.57(c)(12). When questions arise on the use of products, we consult with the FDA.

11. Repairs (Proposed § 424.57(c)(11))

Comment: One commenter stated that the standard stating that a supplier must maintain and repair directly, or through contract, Medicare covered items it has rented to beneficiaries does not address the issue of whether a supplier may

function under the manufacturer's warranty and meet the standard, that is, instead of repairing the item, the supplier simply replaces the product and returns the item in need of repairs to the manufacturer. Another commenter questioned how this was to be documented and what level of repair is needed.

Response: We are modifying this standard, now located at § 424.57(c)(14), to allow suppliers to replace items and to clarify that the level of repair should be sufficient that the item functions as required and intended.

12. Return of Items (Proposed § 424.57(c)(12))

This proposed standard states that a supplier must accept returns from beneficiaries of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and/or sold).

Comment: One commenter suggested that the supplier should be required to maintain a log of all returns from beneficiaries of substandard or unsuitable items. This would be helpful to ensure compliance with the standard. Another commenter suggested that the standard needed a time limit. One commenter stated that, if an item is ordered by a physician and used by the beneficiary, a supplier should not be required to accept returns if the beneficiary no longer wants the item for reasons other than quality.

Response: While we agree that such a log would be helpful in verifying compliance, we believe that such a mechanism is not the only method for ensuring compliance. Therefore, we have not modified this standard. This standard is located at § 424.57(c)(15). With regard to the comments regarding time limits and reasons for return, this standard has been in place since December 11, 1995 with few problems. Since the revision suggested regarding time limit contained no suggestion for a time limit, and we received no other suggestions, we are retaining the requirement without change. We also believe the requirement is clear enough with regard to the intent that it is the quality or suitability of the item that must determine whether it should be returnable. If necessary, we will address this last issue through program instructions.

13. Physical Facility (Proposed § 424.57(c)(16))

This proposed standard states that a supplier must maintain a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this requirement, a post office box or commercial mailbox is not considered a physical facility.

Comment: One commenter suggested that all suppliers need to be in compliance with the Americans with Disabilities Act and be beneficiary accessible. The requirement should apply to both commercial business and residential locations. The commenter also stated that the standard should require that the business have a sign and have hours of operation posted.

Response: Medicare suppliers must meet all laws and regulations that might apply to them, including any applicable provisions of the Americans with Disabilities Act. This is provided for under the standard at § 424.57 (c)(1), which requires that suppliers operate their business in compliance with all applicable Federal and State licensure and regulatory requirements. The requirements apply whether the supplier is located at a commercial location or a residence, because it is still a business. In response to the comment concerning the posting of a sign and hours of operation, we are adding to this final rule a statement at § 424.57(c)(8), that the supplier location must be accessible during reasonable business hours to beneficiaries and to HCFA, and must maintain a visible sign and posted hours of operation.

Comment: One commenter suggested that this standard should restate the guidance established in title XVIII of the Act that only one supplier number is allowed per location, regardless of whether multiple Tax Identification Numbers are obtained. This would eliminate numerous questionable supplier operations in which several supplier numbers are located at the same address. Another commenter suggested that HCFA develop protocols for conducting an on-site inspection of every entity that submits an initial application for a supplier number prior to approving the application. One commenter stated that some suppliers have no physical facility where they treat clients, placing the commenter at a competitive disadvantage because he had a large and ongoing investment in real estate, tools, supplies, equipment, etc. Several commenters suggested that HCFA exempt national concerns with central sites for record storage from this requirement, or more clearly define the objectives underlying this requirement as a performance specification, and allow companies to satisfy the government's needs in other ways. One commenter stated that warehouses should not be covered by the standards.

