information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by us under section 1856(d)(2).

Once a prospective Medicare+Choice contractor submits documentation that one or more of the above conditions has been met, we have 60 days to grant or deny the waiver application. A separate application for PSOs seeking a waiver from State licensure will be available on or about February 15, 1998, on our Internet web site or from HPPAG at the address given above. This application will include the waiver forms as well as the contract application and all definitions. In addition, solvency standards for PSOs seeking a waiver will be available on April 1, 1998. PSOs requesting a waiver that submitted an application prior to April 1 will be required to submit a supplemental application showing how they meet the solvency standards. However, persons are not required to comply with the information collection requirements associated with the PSO application until OMB, PRA emergency approval has been obtained.

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

Information Campaign

To assist Medicare beneficiaries' decision-making process relative to new Medicare+Choice health care options, we will incorporate information on newly-approved plans into our plan comparison database. This database will contain information on all existing and new plans, except for MSAs. Plan comparison information will be posted on the Internet and will be updated at least quarterly. Thus, newly-approved plans will be entered into the plan comparison database at the next update cycle.

February 4, 1998 Public Meeting

In addition to seeking written comments from the public, we will hold a public meeting on Wednesday, February 4, 1998 from 9 a.m. to 3 p.m. in our auditorium at 7500 Security Boulevard, Baltimore, Maryland. The purpose of this meeting will be to discuss issues and concerns from plans, providers, beneficiaries, and other interested parties on the requirements and implementation of the Medicare+Choice program. The agenda for this meeting will be posted on our Internet web site. Further information can be obtained from Rondalyn Kane at (202) 690–7874.

(Secs. 1851 through 1857, 1859, 1876, and 1877 of the Social Security Act (Secs. 4001, 4002, and 4006 of Pub.L. 105–33, 42 U.S.C. 1395*l* and 1395mm))

Dated: December 23, 1997.

Nancy-Ann Min DeParle,

Adminstrator, Health Care Financing Administration.

[FR Doc. 98–1381 Filed 1–16–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[HCFA–1864–P]

RIN 0938–AH19

Medicare Program; Additional Supplier Standards

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish additional standards for an entity to qualify as a Medicare supplier for purposes of submitting claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This proposed rule would establish additional standards that must be satisfied before a DMEPOS supplier could receive payment from the Medicare program. The Social Security Act Amendments of 1994 require that a DMEPOS supplier meet standards related to compliance with State and Federal licensure requirements, maintaining a physical facility on an appropriate site, proof of appropriate liability insurance, and other standards the Secretary may specify.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 23, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1864–P, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,
or
Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1864–P. 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 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890). Electronically submitted comments will also be available for public inspection at the Independence Avenue address.

FOR FURTHER INFORMATION CONTACT: Larry Bonander, (410) 786–4479.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare services are furnished by two types of entities, that is, providers and suppliers. The term ''provider'', as defined in our regulations at § 400.202, means a hospital, a rural primary care 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 a similar agreement 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)).

In general, a supplier is an individual or entity that furnishes certain types of medical and other health services under Medicare Part B. There are different definitions of the term ''supplier'' and specific regulations governing different types of suppliers. A supplier that furnishes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is one category of supplier. Other categories of suppliers could include, for example, physicians, nurse practitioners, and physical therapists. 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.

For purposes of DMEPOS supplier standards, the term ''supplier'' is currently defined in § 424.57(a) of our regulations as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items to Medicare beneficiaries, and that meets certain standards. We are retaining this

definition for purposes of identifying those entities that must meet DMEPOS supplier standards in order to obtain a supplier number. Those individuals or entities that do not furnish DMEPOS items but only furnish other types of health care services, such as physicians' services or nurse practitioner services, would not be subject to these standards. Moreover, a supplier number is not necessary before Medicare payment can be made with respect to medical equipment and supplies furnished ''incident to'' a physician's service.

Durable Medical Equipment

Durable medical equipment (DME) is included in the definition of ''medical and other health services'' as indicated by section 1861(s)(6) of the Act. The term 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.) The term is also defined in § 414.202 of our regulations as meaning ''equipment, furnished by a supplier or a home health agency that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home.'' Examples of DME include such items as blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems, and wheelchairs.

Prosthetic Devices

Prosthetic devices are also included in the definition of ''medical and other health services'' under section 1861(s)(8) of the Act. They 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.

Orthotics and Prosthetics

Section 1861(s)(9) of the Act provides for the coverage of ''leg, arm, back, and neck braces, and artificial legs, arms, and eyes * * *'' under the term ''medical and other health services.'' As indicated by section 1834(h)(4)(C) of the Act, these items are often referred to as ''orthotics and prosthetics.''

Supplies

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

(1) 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.

(2) 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.

(3) 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.

(4) Oral drugs prescribed for use as an anticancer therapeutic agent as noted at section 1861(s)(2)(Q) of the Act.

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

II. Publication of Final Rule With Comment Period

On December 11, 1995, we published a final rule with comment period in the **Federal Register** (60 FR 63440) to reflect the changes made to section 1834 of the Act by section 131 of the Social Security Act Amendments of 1994 (SSA '94, Public Law 103–432, enacted on October 31, 1994). In the SSA '94, a new subsection (j) was added to section 1834 of the Act that established additional requirements that a DMEPOS supplier must meet in order to obtain a supplier number. The final rule set forth additional supplier standards consistent with the new subsection by revising § 424.57(c) of our regulations.

The standards in the final rule included all of the standards that were in the prior § 424.57(c) and those standards specifically required by section 1834(j)(1)(B)(ii)(I) through (III) of the Act. The standards specifically identified in section 1834(j)(1)(B)(ii) require that a DME supplier—

(1) Comply with all applicable State and Federal licensure and regulatory requirements;

(2) Maintain a physical facility on an appropriate site; and

(3) Have proof of appropriate liability insurance. Congress also has expressly delegated authority to the Secretary to specify other requirements through section 1834(j)(1)(B)(ii)(IV) of the Act.

In SSA '94, the Congress enacted numerous substantive provisions designed to protect beneficiaries from abusive practices by suppliers. These legislative changes indicate that the Congress has serious concerns about the business practices employed by certain suppliers, and that beneficiaries require additional protection from these practices. We believe it is the Congress' intent to strengthen existing standards in order to protect the public interest. We also view this proposed rule as another tool to further our efforts to prevent fraud and abuse in the Medicare program. After consulting with representatives of medical equipment and supply companies, carriers, and consumers, we are now proposing to establish additional standards to protect beneficiaries. These standards would not apply to physicians or other practitioners that are only submitting claims for coverage of items that are furnished as incident to their professional services. However, in order to submit claims for items that are not covered under the incident to benefit, physicians must obtain a supplier number and meet supplier standards.

III. Proposed Revisions

Medicare will not pay for any items furnished by a DMEPOS supplier prior to the date a supplier number is issued. In order to obtain a supplier number, a supplier must complete an application certifying that it meets the supplier standards found in § 424.57 of our proposed regulation. In addition, when renewing an application for a DMEPOS supplier billing number, a supplier must recertify that it meets all of the supplier standards.

