In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This rule merely makes a technical amendment to delay the due date for the submission, by a group of physicians that wishes to be identified as a ''group practice,'' of a statement attesting that it meets certain conditions. For this reason, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR part 411 is amended as set forth below:

## PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATION ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

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

2. In § 411.360, paragraph (e) is revised to read as follows:

**§ 411.360 Group practice attestation.**

* * * * *

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§ 411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

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

Dated: November 21, 1995.

Bruce C. Vladeck,

*Administrator, Health Care Financing Administration.*

Dated: November 29, 1995.

Donna E. Shalala,

*Secretary.*

[FR Doc. 95–30064 Filed 12–8–95; 8:45 am]

BILLING CODE 4120–01–P

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## 42 CFR Part 424

**[BPD–838–FC]**

**RIN 0938–AH19**

## Medicare Program; Additional Supplier Standards

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

**ACTION:** Final rule with comment.

**SUMMARY:** This final rule with comment period conforms our regulations to changes made to section 1834 of the Social Security Act (the Act) by section 131 of the Social Security Act Amendments of 1994. Section 1834(j) of the Act requires that suppliers meet additional standards related to compliance with State and Federal licensure requirements, maintaining a physical facility on an appropriate site, and proof of appropriate liability insurance. This final rule retains existing regulatory standards and incorporates the three additional standards specifically cited from the statute.

**DATES:** Effective Date: This rule is effective January 1, 1996.

Comments: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 9, 1996.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–838–FC, 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 BPD–838–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 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).

For comments that relate to information collection requirements, mail a copy of comments to: 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.

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

**SUPPLEMENTARY INFORMATION:**

I. Background

*A. General*

The Medicare Part B program is a voluntary program that pays all or part of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities, and certain other medical and hospital health services not covered by Medicare Part A.

Medicare services are furnished by two types of entities, that is, providers and suppliers. The term ''provider'' as defined in our regulations at 42 CFR 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, suppliers are individuals or entities that furnish certain types of medical and other health services under part B. There are different definitions of the term supplier and specific regulations governing different types of suppliers. Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) encompasses the types of items included in the definition of ''medical equipment and supplies'' found at section 1834(j)(5) of the Act. In

this rule, the term ''DMEPOS supplier'' refers to all individuals or entities that furnish these items.

For purposes of DMEPOS supplier standards, the term ''supplier'' is currently defined in § 424.57(a) as an entity or individual, including a physician or part A provider, which sells or rents part B covered items to Medicare beneficiaries, and which meets certain standards. We are retaining this definition for purposes of identifying those entities that must meet Medicare 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.

For Medicare purposes, DMEPOS suppliers either accept or do not accept assignment. If a DMEPOS supplier accepts assignment, it agrees to accept the Medicare approved amount as payment in full for the covered item. Generally, Medicare pays 80 percent of the approved amount and the beneficiary is responsible for applicable coinsurance and any unmet Medicare deductible amounts. DMEPOS suppliers that have voluntarily agreed to enter into an agreement to accept assignment for all items are referred to as ''participating suppliers''. Participating DMEPOS suppliers are listed in directories available to Medicare beneficiaries and receive part B payment directly from the Medicare program. Nonparticipating DMEPOS suppliers may accept assignment on a case-by-case basis, and for these claims, receive payment directly from Medicare. If a beneficiary receives a service from a nonparticipating DMEPOS supplier on a nonassigned basis, however, payment is made to the beneficiary who in turn pays the DMEPOS supplier. This rule applies to all DMEPOS suppliers for all items furnished to Medicare beneficiaries regardless of whether they accept Medicare assignment or are Medicare participating suppliers.

*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 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) 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).

*B. DMEPOS Supplier Standards*

On June 18, 1992, we published a final rule with comment period (57 FR 27290) that established in § 424.57 certain business standards for entities seeking to qualify as Medicare suppliers of DMEPOS items. Currently, in order to obtain a Medicare billing number, a DMEPOS supplier is required to meet, and to certify that it meets, the following supplier standards:

1. Respond to orders received by filling those orders from its own inventory or inventory from other companies with which it has contracted to fill such orders; or fabricating or fitting items for sale from supplies purchased under a contract.

2. Be responsible for delivery of Medicare covered items to Medicare beneficiaries.

3. Honor all warranties express and implied under applicable State law.

4. Answer any questions or complaints a beneficiary has about the item or use of the item that was sold or rented to him or her, and refer beneficiaries with Medicare questions to the appropriate carrier.