Response: As previously noted in describing our changes to § 424.57(c)(6), section 1834(j)(1)(D) of the Act states that the Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control. We are adding a sentence to state that in the case of a multi-site supplier, records may be maintained at a centralized location. A supplier must demonstrate a legitimate need for additional numbers. With regard to the physical site requirement, it is not our intention to ensure that no entities have competitive advantage over others. This is a natural by-product of the marketplace and business environment. Our intention is to ensure that we do business with legitimate entities who can provide safe and effective service to Medicare beneficiaries. We recognize that some suppliers may have multiple sites from which they do business, and may maintain records at one central site. Such suppliers may supply evidence of such recordkeeping, as long as the central site is an enrolled Medicare supplier site or represents a central function of a larger corporation of which the supplier is a part. We note that locations serving simply as warehouses are not subject to these standards.

14. Business Telephone (Proposed § 424.57(c)(17))

This proposed standard states that a supplier must maintain a primary business telephone at the physical facility. This telephone number must be listed under the name of the business and in the business portion of the local telephone company directory. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone.

Comment: Several commenters strongly supported the standard requiring a supplier to maintain a business telephone at the physical facility where it does business. One commenter, however, noted that some suppliers maintain centralized customer service lines. A strict interpretation of the proposed standard would preclude this practice. Likewise, many suppliers maintain warehouse locations that are not used for retail customers. These types of locations should not be subject to the telephone standard because appropriately trained customer service representatives would not be available

to respond to the public's questions. The commenters suggested that HCFA should modify the proposed regulation to state that the telephone standard would not apply in the above scenarios. One commenter noted that telephone directories are normally published annually, contracts for inclusion are made several months in advance. Therefore, unless the regulations allow adequate time for suppliers to comply with the requirement, they will not be able to meet the standard.

Response: We recognize the practices of large organizations with regard to centralized telephone service as well as centralized records. Therefore, we are modifying the standard now at § 424.57(c)(9) to permit the use of toll free numbers that may not be listed in the business portion of the local telephone directory. Documentation of a paid application for a telephone listing will be considered to meet this requirement. However, the telephone number itself must be in place and available through the telephone company's directory services (information).

15. Liability Insurance (Proposed § 424.57(c)(18))

This proposed standard states that a supplier must have a comprehensive liability insurance policy that covers both the supplier's place of business and any and all customers and employees of the supplier.

Comment: One commenter suggested that, if we feel that minimum coverage of $500,000 is adequate for most businesses, then state it clearly as part of the standard requiring that suppliers have a comprehensive liability insurance policy. Experience has indicated that most suppliers and many agents are confused by the lack of such guidance. Another commenter suggested that $300,000 was adequate for the types of businesses under consideration. Several commenters supported this requirement and some suggested that suppliers of custom devices should be required to have professional and product liability insurance to protect the patient and themselves. One commenter stated that national, publicly traded companies with large assets maintain adequate insurance and reinsurance coverages through multiple carriers, but that coverage necessarily includes self-insured retentions. The commenter further stated that HCFA should make it clear that corporations with assets in excess of some fixed amount should not be required to change their insurance profile to satisfy this requirement. Another commenter stated that HCFA's general description of the required ''comprehensive liability insurance policy'' is inadequate. The commenter felt that it is necessary for a seller and supplier of medical equipment to have a Comprehensive General Liability Insurance Policy plus coverage for product liability and completed operations. The commenter, a national group of home medical equipment supply companies, stated that more than 80 percent of the claims it had received during the last 11 years involved alleged product deficiencies or failures.

Response: We are revising this standard, now at § 424.57(c)(10), to require a comprehensive liability insurance policy of at least $300,000. We agree that partial self insurance is an acceptable means of meeting this requirement for publicly traded companies with sufficient assets. However, we are not able at this time to sufficiently define how this would be accomplished. We are also revising this standard to refer to product and operation liability and clarifying that the insurance must remain in force at all times. In addition, we have revised the language to allow suppliers with multiple sites to procure an umbrella policy for each tax ID number.

16. Telephone Contact (Proposed § 424.57(c)(19))

This proposed standard states that a supplier of a Medicare covered item must agree not to contact a beneficiary by telephone regarding the furnishing of a Medicare covered item to the individual unless certain specified situations apply.