Under current regulations, a DMEPOS supplier must renew its application for a billing number 3 years after the billing numbers are first issued, except for the first reissuance process. For the first reissuance process, one-third of suppliers must renew their applications 2 years after initial issuance of billing numbers. Another one-third of suppliers must reapply 3 years after initial issuance. The last third of suppliers must reapply 4 years after initial issuance. Thereafter, a supplier must reapply 3 years after its last number is issued.

We do not intend to 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. We believe this to be the least burdensome approach for a supplier, as well as the most cost-effective approach, to obtain the required information. However, in certain circumstances (such as an investigation regarding compliance with standards) a supplier may be required to demonstrate compliance with all standards prior to the supplier's billing number expiration date. Although we do not intend to require suppliers with current numbers to certify compliance with these revised standards until they reapply, it is important to note that as of the effective date of this regulation, all DMEPOS suppliers must comply with these standards. We may revoke a supplier number if we find evidence that the standards are not satisfied.

A. Specific Requirements for Supplier Standards

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

In addition to the specific standards cited in this proposed rule, there are other Medicare statutory provisions that establish requirements pertaining to the activities of DMEPOS suppliers. For example, section 1848(g) of the Act establishes requirements regarding the completion and submission of Medicare claims by certain entities, including DMEPOS suppliers. To be consistent and to support and reinforce the implementation of the other provisions of the Act and regulations that pertain to DMEPOS suppliers, we are proposing adding this new standard. This standard would require a DMEPOS supplier to comply with Medicare statutory provisions, as well as all other applicable regulations.

Compliance with Applicable Federal and State Licensure and Regulatory Requirements (§ 424.57(c)(2))

We propose amending § 424.57(c)(9) of current regulations to require a DMEPOS supplier to operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements. If a DMEPOS supplier is found to be out of compliance with any Federal or State licensure or regulatory requirement by the appropriate enforcement agency for that requirement, we may revoke that supplier's number. We will focus on whether the violation negatively affects a supplier's ability to furnish DMEPOS supplies in a manner that protects beneficiaries and the Medicare program. When a supplier is actually found out of compliance, and is cited by the appropriate enforcement agency for a violation, we would determine whether that violation should be deemed indicative of a failure to meet this standard.

Clearly, it is not in the interest of beneficiaries for us to revoke a supplier number for reasons that are unrelated to a DMEPOS supplier's ability to furnish Medicare covered items. For example, and by way of illustration only, it would not ordinarily seem necessary to consider as a violation of this standard necessitating revocation, situations where a supplier is involved in a zoning dispute or has built a fence three feet over the property line. However, when the supplier's violation of applicable Federal or State licensure or regulatory requirements affects the health and safety of Medicare beneficiaries, we would determine that this standard has not been met.

Misrepresentation of Facts (§ 424.57(c)(3))

As stated, a DMEPOS supplier's certification that the standards are met must be completed before a supplier number will be issued. A government contractor verifies the data in the supplier number application and issues numbers to approved DMEPOS suppliers. When a supplier submits an inaccurate or incomplete application, it impedes the ability of the contractor to determine, with reasonable confidence, that a supplier meets and will comply with the DMEPOS supplier standards.

We propose amending the regulations to clarify that a DMEPOS supplier is responsible for accurately completing the application for a supplier number. Any deliberate misrepresentation or concealment of material information in the application constitutes a violation of this supplier standard and may subject a supplier to liability under civil and criminal laws. Also, since the government, through its contractor, issues a supplier number based upon, and after verification of, the information contained in the application, a DMEPOS supplier must notify us within 35 days of any change in the data provided on the supplier number application.

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

When a DMEPOS supplier signs the application for a supplier number, it certifies that all information provided on the application is accurate and that the supplier meets the standards set forth in § 424.57(c). These standards affect how the supplier does business. This proposed standard would require that the individual signing the application understand his or her responsibility for confirming the accuracy of all of the statements in the application and have the authority to certify that the supplier will comply with these standards. The person who signs the application must have the authority to bind the business entity. This standard would help ensure the accuracy of the information on the supplier number application and will help ensure that the DMEPOS supplier is committed to taking the necessary steps to comply with these standards.

Providing Requested Information and Documentation (§ 424.57(c)(5))

We propose adding a standard that specifically requires a DMEPOS supplier to agree to provide us with pertinent information and documentation. As a basic condition for payment, a supplier must furnish sufficient information and documentation for us to make a correct payment determination. We are responsible for ensuring that all claims are medically and reasonably necessary, that all services are rendered as billed, and that all claims are billed in accordance with local, regional and national policies.

Upon request, a supplier must also provide a copy of any contract it has with another company to furnish DMEPOS items or supplies. A DMEPOS supplier also must provide, upon request, documentation substantiating that it has advised beneficiaries about their option to rent or purchase inexpensive or routinely purchased equipment, and also about the purchase option for capped rental equipment. It is important that beneficiaries understand that the overall Medicare payments for renting inexpensive or routinely purchased DME may not exceed the Medicare fee schedule amount for that item.

A DMEPOS supplier must provide, upon request, documentation substantiating that it has explained to beneficiaries the warranty coverage for supplies and equipment. We believe that explaining to beneficiaries the warranty coverage for a particular item will prevent the Medicare program from being billed for repairs to supplies or equipment covered under warranty. A supplier must provide, upon request, documentation that it maintains and repairs directly, or through a service contract with another company, items it has rented to beneficiaries. This would ensure that beneficiaries are aware that any services needed for rented items will be provided by the supplier of the items.

A supplier also must provide, upon request, documentation demonstrating that it has delivered Medicare covered items to beneficiaries. A supplier must provide, upon request, proof of appropriate liability insurance protecting retail customers against accidents or negligence in the sale or rental of medical equipment or supplies.

Scope of Exclusions (§ 424.57(c)(6) and (d))

We propose amending § 424.57(c)(1) and (d) of the current regulations to be consistent with the Office of Inspector General (OIG) regulations on program integrity for the Medicare and State Health Care programs at § 1001.1901. The OIG program exclusion regulations were amended effective August 25, 1995, in accordance with the Federal Acquisition Streamlining Act of 1994 (Pub. L. 103–355), and with the Department's Common Rule at 45 FR Part 76, to explain the scope and effect of an OIG exclusion. The OIG regulations now provide that an OIG exclusion will be recognized and given effect not only for all departmental programs but also for all Executive Branch procurement and nonprocurement activities. Therefore, consistent with the OIG regulations, these regulations would require that a DMEPOS supplier must agree not to contract with entities subject to an OIG exclusion for the purchase of items necessary to fill their orders. These proposed regulations also would provide that if a DMEPOS supplier is subject to an OIG exclusion, we will revoke its supplier number automatically, effective with the date of the exclusion.

