

National Estuarine Research Reserve System.

PART 924—MONITOR MARINE SANCTUARY

PART 929—KEY LARGO NATIONAL MARINE SANCTUARY FINAL REGULATIONS

PART 935—THE CHANNEL ISLANDS NATIONAL MARINE SANCTUARY REGULATIONS

PART 936—THE POINT REYES/FARALLON ISLANDS MARINE SANCTUARY REGULATIONS

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PART 941—FAGATELE BAY NATIONAL MARINE SANCTUARY REGULATIONS

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PART 943—FLOWER GARDEN BANKS NATIONAL MARINE SANCTUARY

PART 944—MONTEREY BAY NATIONAL MARINE SANCTUARY

11. Section 924.4, 929.9, 935.8, 936.7, 937.7, 938.7, 941.10, 942.7, 943.8 and 944.7 are revised to read as follows (Text of each section is identical):

§ _____ Penalties.

(a) Each violation of the act, any regulation, in this part, or any permit issued pursuant thereto, is subject to a civil penalty of not more than \$100,000. Each day of a continuing violation constitutes a separate violation.

(b) Regulations setting forth the procedures governing administrative proceedings for assessment of civil penalties, permit sanctions and denials for enforcement reasons, issuance and use of written warnings, and release or forfeiture of seized property appear at 15 CFR part 904.

[FR Doc. 93-27859 Filed 11-17-93; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Regulatory Program; Show Cause Orders

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with an exception, of a proposed amendment to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment revises the Indiana Surface Mining Rules governing show cause orders and adjudicative proceedings for the suspension and revocation of surface coal mining permits. The amendment is intended to revise the Indiana program to be consistent with corresponding Federal regulations.

EFFECTIVE DATE: November 18, 1993.

FOR FURTHER INFORMATION CONTACT: Roger W. Calhoun, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204, Telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana Program
- II. Submission of the Amendment
- III. Director's Findings
- IV. Disposition of Comments
- V. Director's Decision
- VI. Procedural Determination

I. Background on the Indiana Program

The Secretary of the Interior conditionally approved the Indiana program effective July 29, 1982. Information on the background of the Indiana program, including the Secretary's findings, the disposition of public comments and a detailed explanation of the conditions of approval can be found in the July 26, 1982, *Federal Register* (47 FR 32107).

Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.15 and 914.16.

II. Submission of the Amendment

By letters dated August 15, 1989, and December 5, 1989 (Administrative

Record Numbers IND-0674 and 0723), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program at Indiana Administrative Code (IAC) 310 IAC 06 and 310 IAC 12-6-6.5. The amendment proposed changes to the Indiana program concerning suspension or revocation of permits and adjudicative proceedings. The program amendment was reviewed and approved, in part, by the Director on January 18, 1991 (56 FR 1915). In the same *Federal Register* notice, certain required program amendments were codified at 30 CFR 914.16 (d) and (e) which are intended to require Indiana to revise the Indiana program to be no less effective than the corresponding Federal regulations.

By letter dated February 24, 1993 (Administrative Record Number IND-1214), the IDNR submitted program amendment number 93-2 in response to the required program amendments. The proposed amendment includes revisions in 310 IAC 0.6-1-5, 310 IAC 0.6-1-13, 310 IAC 0.7-3-5, and 310 IAC 12-6-6.5.

OSM announced receipt of the proposed amendment in the March 26, 1993, *Federal Register* (58 FR 16381), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on April 26, 1993.

On July 23, 1993, OSM sent Indiana a letter listing its concerns raised during OSM's review of the proposed amendment (Administrative Record No. IND-1284). Indiana chose not to respond to this letter and informed OSM on September 28, 1993, that it should proceed with a final rulemaking.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Indiana program. Only substantive changes will be discussed in detail. Revisions not specifically discussed are found to be no less stringent than SMCRA and no less effective than the Federal regulations.

1. 310 IAC 0.6-1-5 Petitions for Review; Response

(a) 310 IAC 0.6-1-5, Hearing Procedures

In the January 18, 1991, *Federal Register* (56 FR 1918), the Director of OSM found that Indiana's proposed two-tiered hearing procedure was less effective than 30 CFR 843.13 which provides for only one hearing opportunity. The Director believed that

the two-tiered process would result in undue delays in the issuance of show cause orders. Required program amendment 30 CFR 914.16(d) was promulgated to require Indiana to revise its rules to be no less effective than the Federal regulations at 30 CFR 843.13 and 43 CFR 4.1190 through 4.1196.

Indiana now proposes to satisfy this required amendment by deleting the terms "complaint" and "complaint and proposed" from 310 IAC 0.6-1-5 and other rules governing hearing procedures to avoid the creation of a two-tiered hearing process. The Director finds that the proposed deletion of the terms "complaint" and "complaint and proposed," together with other changes discussed below, have eliminated the presence of a two-tiered system of hearings. He, therefore, finds that the deletions of the terms "complaint" and "complaint and proposed" in 310 IAC 0.6-1-5 create adjudicatory proceedings for the suspension and revocation of permits which are the same or similar to those contained in section 521(a)(4) of SMCR and 43 CFR 4.1190 through 4.1196.

(b) 310 IAC 0.6-1-5(d), Service of Show Cause Orders

Indiana proposes to add a provision that will require each show cause order to be served either by certified mail or personal delivery. 43 CFR 4.1109(b) requires that copies of documents by which any proceeding is initiated shall be served on all statutory parties personally or by registered or certified mail, return receipt requested. All subsequent documents shall be served personally or by first class mail. Indiana's proposed language is substantively identical to 43 CFR 4.1109, insofar as it pertains to the issuance of show cause orders and can, therefore, be approved.

(c) 310 IAC 0.6-1-5(e), Contents of Answer To Show Cause

Indiana proposes to add language to require the permittee's answer to a show cause order to set forth certain details refuting the order. The proposed language would require the permittee to state the reasons in detail why a pattern of violations or any permit condition does not exist or has not existed including reasons for contesting: the fact of any violations alleged in the order as constituting a pattern of violations; the willfulness of the violations; or whether the violations were caused by unwarranted failure of the permittee. The permittee must also state the mitigating factors the permittee believes exist in determining the terms of the revocation or the length and terms of the

suspension, any other alleged relevant facts, and whether a hearing on the show cause order is desired. This proposed language at 310 IAC 0.6-1-5(e) is substantively identical to 43 CFR 4.1192 which sets forth the required contents of a show cause answer in the Federal rules. The Director, therefore, finds that proposed 310 IAC 0.6-1-5(e) can be approved.

(d) 310 IAC 0.6-1-5(f), Timeline for Director's Decision

Indiana proposes to require the director of the IDNR to submit within 45 days of the permittee's receipt of a show cause order, a written recommendation to the Natural Resource Commission (Commission) that the permit be suspended or revoked if the permittee has not filed an answer to the show cause order. There is no Federal counterpart to the State's proposed 45 day timeline for the director of IDNR to submit a written recommendation to the Commission in situations where the permittee fails to respond to a show cause order. However, the Director finds that 310 IAC 0.6-1-5(f) contains the same or similar procedures as those found in section 521(a)(4) of SMCR and at 43 CFR 4.1190 through 4.1196, governing surface coal mining permit suspension and revocation proceedings.

(e) 310 IAC 0.6-1-5(g), Determination by the Administrative Law Judge

Indiana proposes to add language that would require an administrative law judge to consider the factors set forth in 310 IAC 12-6-6.5, the suspension or revocation of permits, in proceedings to suspend or revoke a permit. Since 310 IAC 12-6-6.5 (a), (b), and (c) contain language which is substantively identical to that contained in the Federal regulations at 30 CFR 843.13(a) (1), (2) and (3), governing factors which support the issuance of a show cause order, the Director finds that the language added to 310 IAC 0.6-1-5(g) can be approved.