5. Maintain and repair items rented to beneficiaries directly or through a service contract with another company.

6. Accept returns 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) from beneficiaries.

7. Disclose consumer information to each beneficiary who rents or purchases items. This information consists of the supplier standards to which it must conform.

8. Comply with the disclosure provisions in § 420.206 (Disclosure of persons having ownership, financial, or control interest).

*C. Obtaining a DMEPOS Supplier Number for Identification and Billing Purposes*

Since November 1, 1993, every DMEPOS supplier that submits claims to a Durable Medical Equipment Regional Carrier (DMERC) is required to complete and return the Medicare

Supplier Number Application (HCFA–192 Form) to the National Supplier Clearinghouse (NSC). The NSC distributes applications, verifies the data, issues numbers to approved suppliers, and maintains a national supplier file. The DMEPOS supplier must obtain a supplier number from the NSC before the DMERC will accept a claim. If the DMEPOS supplier attempts to file a claim before obtaining a supplier number the DMERC will reject the claim.

Under this final rule, in order to obtain a Medicare supplier number, a DMEPOS supplier will be required to meet, and to certify that it meets, the supplier standards found in the new § 424.57 as discussed in section II. of this rule. The DMEPOS supplier standards found in the new § 424.57 include the supplier standards that are in the existing § 424.57, and also the standards cited in section 1834(j)(1)(B)(ii) (I) through (III) of the Act.

The DMEPOS supplier's certification that supplier standards are met must be completed before a supplier number will be issued by the NSC. The DMEPOS supplier is accountable to complete the application accurately. Any deliberate misrepresentation or concealment of material information may subject the DMEPOS supplier to liability under civil and criminal laws. Every three years the DMEPOS supplier is required to recertify that it continues to meet the DMEPOS supplier standards.

## II. Provisions of the Final Regulation

Section 131 of the Social Security Act Amendments of 1994 (SSA '94, Pub. L. 103–432, enacted on October 31, 1994), added a new subsection (j) to section 1834 of the Act. Section 1834(j)(1)(B)(i) of the Act requires that for medical equipment and supplies furnished on or after October 31, 1994, and before January 1, 1996, the supplier must meet the current standards established in § 424.57. Section 1834(j)(1)(B)(ii) of the Act requires that for medical equipment and supplies furnished on or after January 1, 1996, the supplier must meet revised standards issued by the Secretary, after consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers.

As a result of SSA '94, we are establishing additional DMEPOS supplier standards by revising paragraph (c) of § 424.57 of the regulations. The revised standards include all of the standards that are in the existing § 424.57 and those standards specifically required by section 1834(j)(1)(B)(ii) (I) through (III) of the Act.

Beginning January 1, 1996, a supplier will be required to meet, and to certify that it meets, the existing standards discussed in section C. of this rule, and also the following additional standards. The supplier must—

(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.

We are issuing this final rule to incorporate those standards that Congress has explicitly identified and indicated should be used beginning January 1, 1996. In addition, our existing regulatory standards have already been subject to the notice and comment process, and both the public and the industry are familiar with those standards. Congress did not indicate any intention to relax those standards. Rather, we believe Congress' intent is to strengthen these standards to protect Medicare beneficiaries. This final rule will provide a base level of protection that will enable us to continue to process applications of individuals and entities who seek to become suppliers, and will provide a basis to revoke the numbers of suppliers who do not fulfill those standards according to our regulations at § 405.874.

The statute also gives the Secretary the authority to establish additional standards besides those included in the existing § 424.57 and those standards specifically cited in section 1834(j)(1)(B)(ii) (I) through (III). As directed by the statute, we have contacted or consulted with representatives of suppliers, carriers, and consumers concerning the need for additional supplier standards. These meetings were productive and we have received numerous comments that suggest that additional standards may be necessary in certain areas. We are currently considering these comments as we develop a proposed rule that would set forth additional substantive supplier standards. At this time, however, we are retaining our existing standards and only adding those standards specifically cited from section 1834(j) of the Act.

## III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, 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 Paperwork Reduction Act of 1995 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:

The information collection requirements in § 424.57 (''Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers''), in paragraph (c)(7), arise as a result of requiring all DMEPOS suppliers to give a copy of the DMEPOS supplier standards to each Medicare beneficiary with whom they do business. The National Supplier Clearinghouse will supply a copy to each enrolled supplier which may be photocopied. We estimate the public reporting burden for this collection of information to average approximately 20 minutes per year, including photocopying and handing out the standards, which totals approximately 46,200 hours.