Rental or Purchase Option (§ 424.57(c)(7))

A DMEPOS supplier must advise beneficiaries of their option to rent or purchase inexpensive or routinely purchased equipment. A DMEPOS supplier also must advise the beneficiary of the purchase option for capped rental equipment. Currently, the decision as to whether inexpensive or routinely purchased equipment should be rented or purchased is made by the beneficiary. Because of the coinsurance implications involved, it is important that beneficiaries understand that the overall Medicare payments for renting such DME may not exceed the Medicare fee schedule amount for that item. If the beneficiary needs an item after Medicare has made its last rental payment, the beneficiary becomes financially liable for any additional payment. Therefore, if a beneficiary anticipates needing an item of inexpensive or routinely purchased DME for an extended period of time, purchasing that item may result in a savings for the beneficiary. This information must be provided in an easily understood and clear manner and should include an explanation of the implications of the rental or purchase choice.

Warranties (§ 424.57(c)(8))

Our current regulations provide that a supplier must honor all expressed and implied warranties. However, in some instances, a supplier does not fully explain warranty coverage to beneficiaries and the Medicare program is billed for repairs to supplies or equipment covered under warranty. We propose to amend § 424.57(c)(3) of our current regulations to require that a DMEPOS supplier check with manufacturers to determine the extent of a warranty for an item they are supplying. A DMEPOS supplier is prohibited from billing either beneficiaries or the Medicare program for repairs, parts, or other equipment or supplies covered either by an expressed warranty or an implied warranty. Items that are furnished to the beneficiary, whether purchased or rented, must include copies of warranty information.

Delivery (§ 424.57(c)(9))

Under our current regulations at § 424.57(c)(2), a supplier is responsible for the delivery of Medicare covered items to beneficiaries. Consistent with the goal of protecting beneficiaries, we propose expanding this standard to require a DMEPOS supplier, at the time of delivery, to provide beneficiaries with necessary information and instructions on how to use Medicare covered items safely and effectively. In addition, we anticipate that beneficiaries may have questions subsequent to delivery and should have telephonic access to the supplier to receive additional instructions, as necessary. Telephonic access is addressed in proposed supplier standard § 424.57(c)(17).

Reassignment of Supplier Numbers (§ 424.57(c)(15))

This proposed standard would prohibit a DMEPOS supplier from conveying or reassigning a supplier number. We have the authority, through our authorized agents, to issue DMEPOS supplier billing numbers. These numbers are issued only after we have verified pertinent information about a supplier and have otherwise taken measures intended to protect the Medicare program, as well as beneficiaries. The supplier billing numbers are issued for the use of a specific supplier. A DMEPOS supplier does not have independent authority to transfer or convey the billing number we issue. All DMEPOS suppliers must undergo our application process in order to obtain a supplier number.

Physical Facility (§ 424.57(c)(16) and (f))

We propose amending § 424.57(c)(10) and (f) of our current regulations to require a DMEPOS supplier to have a physical facility where it can conduct its business operations. The physical facility must be a site where a supplier's delivery, maintenance, and beneficiary communication records can be properly stored and mail can be delivered. In addition, all written complaints and related correspondence taken in response to a beneficiary complaint must be kept at the physical facility.

Using these minimal requirements for a physical facility, there should be no burden on a legitimate supplier. Section 1834(j) of the Act was amended to ensure beneficiary protection. We believe protection of the beneficiary includes requiring a supplier to conduct business at a physical facility that is beneficiary accessible. In the past, a supplier was not required to conduct business at a fixed physical location. We found evidence of vans, as well as station wagons, being claimed as supplier business locations. A supplier using these types of ''establishments'' for business are not easily accessible to the beneficiary or HCFA if there is a problem with the supply or equipment, a repair is needed, or the beneficiary has a question. Requiring that a supplier operate out of a fixed physical facility will help protect beneficiaries, as well as aid in eliminating fraudulent suppliers.

Business Telephone (§ 424.57(c)(17))

In order to accept inquiries from potential customers, maintain relationships with current customers, and conduct business with contractors in today's business markets, virtually every business must allow access by telephone. Telephonic access to a DMEPOS supplier is crucial also to the Durable Medical Equipment Regional Carrier in obtaining additional information to process and pay a claim.

In this proposed rule, a DMEPOS supplier must have a business telephone located at the physical facility. This telephone number must be listed under the name of the business (i.e., name of supplier company) and listed in the business portion of the local telephone company directory. A beeper number, answering machine, answering service, pager, facsimile machine, car phone or residential listing would not adequately

provide telephonic access equivalent to a primary business telephone and, therefore, would not fulfill this requirement. Requiring a business telephone at the physical facility would help ensure that a supplier is a valid business company that is soliciting and conducting business at the physical facility. This requirement would also help filter out those companies that do not have a physical site and may be conducting business out of mobile vans, making it difficult for beneficiaries and the general public to determine the legitimacy of the business, resolve questions, obtain demonstrations of a DMEPOS item and resolve any maintenance or repair concerns.

Liability Insurance (§ 424.57(c)(18))

The December 11, 1995, final rule with comment implementing the changes made by section 1834(j) of the Act, added a standard requiring suppliers to have proof of appropriate liability insurance. One member of the DME industry commented on this standard and suggested certain insurance requirements and limitations. In addition, we consulted with an insurance industry trade group with expertise in liability insurance. Based on the comment received and our consultation, we propose requiring that a supplier 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.

While this proposal would only require comprehensive liability insurance, our concern for beneficiary safety is such that we feel we should specify in the final rule a dollar amount for this coverage. We believe that coverage in the amount of $500,000 would be adequate for most businesses. According to industry sources, there are no State requirements concerning either mandatory liability insurance or the recommended level of protection. However, we believe that most suppliers follow common business practices and obtain adequate insurance in order to limit their financial exposure. We invite the public to comment on the need for and the extent to which suppliers maintain liability insurance and the appropriate coverage level for that insurance.

Telemarketing (§ 424.57(c)(19))

This proposed standard reiterates restrictions found at sections 1834(a)(17)(A) and 1834(h)(3) of the Act that bar a supplier from violating existing telemarketing rules.

Prescription Drugs (§ 424.57(c)(20))

This proposed standard would protect the health and safety of our beneficiaries by ensuring that only those DMEPOS suppliers that are licensed to dispense drugs may furnish drugs used as Medicare covered supplies with durable medical equipment (DME) or prosthetic devices. Although a supplier that furnishes oxygen may not have to be a pharmacy, it must meet applicable State licensure laws. This standard would stipulate that unless a supplier meets applicable State licensing requirements, it may not bill Medicare for prescription drugs used with DME or a prosthetic device.

This standard also would help to ensure payment is not made for prescription drugs, other than oxygen, that are prepared or dispensed by companies not properly licensed and not regulated or monitored by a State's pharmacy board. In addition, this standard would support Medicare's policy of not paying for prescription drugs used with DME or a prosthetic device unless the drugs are furnished by an entity that is licensed to dispense these drug products.