Indiana further proposes new language that will require, upon a determination by the administrative law judge that a pattern of violations exists or has existed, that the judge shall order the permit either suspended or revoked. In making a determination that a pattern of violations exists or existed, the administrative law judge need not find that all violations listed in the show cause order occurred, but only that sufficient violations occurred to establish a pattern. If the permit is suspended, the minimum suspension period shall be three days unless the administrative law judge finds that imposition of the suspension period

would result in manifest injustice or would not further the purpose of Indiana's State regulatory program. Preconditions to be satisfied prior to the suspension being lifted may be imposed by the administrative law judge. This proposed language is substantively identical to 43 CFR 4.1194 (a)-(b) and can, therefore, be approved.

Proposed 310 IAC 0.6-1-5(g)(2) states that, if the administrative law judge determines the facts alleged in the order are true, the administrative law judge shall enter findings and a non-final order under IC 4-21.5-3-27 for final action by the Commission that the permit be suspended or revoked. In making this non-final order, the administrative law judge shall consider the factors in 310 IAC 12-6-6.5, the State's rules which govern the suspension or revocation of permits. The administrative law judge is required to issue the findings and a non-final order within 60 days after conclusion of the hearing. Indiana also proposes to add language to subsection (h) of 310 IAC 0.6-1-5 requiring the Commission to issue a final order within 60 days after the conclusion of the administrative law judge's hearing or 60 days after the answer is filed, if no hearing is requested. The State's proposed rules provide the same concurrent time allotment to both the administrative law judge and the Commission to render a decision which creates the possibility that the administrative law judge could use all the allotted time for issuance of a non-final order leaving no time for the Commission's issuance of a final order. This problem was brought to Indiana's attention in a July 23, 1993, letter (Administrative Record No. IND-1284) to which Indiana did not respond. The Federal rules at 30 CFR 843.13(c) provide that within 60 days after the hearing and within the time limits set forth in 43 CFR part 4, the Office of Hearings and Appeals shall issue a written determination as to whether a pattern of violations exists and, if appropriate, an order. 43 CFR 4.1194(c) states that the decision of the administrative law judge shall be issued within 20 days following the date the hearing record is closed by the administrative law judge or within 20 days of receipt of the answer, if no hearing is requested by any party and the administrative law judge determines that no hearing is necessary. The Director finds that Indiana must reconcile the time periods for its administrative law judge non-final order and the Commission final order so that a final decision is made no later than 60

days after the conclusion of the administrative law judge hearing. Additionally, the State proposes at subsection (h) that the 60 day period may be waived for good cause or extended upon written consent of the State and the operator. This provision is inconsistent with 30 CFR 843.13(c) which provides for no such waiver of the 60-day time period. For these two reasons, the Director finds that proposed 310 IAC 0.6-1-5(h) is less effective than the Federal rules and cannot be approved. Therefore, the required amendment at 30 CFR 914.16(d) cannot be removed.

Indiana proposes to revise 310 IAC 0.6-1-5(i) by making the Commission rather than the IDNR responsible for serving parties with a copy of the final order of the commission and by providing that following notification a party may apply for judicial review under IC 4-21.5. Indiana has added the language "under IC-4-21.5" to reference Indiana's Administrative Adjudication Act. The Director finds that these revisions clarify responsibilities and procedures under the Indiana program and can, therefore, be approved.

2. 310 IAC 0.6-1-13 Awards of Litigation Expenses

The proposed provisions at 310 IAC 0.6-1-13 concern the award of costs and attorney's fees for a proceeding under the Indiana Surface Mine Coal Reclamation Act, Oil and Gas Code, and Entomology and Plant Pathology Code. Paragraph (b) has been revised to provide that no award for costs and expenses, including attorney's fees shall be entered under IC 13-8-15-7 or IC 14-7-11-5, unless there is a finding that the person against whom the award is made acted for the purpose of harassing or embarrassing an opposing party. IC 13-8-15-7 pertains to oil and gas and IC 14-7-11-5 pertains to entomology and plant pathology. All references to the Indiana Surface Mining Control and Reclamation Act (I-SMCRA) have been removed. The proposed revision, therefore, does not apply to the State's surface coal mining program.

Furthermore, revisions to paragraph (c) only apply to those persons who initiate or participate in proceedings under IC 13-8-5-7 which pertains to oil and gas.

Proposed paragraphs (d), (e), (f) and (g) are applicable to proceedings under I-SMCRA. Under proposed paragraph (d), appropriate costs and expenses, including attorney's fees, may be awarded to any person from the permittee, if the person initiates or participates in an administrative proceeding reviewing enforcement and

a finding is made by the administrative law judge or Commission that a violation of IC 13-4.1, 310 IAC 12 or permit has occurred, or that an imminent hazard existed; and that the person made a substantial contribution to the full and fair determination of the issues. A contribution of a person who did not initiate a proceeding must be separate and distinct from the contribution made by a person initiating the proceeding. Appropriate costs and expenses may also be awarded under the proposal to: (1) A person, from the department, other than to a permittee or the permittee's authorized representative, who prevails in whole or in part, achieving at least some degree of success on the merits, upon a finding that the person made a substantial contribution to a full and fair determination of the issues; (2) a permittee from the department if the permittee demonstrates that the department issued a cessation order, notice of violation, or an order to show cause why a permit should not be suspended or revoked in bad faith and for the purpose of harassing or embarrassing the permittee; (3) a permittee from a person where the permittee initiated a proceeding under IC 13-4.1-11 or participated in the proceeding in bad faith for the purpose of harassing or embarrassing the permittee; and (4) to the department where it demonstrates that a person sought administrative review or participated in a proceeding in bad faith and for the purpose of harassing or embarrassing the department. The above provisions of proposed paragraph (d) concerning the award of costs and expenses, including attorney's fees, are substantively identical to 43 CFR 4.1294 (a)(1) and (b) through (e) can, therefore, be approved.

As a result of this approval, the Director finds that the required amendment at 30 CFR 914.16(e) has been satisfied and can now be removed.

3. 310 IAC 0.7-3-5 Delegations for Programs Administered by the Division of Reclamation

Indiana proposes to revise 310 IAC 0.6-1-5(b) by removing language which created a two-tiered hearing procedure for the forfeiture of bonds. While there is no Federal counterpart to 310 IAC 0.6-1-5(b), the Director finds that the proposed change is not inconsistent with SMCRA or the Federal regulations.

4. 310 IAC 12-6-6.5 Suspension or Revocation of Permits

Indiana proposes to revise 310 IAC 12-6-6.5 (c), (d) and (e) by removing language which created a two-tiered

hearing procedure. These deletions reflect proposed changes to 310 IAC 0.6-1-5 which created a hearing procedure that is the same as or similar to its Federal counterpart. The Director finds that the proposed changes render the procedures in 310 IAC 12-6-6.5 the same as or similar to those contained in 30 CFR 843.13 and are necessary in order for Indiana's rules to be internally consistent.

IV. Disposition of Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Indiana program. The U.S. Department of Agriculture, Forest Service; U.S. Department of Agriculture, Soil Conservation Service; and the U.S. Department of Interior, Bureau of Mines responded without substantive comment.

One individual responded to OSM's invitation for public comment by commenting on proposed 310 IAC 0.6-1-13(d) which concerns awards of litigation expenses. In the State's proposal, appropriate costs and expenses including attorney's fees, may be awarded under IC 13-4.1-11-9 "only" as set forth in the rule. The Federal counterpart at 43 CFR 4.1294 states that appropriate costs and expenses including attorney's fees may be awarded as set forth in the rule. The commenter believed the State's use of the term "only" appeared more restrictive than the Federal counterpart and that this could discourage citizen participation. As previously indicated, the Director has determined that the proposed language at 310 IAC 0.6-1-13 is substantively identical to 43 CFR 4.1294. The use of the term "only" does not make the State's rule more restrictive than its Federal counterpart since the Federal and State provisions are substantively identical in content, and since the criteria contained in 43 CFR 4.1294 are the only criteria contained in the Federal regulations which pertain to the award of attorney fees in administrative proceedings.