The information collection requirements in § 424.57(c)(8) cross refers to § 420.206 (''Disclosure of persons having ownership, financial, or control interest'') concern the information necessary for disclosure of ownership and control and the identities of managing employees. The respondents who will provide the information will be the DMEPOS suppliers. Public reporting burden for this collection of information is estimated to be 140,000 hours. We estimate that 140,000 suppliers will complete the information which is estimated at one hour per supplier.

We have submitted a copy of this final rule with comment period to OMB for its review of the information collection requirements in § 424.57(c) (7) and (8). These requirements are not effective until they have been approved by OMB. A notice will be published in the

Federal Register when approval is obtained.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should send them to the Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850 and to the Office of Management and Budget official whose name appears in the **ADDRESSES** section of this preamble.

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. Waiver of Prior Notice With Comment Period and of Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking for a rule to provide a period of public comment prior to the effective date of the rule. This procedure can be waived, however, when an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest. Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay.

In the case of this rule, we find good cause to implement this rule as a final rule because the delay involved in the prior notice and comment procedures for these DMEPOS supplier standards would be contrary to the public interest. In SSA '94, Congress enacted numerous substantive provisions designed to protect Medicare beneficiaries from abusive practices by DMEPOS suppliers. These provisions establish limitations on the information DMEPOS suppliers may include on a certificate of medical necessity (section 1834(j)(2)), establish restrictions on the methods DMEPOS suppliers may use to contact certain Medicare beneficiaries (section 1834(a)(17)), and limit the Medicare beneficiary's liability if the DMEPOS supplier does not comply with these statutory requirements (section 1834(j)(4)). Congress has also established significant penalties, including civil money penalties, if DMEPOS suppliers violate particular statutory provisions (section 1834(a)(18)(B)). Most importantly, for purposes of this regulation, Congress has indicated that beginning January 1, 1996, individuals or entities must meet at least three additional standards in order to obtain a Medicare supplier number.

When considered as a whole, these legislative changes demonstrate that Congress has serious concerns about the business practices employed by certain DMEPOS suppliers, and that Medicare beneficiaries require additional protection from these practices. It would, therefore, be contrary to the public interest to delay establishing the specific additional criteria that Congress has identified by adhering to the normal notice and comment procedures. In addition, as noted previously, the Secretary has already established certain regulatory standards for DMEPOS suppliers that were developed in accordance with the notice and comment procedures. These standards are familiar to the public and the regulated DMEPOS supplier community and provide a base level of protection for Medicare beneficiaries. Congress has not indicated any intention to reduce or eliminate these existing standards. It is necessary to maintain these existing regulatory standards in order to protect the public interest and to further our efforts to prevent fraud and abuse in the Medicare program through Operation Restore Trust.

As directed by statute, we have met with representatives of DMEPOS suppliers, the carriers, and consumers to consider whether additional standards are necessary. Although these meetings were productive, it was not possible to complete the full notice and comment procedure in order to have final rules in place before January 1, 1996. We are currently preparing a notice of proposed rulemaking reflecting our consultations with these entities and individuals and will publish that document in the near future. These final rules will be effective until altered by those regulations.

We believe that it would be contrary to public interest to delay implementation of the revised standards pending the process of publishing both a proposed rule and a final rule. The three new standards are required to be included in any new standards promulgated by the Secretary, and are not discretionary. Moreover, the existing DMEPOS standards had been promulgated in accordance with the notice and comment provisions of the Administrative Procedure Act. Therefore, we find good cause to waive proposed rulemaking for the revised requirements set forth in § 424.57 and to issue these regulations in final. However, we are providing a 60-day period for public comment, as indicated at the beginning of this rule, on the changes to § 424.57. For the above reasons, we also find good cause to waive the delay in effective date of this rule.

VI. Regulatory Impact Analysis

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all providers, physicians, and other suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this final rule was not 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 Part 424 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. Paragraph (c) of § 424.57 is revised to read as follows:

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

* * * * *

(c) Medicare does not issue a billing number to a supplier that submits claims for items listed in § 421.210(b) of this subchapter until that supplier meets, and certifies that it meets, the following standards. The supplier—

(1) In response to orders which it receives, fills those orders from its own inventory or inventory in other companies with which it has contracted to fill such orders or fabricates or fits items for sale from supplies it buys under a contract;

(2) Is responsible for delivery of Medicare covered items to Medicare beneficiaries;

(3) Honors all warranties express and implied under applicable State law;

(4) Answers any questions or complaints a beneficiary has about the item or use of the item that was sold or rented to him or her, and refers beneficiaries with Medicare questions to the appropriate carrier;

(5) Maintains and repairs directly or through a service contract with another company, items it has rented to beneficiaries;

(6) Accepts returns 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) from beneficiaries;

(7) Discloses consumer information to each beneficiary with whom it does business which consists of the supplier standards to which it must conform;

(8) Complies with the disclosure provisions in § 420.206.