B. Additional Revisions

Section 4312(a) of the Balanced Budget Act of 1997 (BBA '97), Pub. L. 105–33, which was enacted on August 5, 1997, amended section 1834(a) of the Social Security Act by adding a new paragraph (16). That new paragraph requires the Secretary, as a condition of providing for the issuance or renewal of a provider number for a DME supplier for purposes of payment under the Medicare statute, to provide the Secretary, on a continuing basis, with a surety bond. Section 1834(a)(16), as amended by section 4312(c) of the BBA '97, further provides that the Secretary may, at the Secretary's discretion, impose a surety bond on some or all providers or suppliers who furnish items or services under Medicare Part B other than physicians or other practitioners. We request 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.

We are adding a new paragraph (e) to stipulate that for every tax identification number for which a supplier billing number is issued, a DMEPOS supplier must obtain a surety bond. The surety bond must be in a form specified by the Secretary and in an amount not less than $50,000.

Although we are authorized to waive the surety bond requirement if a DMEPOS supplier provides a comparable surety bond under State law, we have not implemented that waiver authority in this rule. The limited amount of time available to us, between the enactment of BBA '97 and the effective date of the surety bond requirement, did not permit us sufficient time to effectively analyze the potential specifications of a waiver provision. However, we are mindful that some States may already have, or may be considering implementing, surety bond requirements that could affect DMEPOS suppliers. Moreover, section 4712 of the BBA '97 establishes a Medicaid surety bond requirement that the States will be implementing. We do not want to add unnecessary costs to DMEPOS suppliers that may be required to obtain multiple surety bonds. However, our principal concern is to safeguard the Medicare Trust Funds from the losses resulting from dramatically increasing unrecovered Medicare debts. We solicit comments on useful standards and criteria for implementing a waiver of our surety bond requirements that would, nonetheless, maintain the same or a greater level of protection of the Medicare Trust Funds than our requirements achieve.

A ''surety bond'' is a three-party written agreement under which the surety guarantees to HCFA as surety that it will be responsible for debts owed to HCFA by a DMEPOS supplier. The surety bond can only be obtained through a surety bond company that has been approved by the Department of Treasury and listed in the current edition of the Department of Treasury's Department Circular No. 570 ''Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies''.

We propose establishing a sliding scale for the penal amount of the bond that relates to the volume of business a supplier does with Medicare. The penal amount is the amount for which a surety company would be liable to HCFA. The sliding scale would be used in combination with a $50,000 minimum and a $3,000,000 ceiling. For chain organizations, these amounts would pertain to the chain as a whole. The sliding scale will be based on 15 percent of the amount paid to the supplier by the Medicare program in the previous year with a $50,000 minimum and a $3,000,000 maximum penal bond amount. Thus, the penal amount of the surety bond and the premium for the surety bond are directly tied to the

amount of Medicare payments received by the supplier. We believe that 15 percent is a reasonable percentage on which to base the penal amount of the bond since it would not be too high as to be a barrier to entry for small companies, yet high enough to provide the Medicare Trust Fund with access to funds to recover debts owed to the program. Also, in determining this percentage amount, we consulted with an insurance industry trade group.

In accordance with section 4312(a) of the BBA '97, paragraph (e) includes a $50,000 floor per supplier. Therefore, we are proposing that this $50,000 amount represent the penal amount for a supplier that has not previously participated in the Medicare program. We also propose establishing a penal amount ceiling of $3,000,000 per supplier to accommodate national companies that have several locations. The $3,000,000 ceiling would lessen the burden on national companies that have one supplier number with multiple locations.

HCFA would verify that each supplier has purchased the correct bond amount by having the National Supplier Clearinghouse access either the supplier's IRS Form No. 1099 prepared by the supplier's DMERC (DME Regional Carrier) or historic payment information from the DMERC's provider payment history file. The IRS Form No. 1099 will show the amount of Medicare revenues received by the DMEPOS supplier during the previous year. This verification would be done on an annual basis by the National Supplier Clearinghouse.

As stated, we believe that Congressional intent of section 4312 of the BBA '97 is to protect both Medicare beneficiaries and the Medicare Trust Fund. Under current law, a DMEPOS supplier only may receive payment from the Medicare program if it demonstrates that it meets the standards imposed in the Act and in regulations. Section 4312 of the BBA '97, in effect, authorizes as a supplier standard the requirement that a DMEPOS supplier provides, on a continuing basis, a surety bond of at least $50,000. We believe that Congressional intent is that a surety bond be of an adequate amount to ensure supplier performance and to prompt compliance with Medicare program rules and requirements. The amount of the surety bond must be sufficient to protect both Medicare beneficiaries and the Medicare Trust Fund by providing a mechanism for recovering debts owed to the program. (Debts to the program include overpayments, interest, and any civil money penalties and assessments.) We also believe it will decrease spurious applications for supplier numbers, and ensure that only viable companies who are financially stable obtain supplier numbers. Therefore, we believe it is necessary that the surety bond be based on a sliding scale of 15 percent of the amount paid to the supplier by the Medicare program, for claims for Medicare covered items provided in the previous year and with a floor of $50,000 and a ceiling of $3,000,000.

We also considered including within the scope of the Surety's potential liability a guarantee of payment for unpaid civil money penalties and assessments that were imposed by the Office of the Inspector General. However, because of the short time period between when the BBA '97 was enacted and the effective date of the Surety bond provision, we were unable to fully consider this option. In addition, because of our unfamiliarity with surety bonds as a component of program administration, we believed that we did not fully understand how best to implement this option. We solicit comments on the advisability of including within the scope of the Surety's potential liability unpaid Office of Inspector General-imposed civil money penalties and assessments.

Financial Rationale for the Surety Bond

We have a statutory responsibility under the Act to be a prudent purchaser of medical services. Therefore, we need to address the issue of how to reduce risk to the Medicare Trust Fund. Bonding is a method that has long been employed in the private sector to assure a satisfactory level of performance. We believe a surety bond is a cost effective method to reduce risk to the Medicare Trust Fund. This requirement would provide the Medicare program with the ability to mitigate its losses should a supplier billing number be revoked or if the company no longer conducts business with Medicare. In other words, a surety bond would provide us with the means to recover a portion of the monies due the Medicare program. A claim could be made against the surety bond should a demand letter for overpayments not be satisfied, whether due to insufficient assets by a supplier or inability to locate a supplier.

We do not have a fail-safe method of ensuring that DMEPOS items for which we have been billed actually have been supplied to a beneficiary in the quantity or the type billed. Only with the passage of time do we discover that DMEPOS items for which Medicare payments have been made were not actually supplied in the manner represented in the claim. With Medicare DMEPOS expenditures of $10.2 billion in 1995, even a small percentage of improper payments represents excessive program losses.