The same commenter asked why the State indicated on the side-by-side submitted to OSM that there was no Federal counterpart to 310 IAC 0.7-3-5(a)(1) since the Federal rules do contain a counterpart to permit termination where no mining has started in a certain period. 310 IAC 0.7-3-5 applies to the delegation of programs administered by the division of reclamation. There is no Federal counterpart to the State's rules governing the delegation of authority.

There is, as the commenter points out, a Federal rule at 30 CFR 773.19(e) which requires that a permit be terminated if the permittee has not begun the surface coal mining and reclamation operations covered by the permit within three years of the permit's issuance. In any event, this provision is not being amended as a part of this rulemaking.

V. Director's Decision

Based upon the above findings, the Director is approving, with an exception, program amendment number 93-2 as submitted by Indiana on February 24, 1993. The Director has determined that the amendment which revises 310 IAC 0.6-1-5, 310 IAC 0.6-1-13, 310 IAC 0.7-3-5, and 310 IAC 12-6-6.5 is consistent with SMCRA and no less effective than the Federal rules. The exception is proposed 310 IAC 0.6-1-5(g)(2) and (h) to the extent that these provisions: (1) Provide for concurrent time periods for the administrative law judge to issue findings and a non-final order and for the Commission to issue a final order, and (2) allow for the waiver and extension of the 60 day time period for the Commission to issue a final order. The Federal regulations at 30 CFR part 914 codifying decisions concerning the Indiana program are being amended to implement this decision.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is therefore unnecessary. However, by letter dated March 26, 1993 (Administrative Record No. IND 1227), EPA submitted its concurrence without comment.

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to the State program are not operational until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State

programs. In the oversight of the Indiana program, the Director will recognize only the statutes, regulations and other materials approved by him, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Indiana of only such provisions.

VI. Procedural Determinations

Executive Order 12866

This final rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of the Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based

upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 10, 1993.

Carl C. Close,

Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the code of Federal Regulations is amended as set forth below:

PART 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 914.15 is amended by adding a new paragraph (YY) to read as follows:

§914.15 Approval of regulatory program amendments.

* * * * *

(YY) The following amendment (Program Amendment Number 93-2) to the Indiana regulatory program, as submitted to OSM on February 24, 1993, is approved with an exception, effective November 18, 1993: The approved amendment to the Indiana Administrative Code (IAC) at 310 IAC 0.6-1-5, 310 IAC 0.6-1-13, 310 IAC 0.7-3-5, and 310 IAC 12-6-6.5 pertains to show cause orders and adjudicatory proceedings for the suspension and revocation of surface coal mining permits. OSM is not approving 310 IAC 0.6-1-5(g) (2) and (h) to the extent that these provisions provide for the waiver and extension of the 60 day time period for the Commission to issue a final order and for concurrent time periods for rulings by the Commission and administrative law judge.

3. Section 914.16 is amended by revising paragraph (d) and removing and reserving paragraph (e) to read as follows:

§914.16 Required program amendments.

* * * * *

(d) By July 1, 1994, Indiana shall submit for OSM approval, an

amendment to its permanent regulatory program which provides for adjudicative proceedings for suspension or revocation of permits which are no less effective than the Federal regulations at 30 CFR 843.13 and 43 CFR 4.1190 through 4.1196.

(e) Removed and reserved.

[FR Doc. 93-28369 Filed 11-17-93; 8:45 am]

BILLING CODE 4310-05-M

COPYRIGHT ROYALTY TRIBUNAL

37 CFR Part 307

Cost of Living Adjustment of the Mechanical Royalty Rate; Correction

AGENCY: Copyright Royalty Tribunal.

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to the final rule published November 1, 1993 (58 FR 58282), relating to the cost of living adjustment of the mechanical royalty rate.

EFFECTIVE DATE: January 1, 1994.

FOR FURTHER INFORMATION CONTACT:

Barbara N. Gray, Copyright Royalty Tribunal, 1825 Connecticut Avenue NW., suite 918, Washington, DC 20009, (202) 606-4400.

SUPPLEMENTARY INFORMATION: In the Cost of Living Adjustment of the Mechanical Royalty Rate; Final Rule, in the issue of Monday, November 1, 1993 (58 FR 58282), rule document 93-26883, beginning on pages 58282 and 58283, please make the following corrections:

1. On page 58282, in column 3, in **SUMMARY**, lines 6 and 7, "1993. The rate is increased to either 6.61 cents, or 1.3 cents per minute of playing," should read, "1993. The rate is increased to either 6.60 cents, or 1.25 cents per minute of playing."

2. On page 58283, in column 1, lines 8 and 9, "effective January 1, 1994, shall be 6.61 cents, or 1.3 cents per minute of playing," should read, "effective January 1, 1994, shall be 6.60 cents or 1.25 cents per minute of playing."

3. On page 58283, in column 2, in § 307.3(f), line 5, "shall be either 6.61 cents, or 1.3 cents," should read, "shall be either 6.60 cents, or 1.25 cents."

Dated: November 15, 1993.

Cindy Daub,

Chairman.

[FR Doc. 93-28430 Filed 11-17-93; 8:45 am]

BILLING CODE 1410-09-M

POSTAL SERVICE

39 CFR Part 20

Implementation of Mexico Direct Service

AGENCY: Postal Service.

ACTION: Interim rule and request for comment.

SUMMARY: Mexico Direct service is a new type of international mail service that is available only to customers with operations in both the United States and Mexico that agree to tender to the Postal Service during a 60-day period at least 10,000 items meeting the applicable makeup and preparation requirements for Mexican domestic mail. The Postal Service transports these items to Mexico for entry into Mexico's domestic mail system. The charge for Mexico Direct service is \$1.01 per pound. The customer also is responsible for paying the applicable Mexican domestic postage. Details about each Mexico Direct mailing must be specified in a service agreement between the Postal Service and the customer. Interim implementing regulations have been developed and are set forth below for comment and suggested revision prior to adoption in final form.

DATES: The interim regulations take effect on November 17, 1993. Comments must be received on or before December 17, 1993.

ADDRESSES: Manager, International Product Management, U.S. Postal Service, Washington, DC 20260-2410. Copies of all written comments will be available for public inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, in room 5300, 475 L'Enfant Plaza West, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Rainer Hengst, (202) 268-6095.

SUPPLEMENTARY INFORMATION: Under article 25 of the Universal Postal Convention, a postal administration is not obligated to deliver mail that senders resident in its territory post in large quantities in a foreign country. A postal administration may invoke this provision not only against mail sent by a company organized under the laws of the administration's territory, but also against mail sent by a company organized under the laws of a foreign country if the company does business in the administration's territory.¹ Consequently, a company with

commercial activity in both the United States and another country may be unable to use the Postal Service to mail items to addressees in that country even if the company's operations justify its posting the items in the United States.

Due in large part to the proximity and size of the Mexican consumer market, many U.S. companies either already have established, or are in the process of establishing, operations in Mexico. These companies send a variety of mail to their Mexican customers, including direct mail pieces, parcels containing merchandise, and bills. Whether the companies produce such mail in the United States or Mexico depends on a number of factors. For instance, a company sending bills to its Mexican customers may require data processing capabilities that are available only in the United States. Similarly, a company sending advertising mail to Mexican customers may need to print its promotional material in the United States. In both cases, it may make economic sense for the company to post its Mexico-bound mail in the United States. However, since the Mexican Postal Service may consider the company to be a resident of Mexico by virtue of its Mexican operations, the company may have no choice but to post its mail in Mexico.

Several U.S. companies with operations in Mexico have asked the Postal Service to develop a means for them to post their Mexico-bound mail in the United States. In response, the Postal Service has worked with the Mexican Postal Service to develop a way for the companies to meet their mailing needs. As a result of discussions between the two administrations, the Postal Service is implementing Mexico Direct service. Regulations for this new service appear in Section 610 of the International Mail Manual.