Comment: One commenter suggested that we add an exception to this standard. Specifically, the commenter suggested that we permit telephone contact if the supplier receives a referral from a medical professional involved in the patient's care.

Response: While this may be reasonable in some situations, we find it problematic in that it may have unintended consequences as a loophole by allowing suppliers to purchase ''referrals'' (client lists) from medical professionals. This standard is located at § 424.57(c)(11).

17. Prescription Drugs (Proposed § 424.57(c)(20))

This proposed standard states that only a supplier that is licensed by the State to dispense the drug may bill for a drug used as a Medicare covered supply with durable medical equipment or prosthetic devices. A supplier of drugs must bill and receive payment for the drug in its own name.

Comment: One commenter requested that we clarify that physicians may dispense and bill for drugs if permitted by the State. One commenter requested that we clarify that it is not necessary to have a pharmacy license in order to dispense drugs in connection with ESRD. One commenter requested that we clarify that suppliers may dispense oxygen with a prescription, consistent with FDA requirements. Several commenters supported this requirement completely.

Response: We are revising the standard, now at § 424.57(b)(4) to reflect that physicians may dispense and bill for drugs if authorized to do so under State law. There is no exception to the licensure requirement for dispensing drugs furnished in connection with ESRD.

C. Surety Bonds (proposed § 424.57(e))

We received many comments on the proposed surety bond provisions. Most of the commenters were opposed to the provisions citing costs as their major objection. Because we have decided to make extensive changes to this requirement and build on our experience with surety bond requirements for home health agencies, as well as a General Accounting Office Study of Medicare surety bonds, we have decided not to incorporate the provisions related to surety bonds in this final rule. Rather, we will issue the surety bond provisions as a proposed rule at a future date and will consider the comments in the development of that rule.

D. Other Comments

Comment: One commenter suggested that we require that suppliers be certified by appropriate national certification bodies, including the Board for Certification in Pedorthics, before they are eligible to dispense therapeutic shoes for diabetics.

Response: This is a good suggestion. Because of the potential impact on the supplier community and the need for public opportunity to comment, we will consider it for future revisions.

Comment: One commenter suggested that we implement a specialty code for pedorthics.

Response: This can be done administratively, without a regulation. If deemed feasible, we will consider it.

Comment: One commenter stated that no physician or hospital should own, in whole or in part, a DME supplier. This is a common practice and is strictly self-referral, which leads to corruption.

Response: Although the supplier standards do not address the issue of whether a physician may have an ownership interest in a DME supplier, the physician self-referral provisions in

section 1877 of the Act do address this issue. Under the physician self-referral provisions, a physician may not refer a Medicare or Medicaid patient for any ''designated health services'' listed in section 1877(h)(6) of the Act to an entity with which the physician or an immediate family member of the physician has a financial relationship, unless an exception applies. Designated health services include, but are not limited to, DME and supplies; parenteral and enteral nutrients (PEN); equipment and supplies; and prosthetics; orthotics, and prosthetic devices and supplies. A financial relationship may be through an ownership or investment interest or a compensation relationship. There are certain exceptions that apply to ownership interests. Some exceptions apply to compensation relationships, and some exceptions apply to both ownership and compensation. The physician referral prohibition also has an effect on Federal health care programs (including Medicaid and Medicare). For additional information about physician referral issues, please contact Joanne Sinsheimer at (410) 786–4620.

The current supplier standards do not address the issue of whether a hospital should own a DME supplier. We may consider this suggestion in future revisions because of the potential impact on the supplier community and the need for public opportunity to comment.

We want to draw your attention to the possibility that, based on the facts in each case, referrals may be prohibited under the anti-kickback statute. This statute applies to those who knowingly and willfully offer, pay, solicit, or receive remuneration to induce the furnishing of items or services paid for, in whole or in part, by any Federal health care program, including Medicare or Medicaid. For further information about the anti-kickback statute, please contact the Office of the Inspector General for HHS at (202) 619–0335.

Comment: One commenter suggested that HCFA ensure that the application form itself uses simple, clear terminology to provide unambiguous guidance as to the information required. The Form HCFA–855 should be reviewed by the OIG prior to issuance to ensure that the use of vague and ambiguous terminology is minimized and that instructions are clear.