In calendar year 1995, as a part of our activities associated with Operation Restore Trust, we revoked the supplier billing number of approximately 1,700 Florida suppliers who were found to have billed for DMEPOS items that either were not furnished or were not furnished as billed. These supplier billings were associated with erroneous payments amounting to approximately $40 million.

Our belief is that many of these suppliers would never have sought or obtained a Medicare supplier number if, as a prerequisite, they would have been required to obtain a surety bond. Even if some of these suppliers had been able to obtain a surety bond and still received erroneous payments, the Medicare program, by making a claim against the surety bond, would have had a source to mitigate some of its losses. Based on our estimates of the scope of past fraudulent and excessive expenditures, we must take steps to prevent such practices from continuing. Surety bonds will enhance our control of Medicare Trust Fund expenditures by expanding our options for recovering payments later determined to be improper, whether due to fraud or other reasons. We are interested in any recommendations or suggestions anyone may have on this proposed standard.

In addition to the changes discussed above, we have taken this opportunity to make several clarifying and editorial changes to the existing regulations.

C. Patient Care Standards

The proposed DMEPOS supplier standards set forth business operation standards, however, they do not include standards that relate directly to patient care. By patient care, we are referring to care that goes beyond that which is directly furnished by the covered equipment, such as taking the patient's vital signs. Determinations relating to patient care would be the subject of another rulemaking.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, 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, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. 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 comment 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.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

The following sections of this document contain information collection requirements as described below:

Section 424.57(c)(3) (Supplier Enrollment Form HCFA-855) would require a supplier to provide complete and accurate information on its application for a billing number. However, the burden associated with the requirements set forth in 424.57(c)(3) and (c)(4) are currently captured in HCFA–855 (OMB Approval No. 0938–0685). Thus, there is no additional collection of information burden associated with § 424.57(c)(3) and (c)(4).

Section 424.57(c)(5) (Providing Requested Information and Documentation) would set forth several information collection requirements, as referenced below, which we believe are exempt under the terms of the PRA for the following reasons:

(1) Under 5 CFR 1320.4(a)(2), information collections are exempt during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities;

(2) As described in 5 CFR 1320.3(h)(9), facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections, are exempt from the PRA; and/or

(3) Nonstandardized information collections directed to less then 10 persons, does not constitute an information collection as outlined in 5 CFR 1320.3(c).

The following information collection requirements arise as a result of requiring DMEPOS suppliers to submit all supplemental information or documentation necessary to adjudicate claims. A DMEPOS supplier bears the burden of providing records and information sufficient to support the determination of appropriate Medicare payment. Since we believe that the following collection requirements are either part of the administrative, audit and/or adjudicatory process, collected in a nonstandardized manner, and/or collected from less then ten persons, they fall under these exceptions. We explicitly solicit comment on this PRA determination. The excepted sections are:

—Section 424.57(c)(5)(i)—Adjudication of Claims

—Section 424.57(c)(5)(viii)—Supplemental Documentation

Under 5 CFR 1320.3(b)(2), the burden associated with the time, effort and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of business will be excluded from an information collection. The burden in connection with such types of collection activities can be disregarded if it can be demonstrated that such collection activities are usual and customary. Each of the collection requirements referenced below are of the type that are usual and customary in the conduct of commercial business. Thus, we believe they fall under this exception and solicit comment on this determination:

—Section 424.57(c)(5)(ii)—Contracts with Third Parties

—Section 424.57(c)(5)(v)—Delivery Documentation

—Section 424.57(c)(5)(vi)—Maintenance documentation

—Section 424.57(c)(5)(vii)—Proof of Liability Insurance

—Section 424.57(c)(5)(viii)—Supplemental Documentation.

The information collection requirements and associated burden as summarized below are subject to the PRA:

—Section 424.57(c)(5)(iii) would require a supplier to develop, disclose to beneficiaries, and maintain an attestation document demonstrating that beneficiaries have been advised about their option to rent or purchase inexpensive or routinely purchased equipment and of the purchase option for capped rental equipment. We believe that during the normal course of business the vast majority of suppliers currently advise their beneficiaries of their rental and purchase options. Therefore, the burden associated with this provision is the one-time burden on the provider to create an attestation form and the recordkeeping requirement on the supplier to retain a copy of the beneficiary attestation in their files. We believe that most suppliers would create and maintain a form to suit their specific business needs that a beneficiary would sign to attest that the beneficiary was advised of the rent or purchase option described above (Refer to § 424.57(c)(7)).

—Section 424.57(c)(5)(iv) would require a supplier to maintain documentation demonstrating that beneficiaries have been adequately informed about items covered under warranty. We do not prescribe a specific format and rely on the supplier to develop some mechanism to note that it has advised a beneficiary about warranty coverage. (Refer to § 424.57(c)(8)). We anticipate that suppliers will simultaneously advise beneficiaries of their purchase/rental equipment options and warranty disclosure, and capture the required acknowledgments for both § 424.57(c)(5)(iii) and 424.57(c)(5)(iv) in one form. Thus, the burden associated with § 424.57 paragraph (c)(5)(iv) is reflected in the burden calculations for paragraph (c)(5)(iii). The chart below summarizes the estimated annual reporting and recordkeeping burden for the attestation requirements and the additional requirements referenced below.

—Section 424.57(e) would require when current suppliers apply for renewal of their supplier billing number that they submit a copy of their current surety bond and, as appropriate, copies of previous surety bonds that have been obtained annually for the appropriate amount, thus demonstrating that their surety bond has been in effect. New suppliers must submit a copy of their surety bond at the time of initial application in order to have it approved. The only burden we are imposing would be the amount of time it takes to mail a copy of the surety bond concurrent with the initial submission or renewal of a provider's application (form HCFA–855).

As a note, the provider/supplier enrollment forms HCFA–855, HCFA–855C, HCFA–855R, and HCFA–855S and related instructions, which are currently approved under OMB Approval No. 0938–0685, are in process

of being revised. In particular, an emergency clearance of these information collection requirements was requested by HCFA. A notice was published in the **Federal Register** on December 18, 1997, requesting that OMB approve the revised collection by December 31, 1997. In that notice the public was given from the date of the notice's publication, until December 29, 1997 to comment on the proposed collection. It should be noted that the emergency clearance sought by HCFA would have a maximum approval period of 6 months from the date of OMB approval.

The table below indicates the annual number of responses for each regulation section in this proposed rule containing information collection requirements, the average burden per response in minutes or hours, and the total annual burden hours.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR sections	Annual Number of responses	Annual frequency	Average burden per response (minutes)	Annual burden hours
424.57(c)(5)(iii) and(iv)	68,000	50	5	283,333
424.57(e)	68,000/3=22,667	1	1	378
Total hours				283,711

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in § 424.57 (c) and (e). These requirements are not effective until they have been approved by OMB.