Under Mexico Direct service, customers are able to tender items prepared as Mexican domestic mail to the Postal Service. The Postal Service transports the items to Mexico, where they are presented to the Mexican Postal Service and entered into Mexico's domestic mail system. The charge for this service is \$1.01 per pound or fraction of a pound (plus the applicable Mexican domestic postage). Postage is paid on the total gross weight of the mailing, which includes the weight of the Mexico Direct items plus the weight of the mailing equipment used to prepare the items.

Mexico Direct service is available only to customers with operations in both the United States and Mexico. In addition, the Postal Service's agreement with the Mexican Postal Service

¹ A postal administration invoking article 25 typically detains the incoming international mail and refuses to deliver it until the sender pays the applicable domestic postage.

requires that this be a bulk service. Consequently, the customer must agree to send at least 10,000 Mexico Direct items during a 60-day period.

Mexico Direct customers are responsible for ensuring that their items meet the Mexican Postal Service's applicable makeup and preparation requirements for Mexican domestic mail and for paying the applicable Mexican domestic postage. As part of the service, the Postal Service will provide customers with information received from the Mexican Postal Service regarding makeup and preparation requirements. Further, the two administrations have agreed to work together to develop a mechanism whereby the Postal Service will be able to collect Mexican domestic postage from Mexico Direct customers and remit it to the Mexican Postal Service. Depending on the form that mechanism takes, those customers may be charged an additional fee to cover the Postal Service's costs of providing Mexican postage payment service.

A customer interested in using the service must contact the Postal Service at least 21 days before a planned Mexico Direct mailing date. At that time, the customer must provide the following information to the Postal Service:

- (1) The customer's name and address;
- (2) The planned mailing date;
- (3) Where the mail will be tendered to the Postal Service;
- (4) The type of items that will be contained in the planned mailing;
- (5) The size and weight of items that will be contained in the planned mailing;
- (6) The number of items that will be contained in the planned mailing;
- (7) How the customer intends to sort its items;

(8) The mailing equipment that the customer intends to use to prepare its items; and

(9) How the customer intends to pay postage to the Mexican Postal Service.

Upon receipt of this information, the Postal Service will contact the Mexican Postal Service to ascertain whether the planned mailing is acceptable and, if it is not, how the mailing can be made acceptable. The Postal Service will inform the customer of the Mexican Postal Service's response. If the Postal Service and the Mexican Postal Service both agree to accept the mailing, the Postal Service and the customer will enter into a service agreement that stipulates the following information about the mailing:

- (1) The mailing date;
- (2) Where and when the customer is tendering the mail to the Postal Service;
- (3) The total weight of the mailing;

- (4) How the items are to be prepared;
- (5) How the items are to be sorted; and

(6) How the customer is paying postage to the Mexican Postal Service.

Although 39 U.S.C. 407 does not require advance notice and opportunity for submission of comments, and the Postal Service is exempted by 39 U.S.C. 410(a) from the advance notice requirements of the Administrative Procedure Act regarding rulemaking (5 U.S.C. 553), the Postal Service invites interested persons to submit written data, views, or arguments concerning the interim rule.

The Postal Service adopts the following interim amendments to the International Mail Manual, which is incorporated by reference in the Code of Federal Regulations. See 39 CFR 20.1.

List of Subjects in 39 CFR Part 20

International postal service, Foreign relations.

PART 20—[AMENDED]

1. The authority citation for 39 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 401, 404, 407, 408.

2. Chapter 6 of the International Mail Manual is amended by titling the chapter "Special Programs" and by adding new section 610 to read as follows:

CHAPTER 6—SPECIAL PROGRAMS

* * * * *

610 MEXICO DIRECT

611 Description.

Mexico Direct service is an international mail service that is available only pursuant to a service agreement between the Postal Service and a qualifying mailer. This service enables a mailer to tender items meeting the applicable makeup and preparation requirements for Mexican domestic mail to the Postal Service. The Postal Service transports the items to Mexico for entry into Mexico's domestic mail system. The mailer is responsible for ensuring that the items meet the Mexican Postal Service's applicable makeup and preparation requirements and for paying for applicable Mexican domestic postage.

612 Qualifying Mailers.

To qualify, a mailer must have operations in both the United States and Mexico. In addition, the mailer must agree to send at least 10,000 Mexico Direct items during a 60-day period.

613 Postage

613.1 Rate.

The charge for this service is \$1.01 per pound or fraction of a pound (plus the applicable Mexican domestic postage). Postage is paid on the total gross weight of the mailing, which includes the weight of the Mexico Direct items plus the weight of the mailing equipment used to prepare the items.

613.2 Postage Payment Method.

Mailers must pay through an advance deposit account or affix postage stamps or meter postage to the mailing statement.

613.3 Mailing Statement.

Compute postage on the mailing statement provided by the Postal Service. A separate mailing statement must be completed for each mailing and must be presented at the time of mailing.

614 Preparation Requirements.

Mexico Direct items must be prepared in sacks weighing at least 30 pounds each or in trays, in accordance with the terms of the service agreement.

615 Prenotification.

A qualifying mailer interested in using the service must contact the Postal Service at least 21 days before a planned Mexico Direct mailing date. (Communications should be directed to International Product Management, U.S. Postal Service, Washington, DC 20260-2410; (202) 268-2275 or -2276.) At that time, the customer must provide the following information to the Postal Service:

- a. The customer's name and address.
- b. The planned mailing date.
- c. Where the mail will be tendered to the Postal Service.
- d. The type of items that will be contained in the planned mailing.
- e. The size and weight of items that will be contained in the planned mailing.
- f. The number of items that will be contained in the planned mailing.
- g. How the customer intends to sort its items.
- h. The mailing equipment that the customer intends to use to prepare its items.
- i. How the customer intends to pay postage to the Mexican Postal Service.

616 Service Agreement.

Upon receipt of this information, the Postal Service will contact the Mexican Postal Service to ascertain whether the planned mailing is acceptable and, if it is not, how the mailing can be made acceptable. The Postal Service will

inform the customer of the Mexican Postal Service's response. If the Postal Service and the Mexican Postal Service both agree to accept the mailing, the Postal Service and the customer will enter into a service agreement that stipulates the following information about the mailing:

- a. The mailing date.
- b. Where and when the customer is tendering the mail to the Postal Service.
- c. The total weight of the mailing.
- d. How the items are to be prepared.
- e. How the items are to be sorted.
- f. How the customer is paying postage to the Mexican Postal Service.

A transmittal letter making the changes in the pages of the International Mail Manual will be published and transmitted to subscribers automatically. Notice of issuance of the transmittal letter will be published in the *Federal Register* as provided by 39 CFR 20.3.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 93-28398 Filed 11-17-93; 8:45 am]

BILLING CODE 7710-12-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 421

[BP0-102-F]

RIN 0938-AF59

Medicare Program; Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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

ACTION: Final rule.

SUMMARY: This final rule would address the provisions of section 1834(a)(12) of the Social Security Act that authorizes us to designate one carrier for one or more regions to process all claims within that region. It incorporates in regulations the four designated carriers that will process claims for durable medical equipment, prosthetics, orthotics, supplies and certain other items covered under Part B of Medicare. We expect the above changes to lead to more efficient and economical administration of the Medicare program.

EFFECTIVE DATE: These regulations are effective on December 17, 1993.

FOR FURTHER INFORMATION CONTACT:

Lisanne Bradley, (410) 966-3359, for carrier jurisdiction for claims for

durable medical equipment, prosthetics, orthotics and supplies, and other issues involving suppliers.

Larry Pratt, (410) 966-7403, for criteria and standards for evaluating designated carriers processing durable medical equipment, prosthetics, orthotics, and supplier claims.

Juliette Jenkins, (410) 966-6997, for questions relating to the medical review of claims for durable medical equipment, prosthetics, orthotics and supplies.

Nancy Siebert, (410) 966-6012, for questions about the regional carriers and other questions relating to claims for durable medical equipment, prosthetics, orthotics and supplies.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1842(a) of the Social Security Act (the Act) authorizes the Secretary to enter into contracts with carriers for the payment of claims for Part B Medicare-covered services and items. The statute does not place any restriction on the area that a carrier must serve.