Response: The Form HCFA–855 was reviewed by OIG prior to issuance. In addition, we are in the process of revising the Form HCFA–855. We will solicit input from all concerned parties, via a **Federal Register** notice prior to requesting the Office of Management and Budget's (OMB) approval of the revised form. We will consider detailed recommendations related to the revised Form HCFA–855.

Comment: One commenter stated that we should submit this rule to the Congress for a 60-day review in accordance with the Contract with America Advancement Act (P.L. 104–121).

Response: We are submitting a report to Congress for this rule pursuant to the congressional review procedures established by the Contract with America Advancement Act. We note that OMB has determined that this rule is not a major rule as defined by the Act.

Comment: One commenter stated that the proposed rule did not categorize the range of DMEPOS services and items. In addition, we did not provide in Table 2 a breakdown distribution by service or item speciality.

Response: The range of DMEPOS services and items are stipulated in various sections of the Act. The preamble of the proposed rule makes references to some of the sections of the Act. We do not have the data to provide a national geographic distribution of each type of service or item furnished by DMEPOS suppliers.

E. Orthotics/Prosthetics

Comment: Several commenters stated that orthotics and prosthetics suppliers should be licensed or certified. They believed that the provision of custom orthotic and prosthetic devices should be limited to facilities that are accredited by, or practitioners certified by, the American Board for Certification in Orthotics and Prosthetics or that meet equivalent educational and performance standards. One commenter suggested that we allow accreditation by the American Board for Certification in Orthotics and Prosthetics to serve as the equivalent of meeting the Medicare provider standards. One commenter stated that orthotics and prosthetics suppliers should be required to document each case in writing; should be required to give treatment alternatives in writing to each customer; should be required to give written cost estimates to each customer; and should be required to give a one year guarantee. Several commenters stated that orthotics and prosthetics suppliers should be required to have a bond. Several commenters suggested that orthotics and prosthetics suppliers should have separate standards from other suppliers.

Response: We will consider these suggestions in future revisions because of the potential impact on the supplier community and the need for public opportunity to comment.

IV. Request for Comment on Certain Supplier Standards

The Balanced Budget Act of 1997 (BBA) requires the Secretary to establish service standards for home oxygen suppliers. The U.S. General Accounting Office (GAO), in Report GAO/HEHS–99–56: Access to Home Oxygen Equipment, states that such service standards ''such as the frequency of maintenance visits and the level of patient education * * * would define what Medicare is paying for in the home oxygen benefit and what beneficiaries should expect from suppliers.'' We solicit comments as to what should comprise such supplier standards.

In addition, section 1861(s)(12) of the Act permits Medicare payment for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if, among other things, the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary). We solicit comments as to what standards should be established for suppliers of such shoes and the qualifications to require of the fitting individual.

The Office of the Inspector General in a report titled ''Medicare Orthotics'' (OEI–02–95–00380) recommended that HCFA ''consider stricter standards for who is allowed to bill for orthotics, such as requiring professional credentials for orthotics suppliers.'' We solicit comments as to what standards should be established for suppliers of Medicare-covered orthoses. We also solicit comments as to whether similar standards should be applied to prostheses.

We also welcome comments as to whether and what kind of standards should apply for home infusion therapy, durable medical equipment such as wheelchairs, or any other item provided under the DMEPOS benefit.

V. Provisions of the Final Regulations

We are adopting the provisions set forth in the proposed rule with the exceptions noted in the Analysis of and Responses to Public Comments (section III. above) as well as the following change.

Throughout § 424.57, we are changing most of the references to ''billing number'' to ''billing privileges'', noting in § 424.57(b)(2) that billing privileges must be conveyed along with a billing number.

Also, we reiterate that although we do not intend to require suppliers with

current numbers to immediately certify to HCFA their compliance with these revised standards (they will do so when they reapply), it is important to note that as of the effective date of this regulation, all DMEPOS suppliers must comply with the standards as revised. We may revoke a supplier number if we find evidence that the standards are not satisfied.