If you comment on any of 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, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. ATTN: John Burke HCFA–1864–P

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

VI. Regulatory Impact Analysis

We have examined the impacts of this proposed 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 the following:

- Surety bond requirement (§ 424.57(e)). Approximately $57 million annually. See Table 3 in this section for computations.
- Liability insurance requirement (§ 424.57(c)(18)). We estimate that only 10 percent of DMEPOS suppliers do not already have liability insurance that meets this requirement. Ten percent of the total DMEPOS suppliers is approximately 6,800 suppliers. Multiplying 6,800 by $250 results in an approximate additional liability insurance cost of $1.7 million annually to the DMEPOS industry due to this rule.
- Primary business telephone at a physical facility requirement (§ 424.57(c)(17)). We estimate that only 1% of DMEPOS suppliers do not already meet this requirement. Therefore, 680 times the approximate $600 annual cost of telephone service results in an additional cost of $410,000 annually.

Total Cost = $57 Million + $1.7 Million + $410,000 = $59,110,000 annually.

The Unfunded Mandates Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. The proposed rule has no consequential effect on State, local, or tribal governments. We believe that the private sector costs of this rule fall below these thresholds but nonetheless, due to uncertainties of these estimates, have prepared this RIA providing such an assessment.

Consistent with the Regulatory Flexibility Act, we prepare a Regulatory Flexibility Analysis (RFA) unless we certify that a rule would 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 proposed 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 proposed standards would help bar fraudulent suppliers from participating in the Medicare program, or in the event that a supplier should provide excessive supplies or defraud the Medicare program, we will be assured of recovering a portion of those funds. Therefore, we expect to have a significant impact on an unknown number of persons and entities who will effectively be prevented from repeating their aberrant billing activities. The vast majority of suppliers will not be significantly affected by this rule. The significant reduction in program overpayments that we expect to achieve as a result of this rule justifies the relatively small burden the rule would impose on all entities.

The following analysis, together with the rest of this preamble, explains the rationale for and purposes of the rule, details the 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 recover improper payments.

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 set out from the beginning to establish a business furnishing DMEPOS items. Others evolve into being suppliers. For example, a firm dealing with 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 the 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. As indicated by Table 1, which examines reimbursements to unique billing numbers (a supplier may have multiple locations, e.g., a chain organization, but use only one unique billing number), 97 percent of all DMEPOS suppliers generate billings of less than $350,000 in Medicare revenues annually.

TABLE 1.—TOTAL NUMBER OF SUPPLIERS ARRANGED BY REIMBURSEMENTS

[Dates of Service—January to December 1995]

Dollars reimbursed	Unique billing Nos.
>$3,000,000	102
$1,000,000–2,999,999	430
$500,001–999,999	933
$350,000–499,999	740
<$350,000	66,106
Total	68,311

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 2, suppliers locate in areas where there is greatest demand, leaving other areas to be served by catalogue, mail order or drop shipments. No States appear to be underserved, 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 2

State	Number of suppliers per state	Number of beneficiaries using DME per state	Beneficiary per supplier
AK	206	3300	16
AL	2111	63700	30
AR	1450	59300	40
AZ	2051	59300	28
CA	13028	361000	27
CO	2055	41800	20
CT	2095	50000	23
DC	241	7800	32
DE	371	10000	26
FL	10137	259700	25
GA	3710	82600	22
HI	427	14800	32
IA	2236	47300	21
ID	829	14900	17
IL	5524	161000	29
IN	4152	81900	19
KS	1752	38100	21
KY	2427	58200	23
LA	2254	57700	25
MA	2981	92800	31
MD	2384	59700	24
ME	856	20100	23
MI	4319	134000	21
MN	2513	62800	24
MO	3076	82800	26
MS	1312	39400	30
MT	792	12900	16
NC	4134	101800	24
ND	500	10300	20

TABLE 2—Continued

State	Number of suppliers per state	Number of beneficiaries using DME per state	Beneficiary per supplier
NE	1390	24800	17
NH	669	15500	23
NJ	4447	116200	26
NM	669	20900	31
NV	664	19000	28
NY	7720	262300	33
OH	6675	165700	24
OK	2062	48400	23
OR	1828	46500	25
PA	7610	206000	27
RI	651	16700	25
SC	2041	50400	25
SD	639	11600	18
TN	2762	206200	27
TX	8219	206200	25
UT	829	18600	22
VA	3225	81100	25
VT	355	8200	23
WA	3355	68200	20
WI	2922	75700	26
WV	1134	32800	28
WY	373	6000	16
Total	140,162		

We note that the purpose of Table 2 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 there are more than 140,000 individual suppliers, due to the affiliation of some suppliers with chains, as of December 1995, there were only 68,311 unique billing numbers. Hence, Tables 1 and 3, which describe Medicare payments to 68,311 billing numbers, and Table 2, which describes the more than 140,000 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 1995, submitted charges for DMEPOS items were $10.2 billion. 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, of themselves, 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 Congress' intent to strengthen DMEPOS supplier standards to protect beneficiaries and the Medicare program from potential fraud and abuse in billing practices. Therefore, we did not choose the alternative of staying with the existing supplier standards which we believe are minimal safeguards. Instead of relying on minimal supplier standards, we have expanded the supplier standards, using as our statutory basis either the specific section of the law referenced in this discussion (for example, section 4312 of the BBA'97), or 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 proposed rule would 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 proposed supplier standards into the following two broad categories: statutory requirements and good business practices.

E. Statutory Requirements

Liability Insurance—The statutory authority for § 424.57(c)(18) is section 1834(j)(1)(B)(ii)(III) of the Act. The proposed rule would require a supplier to have comprehensive liability insurance protecting the supplier's place of business and any and all retail customers and employees. We have not specified a minimum amount in this proposed rule, but, as explained elsewhere, suggest a minimum of $500,000 in coverage. We estimate that approximately 10 percent of all suppliers do not currently carry liability insurance. We estimate the cost per year for a supplier to carry liability insurance in the amount of $500,000 would be approximately $250. We believe that the $250 cost per supplier does not represent a significant economic impact on the estimated 10 percent of suppliers not currently carrying liability insurance.

In order to provide the greatest safeguards to Medicare beneficiaries, we considered imposing liability insurance that included: (1) Coverage for damages resulting from the failure of a Medicare covered item to perform as expected that are not otherwise fully covered by the manufacturer's warranty; (2) coverage for liability arising in connection with the rental, sale, delivery, installation and retrieval of the Medicare covered items, including customized items; (3) coverage for damages that arise from premises operations, such as, for example, those arising out of showroom operations or equipment demonstrations; and (4) coverage for damages that arise from

personal injury and from breaches of customer privacy or confidentiality. While the above provisions would provide significant liability protection for beneficiaries, we believe that for two of the provisions, coverage for damages that are not covered by the manufacturer's warranty and coverage for damages that arise from breaches of customer privacy or confidentiality, coverage is not generally available from the insurance industry. Furthermore, we believe that the above provisions, taken as a whole, would be much more costly and rigid requirements than the alternative selected, and would impose an unnecessary burden on suppliers.