Consequently, we have contracts for carriers to process claims in areas that are multi-State, Statewide, or lesser areas. In addition, section 1842(g) of the Act requires the Railroad Retirement Board (RRB) to contract with a carrier or carriers to process claims for services or items furnished to qualified railroad retirement beneficiaries entitled to Medicare in accordance with regulations prescribed by the Secretary.

Our experience has been that there is diversity among carriers in their interpretation of coverage policies, local medical review policies, and pricing for similar items and services. To some extent a carrier's performance is affected by the nature of its workload. That is, the more unusual a piece of equipment or supply is in an area, the more difficult it is for a carrier to make a coverage or pricing determination. To the extent that carrier determinations reflect local conditions, diversity is desirable, but to the extent that local norms result in unwarranted variations in payment amounts, utilization parameters, or claims documentation policies for items furnished nationally, such diversity is undesirable.

Claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are submitted to carriers by suppliers. The Medicare regulations (42 CFR 400.202) define "supplier" as "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare." Section 400.202 also defines "provider" as a

"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, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services."

In practice, before August 17, 1992, an entity, including a provider, that wished to become a supplier to Medicare beneficiaries did so merely by submitting claims for Medicare covered items and services. Most carriers required some identifying information from a supplier before it received a billing number, but there were no national requirements that a DMEPOS supplier had to meet. The absence of a well-defined process for issuing supplier numbers and the diversity in handling claims have resulted in some abuses under the Medicare program. Some suppliers exploited carrier jurisdiction policies by submitting claims only to those carriers whose claims review policies result in more inclusive or expansive determinations of Medicare coverage, or in higher payment amounts, for the items they supply.

Section 1834(a)(12) of the Act authorizes the Secretary to "designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section." When read in conjunction with sections 1834(a)(13) and (h)(3), the covered items include all covered durable medical equipment (DME), prosthetics, prosthetic devices, and orthotics. Other items for which claims may be processed by regional carriers include: home dialysis supplies and equipment; surgical dressings; immunosuppressive drugs; parenteral and enteral nutrients, equipment and supplies; and other items that we may designate, including those provided by a physician for home use, but not those items covered "incident to" a physician's service or bundled into a facility payment.

II. Provisions of the Final Rule With Comment Period

We published a final rule with comment period in the *Federal Register* on June 18, 1992 (57 FR 27290), that amended 42 CFR parts 405, 420, 421, and 424. The final rule had an effective date of August 17, 1992, with the comment period ending on August 17, 1992. The disclosure of ownership provisions were applied to new suppliers on August 17, 1992, and for all other suppliers on January 1, 1993. The supplier standards provisions were

applied to all suppliers on August 17, 1992. The requirement to use beneficiary residence claims jurisdiction for claims submitted to regional carriers were effective on July 1, 1993. This criterion will not be implemented until October 1, 1993, since it took longer to award the contracts than we anticipated. Claims will be transferred to the four durable medical equipment regional carriers (DMERCs) over a 5-month period beginning October 1, 1993.

The June 1992 final rule—

- Modified regulations to provide that claims for DMEPOS and certain other items covered under Part B of Medicare be processed by designated carriers.

- Specified the jurisdictions each designated carrier will serve, and changed the method by which claims for DMEPOS are allocated among the carriers from "point of sale" to "beneficiary residence."

- Established certain minimum standards for suppliers for purposes of obtaining supplier billing numbers.

- Incorporated in regulations certain supplier disclosure requirements imposed under section 1124A of the Act, as amended by section 4164 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), as a supplier standard that must be met before a supplier billing number is issued or renewed.

- Described the criteria and standards to be used beginning October 1, 1993, for evaluating the performance of designated carriers processing claims for DMEPOS in the administration of the Medicare program.

- Established that DMEPOS claims for RRB beneficiaries entitled to Medicare be processed by the DMERCs.

- Made the following technical changes:

- It revised the definition of "locality" to specify that a locality is the geographical area for which the carrier derives the reasonable charges or fee schedule amounts for services or items, and can include a State or larger area.

- It clarified that a regional DMEPOS carrier is exempt from the requirements of § 421.200 regarding carrier functions that apply to other carriers, by adding the phrase "other than a regional DMEPOS carrier." The DMERCs are bound, instead, by their contracts, which include most of the same functions.

- It allowed us to assign to DMERCs the processing of claims for Part B items not bundled into a physician or facility payment or provided as an integral part of a physician's service. (Claims for items sold or rented by a physician to his or her Medicare patients for home use will be processed by the DMERCs.)

- Added definitions for the acronym "DMEPOS" and the term "supplier". Defined "supplier" as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered items to Medicare beneficiaries under the standards of § 424.57(c), and an "enrolled supplier" is a supplier that has an active billing number.

III. Analysis of and Responses to Public Comments

In response to the June 1992 final rule with comment period, we received 22 timely items of correspondence. Comments were submitted from Medicare carriers, a Medicaid agency, various associations and organizations representing facilities and suppliers, medical and other professional individuals, and law firms. Some of the comments duplicated previous comments we received in response to the proposed rule we published on November 6, 1991 (56 FR 56612). A summary of individual comments and responses to our rule are discussed below:

Regionalization

Comment: Four commenters continue to recommend that the existing specialty carriers for parenteral and enteral nutrition (PEN) claims be retained.

Response: As we have previously responded (57 FR 27291), it would not be cost effective for us to retain these special arrangements when PEN claims can be processed just as correctly, but more efficiently, by the four DMERCs. One of the DMERCs is currently a PEN specialty carrier and will assist the other DMERCs in maintaining the national PEN program.

Comment: Another commenter again requested that there be a specialty carrier arrangement for home dialysis supplies.

Response: This arrangement would also not be an efficient or cost effective plan for the Medicare program. Claims for home dialysis supplies are very similar to other claims to be processed by DMERCs. The more claims that are pooled together, the lower the cost of processing a claim.

Comment: One commenter asked that suppliers be allowed to submit all their claims to one DMERC.

Response: Based on the residence of the beneficiary, suppliers must submit proper claims to one of four DMERCs. Suppliers may submit claims electronically or on paper. Suppliers who submit claims electronically may submit all of their claims to one DMERC, no matter where their customers reside. The DMERC receiving

the electronic submissions will forward claims (also electronically) to the appropriate DMERCs for processing and payment, although we will not be able to send electronic remittance notices for claims processed by other than the receiving DMERC. Pricing will continue to be done on a State-by-State basis and coverage and utilization rules will be established for each DMERC. A DMERC for one region will not maintain pricing and policy for another region.

Comment: One commenter relayed the following comments:

- It is too burdensome for doctors of medicine, osteopathy, and optometry to submit claims to the DMERCs for V code items such as cataract lenses and frames when they have to submit claims for professional services to local carriers.

- Submission of V code claims to the DMERCs is confusing for beneficiaries and carriers.

- Implementation of the OBRA '90 requirement, which limits the number of cataract lenses or eyeglasses per beneficiary to "one per lifetime" is difficult to implement.

Response: The V code situation is no different from that of claims for supplies submitted by physicians for items that they have sent home with beneficiaries, such as surgical dressings and ostomy bags. Since physicians are in competition with non-physician suppliers for these supply items, just as they are with non-physician suppliers that sell eyeglass frames, etc., it is proper that all claims for these items be adjudicated by the same processors. We do not believe that this is confusing for beneficiaries since the DMERCs will inform them that all items used at home are processed by the DMERC for their area. Local carriers will simply deny V code claims. Regionalization of V codes will not inhibit the implementation of the "one per lifetime" rule since the Common Working File (CWF) stores data on Medicare beneficiaries residing within the area, and contains information on all cataract patients.

Competition for Regional Carrier Contracts

Comment: One carrier believes the Request for Proposals (RFP) precluded its submission of a proposal.