VI. Collection of Information Requirements

This final regulation contains requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). However, all have been approved by OMB. The OMB approval numbers associated with these approved requirements are 0938–0717, DMEPOS Supplier Standards: Additional Information Collection Requirements, for which the approval expires on April 30, 2001, and 0938–0685, Medicare Carrier Provider/Supplier Enrollment Application, for which the approval expires on September 30, 2001.

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

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Attn: John Burke, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

VII. Regulatory Impact Analysis

We have examined the impacts of this final rule under Executive Order 12866, the Unfunded Mandate Act of 1995, and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. In addition, a Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

The costs associated with this rule are as follows:

- Liability insurance requirement (§ 424.57(c)(10)). We estimate that only 10 percent of DMEPOS suppliers do not already have liability insurance that meets this requirement. Based on Medicare data as of May 1999, 10 percent of the total DMEPOS suppliers is approximately 6,600 suppliers. We note that commenters on the proposed rule gave varying estimates of the cost of liability insurance. The range commenters suggested was between $1300 and $1800 annually. Using the highest estimate received ($1,800 annually), results in an approximate additional liability insurance cost of $11.9 million annually (6,600 times $1,800) to the DMEPOS industry due to this rule.
- Primary business telephone listed under the name of the business locally or toll-free for beneficiaries requirement (§ 424.57(c)(9)). We estimate that only 1 percent of DMEPOS suppliers do not already meet this requirement. Based on Medicare data as of May 1999, we determined that one percent of DMEPOS suppliers is 660 suppliers. Therefore, 660 times the approximate $600 annual cost of telephone service results in an additional cost of $0.4 million annually.

Total Cost = $11.9 Million + $0.4 = $12.3 million annually.

The Unfunded Mandates Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This final rule has no consequential effect on State, local, or tribal governments.

Consistent with the Regulatory Flexibility Act, we prepare a Regulatory Flexibility Analysis (RFA) unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the Act, suppliers with annual sales of $5 million or less are considered to be small entities. (Individuals and States are not included in the definition of a small entity.) The RFA is to include a justification of why action is being taken, the kinds and number of small entities which the rule will affect, and an explanation of any considered meaningful options that achieve the objectives and would lessen any significant adverse economic impact on the small entities.

We believe that our standards will help bar fraudulent suppliers from participating in the Medicare program and provide an added level of protection to Medicare beneficiaries. Therefore, we expect to have an impact on an unknown number of persons and entities who will effectively be prevented from practicing their aberrant billing activities. The vast majority of suppliers will not be significantly affected by this rule. The reduction in program overpayments and the added level of protection to beneficiaries that we expect to achieve as a result of this rule justifies the relatively small burden the rule would impose on all small entities.

The following analysis, together with the rest of this preamble, explains the rationale for and purposes of the rule, details the estimable costs and benefits of the rule, analyzes alternatives, and presents the measures we propose to minimize the burden on small entities.

A. Rationale and Purposes

We expect this rule to deter some entities that supply DME to Medicare beneficiaries from abusive billing practices or defrauding the Medicare program. For example, abusive practices include refusing to honor manufacturers' warranties or improperly installing equipment in Medicare beneficiaries' homes.

Fraudulent practices include billing the Medicare program for supplies that were not furnished. In a surprisingly large number of instances, when either the beneficiaries or HCFA attempted to contact suppliers alleged to have committed abuses, it was difficult to reach them because they did not have a fixed address or had closed the business and fled. Our experience has been that the market has failed to address these problems because of the motivation for unseemly profits, inadequate control by gatekeepers, and insufficient information on the part of Medicare beneficiaries to detect abuse. This market failure makes it necessary for HCFA to impose standards on DME suppliers and establish safeguards that enable the Medicare program to better protect beneficiary interests.