Thus, we have chosen an alternative that we believe is cost effective and will ensure that suppliers have appropriate liability insurance. Nonetheless, we request comments on whether there are alternative insurance coverage standards that would strengthen protections in a cost effective manner and information about the cost and availability of such coverage.

F. Good Business Practices

Most of our proposed supplier standards speak directly to business practices. We do not believe that these would result in a significant impact on any sizeable number of legitimate suppliers. For these additional proposed standards, the economic impact on most suppliers is negligible, although the benefits to the program and to the beneficiary may be greater. For example, the requirement at § 424.57(c)(8) 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 at § 424.57(c)(5)(iv) 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 the program. The monies paid out by the program and the beneficiary may also 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 proposed 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. Because, we consider these basic requirements that a business would have to meet to provide satisfactory customer service and to manage properly its inventory we did not develop alternatives.

Under § 424.57(c)(17), a supplier would be required to maintain a separate phone that is used primarily for business purposes at its physical facility. 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 to have access to their supplier in case they have a problem with or questions about their DMEPOS items.

We believe that this standard would be 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 separate phone 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 would far exceed any minor economic impact on a supplier. In addition, we note that requiring the supplier to have a primary business telephone listed in the business portion of the local telephone directory and maintained at the physical location of the supplier business may even result in increased business for a supplier.

This proposed requirement would help beneficiaries to contact their suppliers in the event of equipment problems, failures, and to resolve questions. Telephonic access to a supplier is crucial so that the Durable Medical Equipment Regional Carriers may call and obtain additional information to process and pay claims. We are aware that telephone technology is rapidly changing. We had considered putting limitations on the use of mobile telephones, which have been associated with abusive practices. However, we concluded that additional limitations might penalize legitimate suppliers, or might not be responsive to technological change. We specifically solicit comments on whether there are alternative ways to establish telephone requirements that minimize potential abusive practices while not raising costs for legitimate small businesses.

G. Protection of the Trust Fund and Beneficiary

While each of these proposed supplier standards is designed to protect the Medicare trust fund and beneficiaries, one standard warrants separate discussion. In accordance with section 4312 of the BBA '97, a surety bond will be required as long as an entity remains a DMEPOS supplier. Under § 424.57(e), a supplier would be required to obtain a surety bond equal to at least 15 percent of the amount paid to the supplier by the Medicare program for the previous year as reflected in their IRS Form No. 1099, or by the historic payment information from the DMERC provider payment history file. We propose establishing a sliding scale that reflects the volume of business a supplier does with Medicare. The sliding scale would be used in combination with a $50,000 floor and a $3,000,000 ceiling. By using a sliding scale, based on 15 percent of the amount paid to the supplier by the Medicare program for the previous year, the penal amount of the surety bond and the premium for the surety bond are directly tied to the amount of Medicare payments received by the supplier. We believe that 15 percent is a reasonable percentage on which to base the penal amount of the bond since it would not be too high as to be a barrier to entry for small companies, yet high enough to provide the Medicare Trust Fund with some recourse for compensation for debts owed to the program. We are interested in comments about the reasonableness of the percent amount and the proposed floor and ceiling.

A surety company charges its underwriting fee based on the penal amount of the bond. For this type of surety bond, the industry usually has an underwriting charge of 1 to 2 percent. Based on this information Table 3 indicates the costs of a surety bond based on the supplier's annual Medicare revenue assuming that bonds cost 1.5 percent of the protected amount. This table also shows that the total costs of bonds is likely to be about $57 million and that on average the cost of bonds will be about one-half of one percent of gross sales (somewhat less for larger suppliers) for the smallest suppliers who make up the overwhelming majority of all suppliers. We request comment on the accuracy of these estimates.

TABLE 3.—COST OF PROGRAM-UNIVERSAL BONDING WITHOUT TIME LIMIT

Range of sales (1000s)	Bond cost	Number of suppliers	Total sales (1000s)	Total bond cost (1000s)	Cost/sales (percent)
<$350	$788	66,106	$9,915,900	$52,092	0.53
$350–499	956	740	314,500	707	0.22
$500–999	1,688	933	699,750	1,575	0.23
$1,000–2,999	4,388	430	860,000	1,887	0.22
>3,000	6,750	102	408,000	689	0.17
Total		68,311	12,198,150	56,950	0.47

For 97 percent of the suppliers the cost of a surety bond would be on average $788 annually. The Durable Medical Equipment Regional Carriers report that each year tens of millions of dollars cannot be recovered because the supplier has gone out of business or does not have resources to repay debts owed to Medicare. We believe that if these suppliers had possessed a surety bond, the Medicare program could decrease its potential losses.

We realize that surety bonds represent a new cost of approximately $57 million to DMEPOS suppliers, with the use of a sliding scale adding approximately $5 million to the cost when compared to what it would cost if we required only the $50,000 surety bond amount for each supplier. However, we believe that the benefits to the Medicare program and Medicare beneficiaries would outweigh these costs. For example, as part of Operation Restore Trust in 1995 in Florida we found that $40 million was billed for nonfurnished DMEPOS items. This $40 million represented 8% of the total Medicare expenditures made for DMEPOS items in the State of Florida in 1995. If we assume that this 8% figure represents a typical experience, and multiply the 8% times the total Medicare expenditures made nationally, we can project potential Medicare erroneous payments to be $492 million for the entire nation. However, Florida may not necessarily be typical of other States or the Nation as a whole.

In addition, the use of an 8% figure, which has been extrapolated from 1995 data, to make cost saving projections in 1997 does not take into account the advances that Medicare has made over the last two years to protect Medicare funds. For example, as a result of the Operation Restore Trust project, which was conducted in five States, Medicare has strengthened its efforts to identify and exclude from the program companies engaged in fraud or that fail to meet other supplier standards.

Efforts to reduce improper Medicare payments include section 201(b) of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104–191), enacted August 21, 1996, that amended section 1817 of the Act by creating a Health Care Fraud and Abuse Control Account. Funds will be appropriated to this Account each year to carry out the Medicare Integrity Program under section 1893 of the Act.

While it is not possible to estimate with accuracy the savings that will result from this provision, we believe it is important to set standards for DMEPOS suppliers that do business with the Medicare program, for program integrity purposes. We believe that surety bonds combined with other efforts will diminish the number of suppliers that currently fraudulently bill Medicare, while serving as a deterrent to others tempted to engage in fraudulent behavior.

H. 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, even though some may view the additional standards as impeding their competitiveness. 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 supplier as a result of these supplier standards, for example one who operates out of a van or who does not provide a value added service, is far outweighed by what these standards would do in terms of protecting the health and safety of beneficiaries and preserving the Medicare Trust Fund.

I. 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 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 50 beds. We are not preparing a rural impact statement since we have determined, and certify, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects in 42 CFR Part 424

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

42 CFR Chapter IV would be 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 amended by revising paragraphs (b) through (f) and adding a new paragraph (g) to read as follows:

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

* * * * *

(b) Medicare will not pay for any Medicare covered items provided by a DMEPOS supplier prior to the date HCFA issues a DMEPOS supplier number. Medicare will not pay for any covered items provided by a DMEPOS supplier during any period when a DMEPOS supplier number is revoked or during a period of exclusion.