Response: A full and open competition was held for the four regional carriers, and all potential offerors were given a chance to comment on a pre-solicitation notice before the issuance of the RFP. We believe the specific criteria, as well as the weights for those criteria, published in the RFP did not preclude the participation of any entity qualifying as a carrier.

Claims Jurisdiction Policy

Comment: One commenter asked that there be an exemption from basing the claims jurisdiction on a beneficiary's residence when the beneficiary resides within 60 miles of the border of a region or has more than one domicile or quasi-domicile.

Response: We do not agree with the commenter. Those exceptions would be very difficult to implement and monitor. Instead, we have structured the regions to limit the number of suppliers operating over regional borders. Also, only a small percentage of DMEPOS is purchased or rented by "snowbirds" who tend to be healthier than their less mobile counterparts. The small numbers of claims in each category do not justify the operational expense and effort that would be needed to implement the exceptions.

Standardization

Comment: Over half of the commenters restated that the transition to DMERCs should be done in conjunction with national standardization of DMEPOS coverage guidelines and utilization parameters.

Response: As we previously explained in the June 1992 final rule (57 FR 27298), in order to require standardization of DMEPOS coverage guidelines and utilization parameters, we would have to engage in a long and cumbersome process involving publication of each decision in the *Federal Register*. Instead, the Medical Director for each DMERC will determine the guidelines and parameters for his or her region after taking into account any national coverage policies and discussions with the other DMERC Medical Directors. We believe that the regional guidelines and parameters will be very similar in the four regions.

Comment: Two commenters recommended that we establish national pricing, with one suggesting local variations, for DMEPOS items.

Response: As we stated in our response to similar comments to the final rule (57 FR 27299), we are limited to the pricing areas prescribed by statute. We cannot establish national pricing without authorizing legislation.

Disclosure of Ownership and Control

Comment: One supplier asked that we not require information on subcontracting entered into before publication of the final rule.

Response: Section 1124A of the Act does not allow us to exclude this information. Section 1124A specifically requires a "disclosing part B provider," as defined in that section, to identify

each person with an ownership or control interest in the provider or in any subcontractor that the provider directly or indirectly has a 5 percent or more ownership interest.

Comment: One commenter asked that we define "significant business transaction" and shorten the period for reporting a transition from 5 to 3 years.

Response: The term "significant business transaction" is defined in § 420.201 "as any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of \$25,000 and 5 percent of the total operating expenses of the provider." This definition is unchanged by this regulation.

The 5-year requirement for reporting a "significant business transaction" is consistent with the reporting requirements for transactions for other Medicare providers. The 3-year period applies to the reporting of ownership or control interests (section 1124A(a)(2)(A) of the Act).

Comment: One commenter asked that we specify what records must be kept in order to comply with disclosure rules.

Response: No particular types of records are required.

Comment: Two other commenters insisted that disclosure of ownership requirements not be imposed on suppliers that do not accept assignment.

Response: Section 1833(e) of the Act gives us the general authority to obtain any information we need to pay part B claims correctly. We believe that this authority extends to ownership information, which can be relevant in determining whether there are outstanding overpayments for individuals involved with a supplier. We also believe that the disclosure provision in section 4164(b) of OBRA '90 also provides authority, as specified in section 1124A of the Act, to request information from all suppliers. The statute states that "No payment may be made under part B of title XVIII for items or services furnished by any disclosing part B provider unless such provider has provided the Secretary with full and complete information * * *." Under the statute, a "disclosing part B provider means any entity receiving payment on an assignment-related basis for furnishing items or services for which payment may be made under part B * * *." Even suppliers that do not "participate," that is, agree always to accept assignment, may accept assignment on any claim. The statute does not require that more than one assigned claim be presented, but does require that full disclosure be made before payment of that claim. Therefore, it is reasonable to require

disclosure routinely from all suppliers. It is also much more administratively efficient, since over 90 percent of all DMEPOS claims are, indeed, assigned.

We have made disclosure a supplier standard. All entities, including individuals selling personal property, must attest that they have made full and accurate disclosure in order to qualify as a Medicare supplier and to obtain and retain a billing number. However, claims submitted by beneficiaries for used equipment purchased from an individual selling personal property (for example, at a yard or garage sale) will be processed by the DMERCs, subject to all other claims processing rules such as physician certification of medical necessity.

Supplier Standards

Comment: Two commenters repeated their comments on the proposed rule that suppliers of DMEPOS should be held to health and safety standards.

Response: We explained in the June 1992 final rule (57 FR 27296) that we do not believe it would be appropriate to establish standards other than those business standards we have established for suppliers, since we only pay for the items themselves and not for the associated services. We also believe that those health and safety standards might be inappropriately stringent for small businesses causing them to have to discontinue their participation in the Medicare program and limiting access for Medicare beneficiaries.

Comment: Two commenters asked that there be a supplier standard that requires the acceptance of assignment on all claims for dually-eligible Medicare and Medicaid recipients.

Response: We do not have the statutory authority to implement this requirement.

Comment: One commenter requested that we modify the supplier standard on equipment returns to eliminate as a reason for return "not what the beneficiary thought they were purchasing", unless it was the supplier's mistake. They also want a time frame after which used items cannot be returned.

Response: Much of the "accepts return" standard merely acts as a warranty for areas where there are restricted warranties. The major innovation in this standard is to assure that beneficiaries understand what they are purchasing or renting. We believe that this is an appropriate business standard to impose on suppliers. They are in the best position to explain whatever options their physicians' prescriptions allow and the use, maintenance, purpose, etc., of the item.

We also do not believe that any given time limit would be appropriate for all types of items. Most defects or mistakes should be immediately apparent; others may not be discovered until after a period of reasonable use.

Supplier Numbers

Comment: One commenter asked that supplier number revocation notices include the reasons for the revocation and that before revocation an intermediate sanction, such as a temporary suspension, be imposed.

Response: Revocation notices include the reasons for the revocation, as well as how to appeal the decision.

Intermediate sanctions are not appropriate. The supplier standards define those entities for which Medicare allows payment for covered items and services. If an entity does not meet those standards, it cannot be paid. Suspension of payment merely would delay when an entity is paid.

Comment: One commenter believed that the 8-week period for final administrative review of a National Supplier Clearinghouse decision, with the concurrence of HCFA, to deny or terminate a supplier billing number, is too long. The commenter would prefer that either the administrative review period be shortened to 1 week or that claims be paid during the intervening 8 weeks.

Response: We do not agree with the commenter. Action to deny or terminate a supplier billing number is taken in only the most egregious cases. It would be inappropriate to continue to pay the suppliers, especially since, if the decision is upheld, there would be no monies coming due to the supplier from which to withhold the 8-week overpayment.

Complaint Log

Comment: One commenter asked that we clarify the amount of time that complaint files must be kept by suppliers.

Response: We recommend that complaint files, like any Medicare-related records, be kept for up to 7 years from the filing of a complaint, since the statute of limitations for fraud cases arising under the False Claims Act is 6 years. These files should help a supplier show its business practices for the entire period covered by any fraud complaint and the time it may take to prosecute the complaint.

Comment: One commenter thought there should be a limit on the amount of time beneficiaries have to lodge complaints about rented or purchased items.

Response: We do not agree that there should be a time limit. However, complaints about a newly purchased or rented item, depending on the seriousness of the complaint, are more compelling than a complaint on an item purchased 5 years ago.

Comment: Two commenters stated that some sort of due process procedures should be met before a DMERC can impose on a supplier the requirement to keep a fully documented complaint log. Three commenters stated that the complaint log requirement should be imposed only when there are repeated complaints of the same nature after the supplier has received verbal and written warnings.

Response: We do not view requiring a complaint log as a punishment but rather as an administrative requirement that will protect Medicare beneficiaries, the supplier, and the Medicare program when there are questions about the supplier's business practices. Some complaints or series of complaints are so serious that they will require a DMERC to act immediately. If appropriate, DMERCs will use verbal and written warnings. When there are questions about the business, it is a good business practice to keep detailed records of alleged problems.