B. Characteristics of Suppliers

The single most striking characteristic of Medicare DMEPOS suppliers is their diversity. DMEPOS suppliers fill a business need and do it in a variety of ways. Some suppliers set out from the beginning to establish a business furnishing DMEPOS items; others evolve into being suppliers. For example, a firm dealing with the oxygen needs of the medical community may add a department that provides oxygen services and supplies as a medical supply as a logical extension of an existing business.

Similarly, a retail rental store may add wheelchairs or hospital beds and a pharmacy may add walkers to an inventory of otherwise unrelated commodities and use existing

advertisements to announce the availability of these items.

Based on the small size of some businesses, it is more characteristic that suppliers furnish a limited number of items in greater demand than to maintain a large inventory of items covering the gamut of covered DMEPOS items. Thus, the only things any two suppliers may have in common is their provision of DMEPOS items and their understanding that the activity will meet the needs of the business. Suppliers are in a position to direct their marketing activities to optimize their most profitable revenue sources, and in seeking to meet patient demand, can choose to provide only those items that meet their business objectives.

For purposes of the RFA, a small entity is one with annual revenues of less than $5 million. Medicare data indicates that more than 95 percent of all DMEPOS suppliers generate billings of less than $350,000 in Medicare revenues annually, and 99 percent less than $5 million.

C. Geographic Distribution of Suppliers

Individual patients may receive their durable medical equipment, supplies, and prosthetics either from a local supplier or from a regional or national concern that functions much like a mail order catalogue distribution center. As shown in Table 1, which is based on Medicare data as of May 1999, suppliers locate in areas where there is greatest demand, leaving other areas to be served by catalog, mail order or drop shipments. No States appear to be under served, and competition exists in large population areas, leading us to believe that the imposition of some additional standards will not have adverse effects on competition or on the availability of an adequate number of suppliers to meet patients' needs.

TABLE 1

State	Number of suppliers per State	Number of beneficiary per State	Beneficiary per supplier
AK	140	5500	39
AL	1960	151600	77
AR	1207	92400	77
AZ	1518	73100	48
CA	9612	469800	49
CO	1383	64200	46
CT	1552	79700	51
DC	167	10800	65
DE	274	17400	63
FL	7894	491200	62
GA	3180	186400	59
HI	345	16700	48
IA	1733	98400	57
ID	603	33500	56
IL	4212	268000	64
IN	2731	163800	60
KS	1386	76300	55
KY	2008	126200	63
LA	1996	115900	58
MA	2175	125200	58
MD	1837	102600	56
ME	636	38500	60
MI	3196	295600	92
MN	2001	105100	53
MO	2363	156100	66
MS	1094	96700	88
MT	608	28000	46
NC	3472	235000	68
ND	388	22200	57
NE	1026	48300	47
NH	520	24800	48
NJ	3291	172700	52
NM	539	34300	64
NV	553	27900	50
NY	6152	404700	66
OH	5101	294000	58
OK	1576	96700	61
OR	1316	61400	47
PA	5749	325900	57
RI	455	22000	48
SC	1666	124400	75
SD	458	23800	52
TN	2494	171600	69
TX	7021	408700	58
UT	690	36000	52
VA	2864	163300	57
VT	275	13600	49
WA	2268	107900	48
WI	2356	146200	62
WV	947	64400	68
WY	294	13300	45

TABLE 1

State	Number of suppliers per State	Number of beneficiary per State	Beneficiary per supplier
Total	109,782		

We note that the purpose of Table 1 is to illustrate the locations that provide durable medical equipment and supplies to Medicare beneficiaries. Many of these entities are members of chain organizations. While Table 1 indicates there are more than 109,000 suppliers, due to the affiliation of some suppliers with chains, as of May 1999, there were only 65,528 unique billing numbers. Hence, although in several sections of this preamble we mention 65,528 billing numbers, this reference and Table 1, which describes the more than 109,000 actual locations, describe the same universe of suppliers. According to an industry source, Medicare accounts for approximately 40 percent of the average DMEPOS supplier's revenue. The approximate percentage amounts for other revenue sources are 25 percent private insurance, 15 percent Medicaid, 10 percent institutional, and 10 percent private credit and cash sales. For calendar year 1997, Medicare program allowed charges amounted to $6.7 billion for DMEPOS items. We believe that for most suppliers any additional costs imposed by our standards would be outweighed by the benefits gained by continuing to be a Medicare DMEPOS supplier.