(9) Complies with all applicable State and Federal licensure and regulatory requirements;

(10) Maintains a physical facility on an appropriate site; and

(11) Has proof of appropriate liability insurance.

* * * * *

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

Dated: November 22, 1995.

Bruce C. Vladeck,

*Administrator, Health Care Financing Administration.*

[FR Doc. 95–30065 Filed 12–8–95; 8:45 am]

BILLING CODE 4120–01–P

## DEPARTMENT OF TRANSPORTATION

## Office of the Secretary

## 49 CFR Part 1

**[OST Docket No. 1; Amendment 1–272]**

## Organization and Delegation of Powers and Duties; Transfer of Great Lakes Pilotage Authority From the Coast Guard to the Saint Lawrence Seaway Development Corporation

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard's responsibility for administering the Secretary's functions under the Great Lakes Pilotage Act of 1960, as amended, and the Secretary's authority to enter into, revise, or amend arrangements with Canada, are being transferred to the Saint Lawrence Seaway Development Corporation. This rule affirms the interim final rule amending the delegations to be in accordance with the changed responsibilities. Although a comment period for the Secretary's delegations is not required by the Administrative Procedure Act, the Department of Transportation requested public comment on the interim final rule because of public and Congressional interest in Great Lakes Pilotage. This final rule responds to the comments and is necessary to inform the public that the interim final rule has been affirmed.

**DATES:** This rule is effective on December 11, 1995.

**FOR FURTHER INFORMATION CONTACT:** Steven B. Farbman, Office of the Assistant General Counsel for Regulation and Enforcement (202) 366–9306, United States Department of Transportation, 400 7th Street SW., Washington, DC 20590.

**REGULATORY HISTORY:** On July 31, 1995, the Department of Transportation (Department) published an interim final rule with request for comments (60 FR 38971). The interim final rule contained language that would transfer Great Lakes Pilotage authority from the Coast Guard to the St. Lawrence Seaway Development Corporation (SLSDC). The comment period for the interim final rule ended on September 29, 1995, and was to become effective October 30, 1995. On October 27, 1995, the Department issued a rule suspending the effectiveness of the interim final rule. This final rule affirms the interim final rule and establishes a new effective date.

**SUPPLEMENTARY INFORMATION:** The Coast Guard's responsibility for administering the Secretary's functions under the Great Lakes Pilotage Act of 1960, as amended, (the Act) is being transferred to the SLSDC. This rule amends the delegations and enabling regulations to be in accordance with the changed responsibilities. The functions that are being transferred are: (1) Investigation and prosecution of violations of the Act; (2) registration, qualification, and training of registered pilots; (3) association working rules and dispatching procedures; (4) pilot working conditions; (5) selection of pilots; (6) number of pilots; (7) availability of pilots; (8) number of pilotage pools; (9) articles of association; (10) auditing; and (11) ratemaking. The licensing of pilots and the investigation and prosecution of marine accidents and incidents are essential Coast Guard safety functions that are separate from the Act and Great Lakes Pilotage Regulations. These functions will remain with the Coast Guard.

Transfer of pilotage responsibilities to the SLSDC will place pilotage under permanent civilian authority, and placing pilotage in a smaller organization with an established presence on the Great Lakes will give pilotage issues greater visibility and more timely attention. In addition, the SLSDC is being given authority to negotiate directly with Canada, which will allow timely adjustments to pilotage rates. The lack of timely adjustments has been a subject of past pilot criticism.

The Secretary's authority to enter into, revise, or amend arrangements with Canada is being delegated to the SLSDC Administrator in coordination with the General Counsel of the Department. A Memorandum of Arrangements between the United States and Canada, last renegotiated in 1977, states that the Secretary and the Minister of Transport of Canada ''will arrange for the establishment of regulations imposing identical rates, charges, and any other conditions or terms for services of pilots in the waters of the Great Lakes. * * *.'' In 1983, the Act was amended to provide that the ''Secretary, subject to the concurrence of the Secretary of State, may make agreements with the appropriate agency of Canada to * * * prescribe joint or identical rates and charges .''

Discussion of Comments and Changes

The Department received comments from well over 100 commenters regarding the transfer of Great Lakes Pilotage oversight from the Coast Guard to the SLSDC. Comments on the interim final rule were received from Federal and State legislators, pilot associations