Transition to DMERCs

Oversight

Comment: Two commenters asked that we oversee closely the transition to DMERCs.

Response: We agree with the commenters. Each DMERC has a detailed implementation plan that is being closely monitored by us.

Comment: Another commenter asked that administration of the DMERCs be handled by HCFA's central office.

Response: The project officer for each DMERC will be the Associate Regional Administrator for Medicare in the lead regional office for that DMERC. The following regional offices are lead regions:

- Region A DMERC—Philadelphia region.
- Region B DMERC—Chicago region.
- Region C DMERC—Dallas region.
- Region D DMERC—Seattle region.

Our central office will continue technical coordination and will monitor the implementation process.

Losing Carriers

Comment: Several of the commenters seemed to believe that local carriers would be "losing their contracts" when the DMEPOS claims are transferred.

Response: This is not true. DMEPOS claims are about 5 percent of the average

carrier's workload. Local carriers will continue to process all other types of Part B claims and to be subject to claims processing standards.

Comment: Since reviews and hearings would be handled by the local carrier or DMERC that processed the underlying claim, a commenter was concerned that local carriers might put a low priority on processing these reviews and hearings and that they might take years to resolve.

Response: Again, because these are carriers subject to evaluation and contract renewal each year we do not believe this will occur. If there is evidence of "slow downs", we should be notified.

Phase In

Comment: Two commenters repeated their request that the DMERCs be phased in by type of product rather than State.

Response: As we responded in the final rule with comment (57 FR 27293), we believe that phase in by product would impose a hardship on suppliers that provide more than one type of product. Also, it would be more costly for the Medicare program, which would have to continue the DMEPOS program in all local carriers until the last claims are transferred to the DMERCs.

Comment: Another commenter asked how multi-State suppliers would be handled in the transition.

Response: We will designate one DMERC as the National Supplier Clearinghouse for processing all supplier number applications and for housing files on all DMEPOS suppliers. The National Supplier Clearinghouse will, when re-enrolling all suppliers, ask multi-State suppliers if they wish to transfer all their claims to the DMERCs during the first month of regional processing. Suppliers whose claims constitute no more than 10 percent of all DMEPOS claims will be chosen for processing during the first month. All of their claims from the first date of processing will be handled by the DMERCs. All other multi-State suppliers will continue to bill as they have been billing. As a local carrier to which they have been billing is phased out of DMEPOS processing, the claims that they would have submitted to that carrier must be submitted to the appropriate DMERC(s). A multi-State supplier may, during the various transition months, be billing both local and regional carriers.

Information Transfer

Comment: One commenter emphasized the need to ensure that there is adequate transfer of beneficiary

information, provider numbers, coverage guidelines, and customary charge profiles to new carriers.

Response: The RFP clearly outlined the procedures that must be followed to perform a successful transition. Some of the necessary information, such as customary charge profiles, must be transferred from the local carriers. Beneficiary history and entitlement information is obtainable from the Common Working File. New national supplier numbers will be issued. In the absence of national coverage determination guidelines and medical review policies, a regional carrier will develop its own, in consultation with the other DMERCs.

Public Relations

Comment: One commenter asked that we closely monitor transition education for suppliers, beneficiaries, physicians, and carrier staff.

Response: The RFP was very explicit on these requirements. Their fulfillment, as outlined in each transition plan, will be closely monitored.

Payment Amounts and Policy

Comment: One commenter asked about how regional pricing and DMERC coverage and medical review policy would be implemented by carriers whose DMEPOS claims have not yet been incorporated into DMERC processing.

Response: Beginning January 1, 1993, the basis for pricing for items paid on the basis of reasonable charges was standardized to Statewide localities. These prices, as well as the fee schedule prices for DMEPOS, will be carried over and used by the DMERCs. PEN pricing is made on a national basis, and will continue to be, after transition to the DMERCs. The DMERCs will be establishing new coverage and medical review policies. These will not be used by the local carriers, which will continue to use their own policies on any DMEPOS claims that they process during the transition period.

Grandfathering

Comment: One commenter asked that beneficiaries be allowed to choose whether or not their claims are "grandfathered", by the DMERCs; that is, processed under the medical review guidelines of the local carrier that had previously processed their claims.

Response: We believe this would be inappropriate and would lead to inequitable results. Instead, each DMERC will determine, in consultation with the other DMERCs, a beneficiary-specific "grandfathering" policy for a

limited time. This policy will take into account the types of DMEPOS involved, the beneficiary's condition, and whether or not the beneficiary resides at home or in a nursing home.

PEN Claims

Comment: One commenter stated that DMERC staff should receive thorough training on PEN issues with input from the PEN industry. The association further requested that there be separate medical review staff for PEN claims.

Response: DMERC staff will receive thorough training on PEN and other benefits. Some DMERCs may choose to request PEN industry input to this training. Each DMERC will determine whether it will have medical review staff who specialize in PEN claims.

Comment: A commenter asked that DMERCs implement a streamlined process for approving new PEN products.

Response: We will develop a process with the DMERCs to assure timely determination of coverage for PEN and other DMEPOS items. Regional and national coverage decisions will be announced in quarterly newsletters that are published by each DMERC for its area, as well as by written response to those who request the decision.

Electronic Claims

Comments: One commenter asked that we correct the modifications of fields made by local carriers to the national standard format (NSF) adopted by us for submission of Part B electronic claims, before transition to the regional carriers.

Response: All local carriers are required to accept the NSF without modifications. Suppliers can change to using the NSF now, so that the conversion to regional processing will be easier.

Comment: Another commenter asked that we modify the NSF certificate of medical necessity for PEN claims or use another existing PEN software package rather than NSF.

Response: It is most efficient for Medicare to use one national format, and we have chosen the NSF. A PEN certification form is being developed under the NSF.

Non-Calendar Month Billing

Comment: One commenter asked that suppliers that bill for a month's worth of supplies, when the start of the billing period does not coincide with the first day of the month, be allowed to bill their existing local carriers, as usual, for the month before their claims are transferred to the DMERCs.

Response: We agree with the commenter.

Advance Payments

Comment: Six commenters wanted assurance that advance payments would be available during the transition to the DMERCs, both for claims payable by the local carriers before transition to the DMERCs and for claims payable by the DMERCs.

Response: As we stated in the June 1992 final rule (57 FR 27292), there will be no special advance payment rules for DMEPOS claims. We are developing a regulation that will prescribe the conditions under which Medicare will make advance payments. We will issue instructions in the Medicare Carriers Manual before the transition to the new regional carriers. These instructions will prescribe how to handle advance payments, to the extent permissible, during the interim period before publication of the final regulation.

Supplier Review Council

Comment: Two commenters suggested that there be a supplier council to review and support the DMERC transition plan and implementation.

Response: We are interested in support from the supplier community during the transition to regional DMEPOS processing. We are particularly interested in any perceived problems with the transition plan and process. However, we do not believe that it would be appropriate for suppliers or their representatives to participate in the government's transition team or process.

DMERC Operations Policy

Comment: One commenter asked that the beneficiary and supplier communities be given 45 days notice of any HCFA directive and a penalty for retroactive implementation. Two commenters requested that there be no retroactive changes in coverage, payment, etc.

Response: We do not believe that one rule would be correct for all types of directives. Some HCFA directives are due to court orders or legislative and budget changes. If they require immediate implementation, the effect may, in fact, be retroactive for suppliers that submit claims between HCFA's notice to the carriers and the carrier's notice to the suppliers. Other HCFA directives are the result of changes in regulations. Before implementing a regulation change, we publish a proposal of our intentions and generally allow a 60-day public comment period.

Except in unusual circumstances, a final regulation is not effective until 30 days after its publication in the **Federal Register**. Still other directives are the result of administrative changes, some of which are transparent to beneficiaries and suppliers. The degree of impact on the supplier and beneficiary communities generally dictates the amount of notice that is given for these directives. In addition, carriers set their own policies in certain areas when no national coverage policy is available. Carrier-developed coverage and medical review policy is subject to notice and comment requirements. Currently, a 45-day comment period is required; 30 days notice of a change is also required. Changes in pricing due to inherent reasonableness determinations have similar notice and comment requirements. Other types of changes, such as those due to mistakes in pricing that need to be corrected, are not subject to notice and comment requirements, since immediate correction of processing errors is in the best interest of the Medicare program.