(c) Medicare will issue a DMEPOS billing number, or reissue a number previously issued, to a supplier that submits a completed application to furnish Medicare covered medical equipment and supplies, as defined in section 1834(j)(5) of the Act, after the

supplier meets, and certifies in its application for a billing number that it meets, the following standards:

(1) A supplier must agree to comply with the provisions of Title XVIII of the Act and any applicable regulations.

(2) A supplier must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements.

(3) 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.

(4) A supplier's application for a billing number must be signed by an individual whose signature binds a supplier.

(5) A supplier must agree to furnish to HCFA all information or documentation HCFA requires, including—

(i) Information or documentation needed to process or adjudicate Medicare claims;

(ii) Upon request, copies of contracts with third parties for furnishing Medicare covered items to Medicare beneficiaries;

(iii) 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;

(iv) Upon request, documentation that it has advised Medicare beneficiaries about Medicare covered items covered under warranty;

(v) Upon request, documentation demonstrating that it has delivered Medicare covered items to Medicare beneficiaries;

(vi) Upon request, documentation that it maintains and repairs directly, or through a service contract with another company, Medicare covered items rented to beneficiaries;

(vii) Upon request, proof of liability insurance; and

(viii) Any other information required by this or other Medicare requirements.

(6) A supplier must fill orders from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. A supplier may also fabricate or fit items for sale from supplies it buys under contract. A supplier may not contract with any entity that currently is excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity.

(7) A supplier must advise beneficiaries that they may either rent or purchase inexpensive or routinely purchased equipment, and of the purchase option for capped rental equipment, as defined in § 414.220(a) of this subchapter.

(8) 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. This standard applies to all purchased and rented items, including capped rental items, as described in § 414.229 of this subchapter.

(9) 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.

(10) A supplier 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.

(11) A supplier must maintain and repair directly, or through a service contract with another company, Medicare covered items it has rented to beneficiaries.

(12) 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).

(13) A supplier must disclose consumer information, which must include these supplier standards, to each beneficiary whom it supplies a Medicare covered item.

(14) A supplier must comply with the disclosure provisions in § 420.206 of this subchapter.

(15) A supplier cannot convey or reassign a supplier number.

(16) 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.

(17) 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 for purposes of this regulation.

(18) 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.

(19) As required by sections 1834(a)(17)(A) and 1834(h)(3) of the Act, 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 one of the following applies—

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a Medicare covered item;

(ii) The supplier has furnished a Medicare covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such Medicare covered item; or

(iii) If the contact is regarding 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.

(20) Only a supplier that is licensed 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.

(d) If a supplier is found not to meet the standards in paragraph (c) of this section, its billing number will be revoked. The revocation will be effective 15 days after the entity is sent notice of the revocation, as specified in § 405.874(b) and (e) of this subchapter.

(e) *Surety bond.* (1) A supplier must obtain a surety bond for each tax identification number for which it has a billing number issued by Medicare. When a supplier applies for renewal of its supplier billing number the supplier must submit with the supplier application to the National Supplier Clearinghouse a copy of its current surety bond. Copies of previous surety bonds demonstrating compliance with the surety bond requirement since the last renewal or initial application must also be submitted when renewing a supplier number. New suppliers must submit a copy of their surety bond for

the appropriate amount at the time of their initial application in order to have the application approved. The company issuing a surety bond must be listed in the Treasury Department Circular 570, ''Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies.'' This list appears in the **Federal Register** on or about July 1 of each year. Copies of the Circular and interim changes may be obtained directly from the Government Printing Office (202) 512–1800, or contact the U.S. Department of the Treasury, Financial Management Service, Surety Bond Branch, 3700 East West Highway, Room 6F04, Hyattsville, Maryland 20782, telephone (202) 874–6850 or Fax (202) 874–9978.

(2) The surety bond must be for a term of 12 months and must be renewed annually. The surety bond must be in an amount equal to at least 15 percent of the amount paid to the supplier by the Medicare program for claims for Medicare covered items provided in the previous year, as reflected in a supplier's IRS Form No. 1099, or by the historic payment information from the durable medical equipment regional carrier provider payment history file. The minimum surety bond amount for a supplier billing number, regardless of its Medicare revenues, is $50,000 annually. The maximum surety bond amount for a supplier billing number, regardless of its Medicare revenues, is $3,000,000 annually.

(3) For a supplier that has not previously participated in the Medicare program, the amount of the surety bond for each billing number must be equal to the sum of $50,000 for the first year of participation in the Medicare program. Thereafter, the rules set forth in § 424.57(e)(1) and (2) apply.

(4) As the obligee of the bond, HCFA may seek recovery by resorting to the surety bond if there are outstanding debts to the Medicare program, including overpayments, interest, civil money penalties and assessments or if a supplier's number is revoked.

(f) A supplier number will expire and a supplier must renew its application for a billing number 3 years after the billing number is first issued. Each supplier must complete an application for a billing number 3 years after its last number is issued.

(g) A supplier must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and to keep written complaints and 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. Such information must be kept at its physical facility and made available to HCFA, upon request. A supplier must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

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

(2) A summary of the complaint and the date it was made; the name of the person taking the complaint; and a summary of any actions taken to resolve the complaint.

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

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

Dated: January 24, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: August 14, 1997.

Donna Shalala

Secretary.

[FR Doc. 98–963 Filed 1–16–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 15

[USCG 98–3323]

RIN 2115–AF57

Federal Pilotage for Vessels in Foreign Trade

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to require that foreign-trade vessels, under way on the Cape Fear River and the Northeast Cape Fear River in North Carolina, be under the direction and control of Federal pilots when not under the direction and control of State pilots. This measure is necessary to ensure that vessels are navigated by competent, qualified persons, knowledgeable in the local area and accountable to either the State or the Coast Guard. This measure would promote navigational safety by increasing the level of accountability and reducing the risk of accidents and the discharge of oil and other hazardous substances into these waters.

DATES: Comments must reach the Coast Guard on or before February 19, 1998.

ADDRESSES: You may mail comments to the Docket Management Facility, USCG 98–3323, U.S. Department of Transportation, Room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001, or deliver them to room PL–401, located on the Plaza Level of the Nassif Building at the same address between 10:00 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

The Docket Management Facility maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at room PL–401, located on the Plaza Level of the Nassif Building at the above address between 10:00 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Paulette Twine, Chief, Documentary Services Division, U.S. Department of Transportation, telephone 202–366–9329 or Mr. Stewart Walker, Licensing and Manning Division, Office of Compliance (G–MOC–1), room 1116, 202–267–0745.

SUPPLELMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking USCG 98–3323 and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations would aid this rulemaking, the Coast