These standards should not result in changes in the number of legitimate business suppliers, because, as set forth below and elsewhere in this preamble, most requirements are logical extensions of good business practices that we believe currently are being met by the vast majority of suppliers.

D. Discussion of Alternatives

We believe it was the intent of the Congress to strengthen DMEPOS supplier standards to protect beneficiaries and ensure the integrity of the Medicare program. Therefore, we proposed expanded supplier standards, using as our statutory basis section 1834(j)(1)(B)(ii)(III) of the Act for liability insurance and section 1834(j)(1)(B)(ii)(IV) of the Act, which states that the supplier must meet such other requirements as the Secretary may specify. This final rule will provide a basis to better screen applicants and to revoke the supplier numbers of those who do not meet these standards.

For purposes of this impact statement, we have divided the supplier standards into the following two broad categories: statutory requirements and good business practices.

1. Statutory requirements

Liability Insurance—The statutory authority for § 424.57(c)(10) is section 1834(j)(1)(B)(ii)(III) of the Act. This rule requires a supplier to have comprehensive liability insurance, including product liability and completed operations in the case of a supplier that makes its own items, that covers the supplier's place of business and any and all customers and employees. Based on comments received on the proposed rule, we are requiring a minimum of $300,000 in coverage. Based on discussions with industry experts, we estimate that approximately 10 percent of all suppliers do not currently carry liability insurance. Based on comments received, we estimate the cost per year for a supplier to carry liability insurance in the amount of $300,000 would be no more than approximately $1,800. We believe that the $1,800 cost per supplier does not represent a significant economic impact on the estimated 10 percent of suppliers not currently carrying liability insurance. We also believe that it is good business practice to carry such insurance, as indicated by the fact that 90 percent or more of suppliers already do so.

2. Good Business Practices

Most of the supplier standards in this final rule deal directly with business practices. We do not believe that these standards will result in a significant impact on any sizeable number of legitimate suppliers. For these additional standards, the economic impact on most suppliers is negligible, although the benefits to the program and to the beneficiary will be greater. For example, the requirement at § 424.57(c)(6) that a supplier must not charge Medicare for repair or replacement of Medicare covered items or for services covered under warranty, coupled with the requirement that the supplier provide documentation, upon request, that it has advised Medicare beneficiaries about Medicare covered items covered under warranty, should result in claims for repairs, parts or replacement being made against the warranty, thus decreasing the monies paid by Medicare. The monies paid out by the program and the beneficiary also may decrease as a result of the requirement that the supplier inform the beneficiary of the rental or purchase option and the copay implications involved. More beneficiaries may elect to purchase their equipment, instead of renting for long periods of time.

In most instances, these standards do not exceed the usual business practices necessary for any retail business to succeed. In other words, we believe that a supplier that expects to conduct a successful business would already have in place procedures to meet these standards. We did not develop alternatives because we consider the final supplier standards to be basic requirements that a business would have to meet in order to provide satisfactory customer service and manage properly its inventory.

Under § 424.57(c)(9), a supplier is required to maintain a telephone that is used primarily for business purposes at its physical facility and is listed under the name of the business locally or toll-free for beneficiaries. In order to accept inquiries from potential customers, maintain relationships with current customers, and conduct business with contractors in today's business market, it is necessary that virtually every business have telephonic access. Beneficiaries also need access to their supplier in case they have a problem with or questions about their DMEPOS items.

We believe that this standard is currently met by nearly all legitimate businesses. However, we believe approximately one percent of DMEPOS suppliers currently do not meet the fixed telephone requirement. The estimated cost per year for any supplier to establish and maintain a telephone line to conduct business would be approximately $600 ($50 a month). Thus, the aggregate cost is negligible. We believe the benefits of full time access to the supplier will far exceed the minor economic impact on a supplier.

This requirement will help beneficiaries contact their suppliers in

the event of equipment problems and failures, and to resolve questions. Telephonic access to a supplier is also crucial so that the Durable Medical Equipment Regional Carriers may call and obtain additional information to process and pay claims.

E. Conclusion

As indicated elsewhere in this preamble, to the extent that we are imposing a burden, it is a necessary one. The public interest is best served by establishing safeguards that prevent suppliers from taking advantage of the current minimal supplier standards. It is by design that these standards would have the greatest impact on those suppliers that need to change the most. We believe that the loss of a few suppliers as a result of these supplier standards, for example those who operate out of a van or who do not provide a value added service, is far outweighed by the benefits of protecting the health and safety of beneficiaries and preserving the Medicare Trust Fund.

F. Rural Hospital Impact Statement

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. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural impact statement since we have determined, and certify, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VIII. Federalism

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism and we have determined that it does not significantly affect the rights, roles, and responsibilities of States.

List of Subjects in 42 CFR Part 424

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

42 CFR chapter IV is amended 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).

2. Section 424.57 is revised as follows:

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

(a) *Definitions.* As used in this section, the following definitions apply:

DMEPOS stands for durable medical equipment, prosthetics, orthotics and supplies.

DMEPOS supplier means an entity or individual, including a physician or a Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards in paragraph (c) of this section.

Medicare covered items means medical equipment and supplies as defined in section 1834(j)(5) of the Act.

(b) *General rule.* A DMEPOS supplier must meet the following conditions in order to be eligible to receive payment for a Medicare-covered item:

(1) The supplier has submitted a completed application to HCFA to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)

(2) The item was furnished on or after the date HCFA issued to the supplier a DMEPOS supplier number conveying billing privileges. (HCFA issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.

(3) HCFA has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.

(4) A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)

(5) The supplier has furnished to HCFA all information or documentation required to process the claim.

(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. The supplier:

(1) Operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;

(2) Has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to HCFA any changes in information supplied on the application within 30 days of the change.);

(3) Must have the application for billing privileges signed by an individual whose signature binds a supplier;

(4) Fills orders, frabicates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;

(5) Advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in § 414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);

(6) Honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all purchased and rented items, including capped rental items, as described in § 414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices;

(7) Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a

physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location;

(8) Permits HCFA, 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 reasonable business hours to beneficiaries and to HCFA, and must maintain a visible sign and posted hours of operation;

(9) Maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation;

(10) 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;

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

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

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

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

(12) 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);

(13) Must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) Must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) Must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) Must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) Must comply with the disclosure provisions in § 420.206 of this subchapter;

(18) Must not convey or reassign a supplier number;

(19) Must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to HCFA, upon request.);

(20) Must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) The name, address, telephone number, and health insurance claim number of the beneficiary.

(ii) A summary of the complaint; the date it was received; the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(iii) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) Provides to HCFA, upon request, any information required by the Medicare statute and implementing regulations.

(d) *Failure to meet standards.* HCFA will revoke 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.)

(e) *Renewal of billing privileges.* A supplier must renew its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last renewal of privileges.)

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

Dated: December 15, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing, Administration.

Approved: March 29, 2000.

Donna E. Shalala,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register September 29, 2000.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00–2205, MM Docket No. 00–76; RM–9809]

Digital Television Broadcast Services; Urbana, IL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of The University of Illinois Board of Trustees, licensee of noncommercial education Station WILL–TV, substitutes DTV Channel *9 for DTV Channel *33 at Urbana, Illinois. *See* 65 FR 30599, May 12, 2000. DTV Channel *9 can be allotted to Urbana at coordinates (40–02–18 N. and 88–40–10W.) with a power of 30, HAAT of 302 meters, and a DTV service population of 1005 thousand. With this action, this proceeding is terminated.

DATES: Effective November 16, 2000.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 00–76, adopted September 29, 2000, and released October 2, 2000. The full text of this Commission decision is available