Comment: Two commenters asked that the DMERCs be required to publish the utilization parameters and screens.

Response: We currently require publication in carrier bulletins of our policy for establishing utilization parameters and screens according to which claims are adjudicated. We are currently studying the effect the release of the parameters would have on utilization.

Supplier Review

Comment: One supplier commented that all suppliers under special review or operating outside normal parameters should be notified by the DMERCs.

Response: Many of those suppliers will be notified and asked to provide information or an explanation. However, we do not generally notify a supplier that is under review for suspected fraud, unless we confirm the supplier is acting inappropriately.

Supplier Relations

Comment: One commenter asked that we require that the carrier medical directors "directly consult" with representatives of the supply industry and beneficiaries twice per year: that is, physicians, nursing home administrators, suppliers, carriers, home health agencies, and consumers.

Response: The DMERCs are required by the RFP to conduct training and/or provide information to all parts of the DMEPOS industry, beneficiaries, physicians, etc. The plans will differ somewhat among the regions depending on variables such as the size of the

region and the cooperation of local carriers, intermediaries, and professional and beneficiary representative associations. In addition, the DMERCs are required to consult with representative organizations on all new medical review policy.

Beneficiary Data

Comment: Two commenters again asked that suppliers be given access to the Common Working File or other beneficiary system to confirm beneficiary eligibility.

Response: There are always privacy considerations in the release of beneficiary information contained in the Common Working File system. We will be initiating next year several tests to determine the effects of disclosing beneficiary information to participating doctors (and one supplier) meeting predetermined requirements.

Comment: Another commenter asked that we establish a system that suppliers could use to confirm a beneficiary's residence.

Response: We previously stated in the June 1992 final rule (57 FR 27294) that we do not believe this is necessary. Permanent residence is defined as the address at which a beneficiary intends to spend over 6 months of the calendar year. If a beneficiary moves to another address with the intent to stay at that address for over 6 months of the calendar year, then that address becomes the permanent residence. Thus, only the beneficiary can designate his or her permanent residence. A supplier must obtain permanent residence information from its customer, the beneficiary, or his or her authorized representative.

Crossover Claims

Comment: Three commenters asked that we require the DMERCs to furnish deductible and coinsurance information via electronic media to State Medicaid agencies and that they also provide State Medicaid agencies with copies of provider memoranda and pricing information.

Response: Each DMERC is required to negotiate crossover agreements with each Medicaid agency in its region in sufficient time to implement those agreements before they begin processing claims. During those negotiations, each State Medicaid agency will be able to come to agreement with the region's DMERC about what information, in addition to the claims, they would like to receive from the DMERC.

Criteria and Standards for Evaluating DMERC Performance

Additional Performance Standards

Comment: One commenter suggested a performance standard for the timely response to requests for information under the Freedom of Information Act (FOIA).

Response: Requests for information under the FOIA that are received directly by our contractors are responded to within 6 days after the requests are reviewed and approved for release either by our regional office or our central office. Therefore, we do not believe it would be appropriate to require a performance standard for our contractors for this activity.

Comment: Three commenters suggested a performance standard for the accuracy with which the DMERC identifies a claim as "clean".

Response: "Clean" claims are defined in sections 1816(c)(2)(B)(i) and 1842(c)(2)(B)(i) of the Act as "a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim". We do not believe that there is a significant problem among our contractors in identifying claims as "clean claims." However, we will continue to monitor our contractors on this issue and, if circumstances change, we will further evaluate the situation.

Comment: Two commenters suggested performance standards to evaluate the capability of the DMERCs to perform certain functions, that is, automated crossovers, system/software testing, and retention of staff knowledgeable in the home medical equipment field.

Response: Minimum standards were included in the RFP. Those standards will be incorporated into the DMERC's contract. If the DMERCs do not meet the RFP standards, they are subject to contract termination. The above capabilities were appropriately evaluated as a part of the procurement process used for selecting the DMERCs.

Comment: Five commenters suggested performance standards for timely claims processing, correct payment of fees, timely processing of reviews and hearings, and timely implementation of our directives.

Response: These suggestions have already been made a part of proposed criteria and standards. The timeliness of claims processing is evaluated under the Efficiency Criterion, Standard 1 (95.0 percent of clean claims processed within mandated timeframes and 97.0 percent of all claims must be processed

within 60 days). The correct payment of fees is evaluated under the Quality Criterion, Standard 1. (Claims must be processed at an accuracy rate of 98.5 percent.) The timeliness of processing reviews and hearings is evaluated under the Service Criterion, Standard 1 (95.0 percent of reviews and hearings must be accurate and timely). Our directives are issued to Medicare contractors with specific implementation dates. None of our directives are retroactively applied.

Comment: One commenter suggested that we conduct customer satisfaction surveys regarding the DMERC's handling of inquiries.

Response: While customer satisfaction surveys currently are not a part of the criteria and standards, we are proposing to include a national survey of physician satisfaction in the evaluation of Medicare carriers for FY 1994. Consideration will be given to developing a customer satisfaction survey for evaluating the DMEPOS after we have had an opportunity to study the results from the national physician survey.

Comment: One commenter suggested that we establish a performance measure of provider interaction in setting coverage and medical necessity policies.

Response: This suggestion has already been included as a part of the DMEPOS criteria and standards under the Service Criterion, Standard 3 (Respond to Beneficiary and Supplier Education and Training Needs).

Comment: One commenter suggested an evaluation of the clarity and accuracy of communications including education materials and DME-specific Explanation of Medicare Benefits.

Response: This suggestion has also been included as a part of Standard 3 of the Service Criterion.

Revisions/Clarifications to Proposed Criteria and Standards

Comment: One commenter suggested tighter claims processing timeliness standards.

Response: We believe that requiring DMERCs to process 95.0 percent of clean claims within mandated timeframes (currently set at 15 to 24 days) to be reasonable and appropriate in light of similar timeframes for processing of all other Part B claims.

Comment: One commenter suggested that we evaluate the DMERCs' responsiveness to inquiries by posing as beneficiaries or suppliers.

Response: As a part of our evaluation of the DMERCs' performance in responding to beneficiary and supplier inquiries, Standard 1 of the Service Criterion, we propose the use of questions called in to the DMERCs to

test the accuracy of responses on a variety of topics. However, we believe it would be inappropriate to "pose" as a beneficiary or supplier.

Comment: One commenter asked how we would evaluate the processing of specific claim types, for example, PEN, DME, prosthetics, orthotics, and other claim types.

Response: All claim types will be evaluated under the criteria and standards together without distinction for the type of service or supply billed.

Comment: One commenter asked for definitions of "mandated timeframes" and "clean claims."

Response: As previously noted, the term "clean claim" is defined in sections 1816(c)(2)(B)(i) and (c)(2)(B)(ii) as "a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment". The term "mandated timeframes" is used to refer to the timeframes established in sections 1816(c)(2)(B)(ii) and 1842(c)(2)(B)(ii). These timeframes may change as new legislation is enacted. The claims processing timeliness performance standards use the terms "clean claim" and "mandated timeframe" to automatically apply whatever specific changes may occur in legislation.

Performance Standards for Local Carriers During Transition

Comment: One commenter suggested that local carriers should be persuaded to continue to expedite appeals and hearings in a reasonable timeframe.

Response: Part B carriers will be evaluated under the Contractor Performance Evaluation Program for their processing of all reviews and hearings, including DMEPOS claims previously processed, during Fiscal Year 1994. We will be closely monitoring the performance of a DMERC's Part B contractors in a number of key areas related specifically to the handling of DMEPOS claims and corollary issues. We do not anticipate any increase in the amount of time that it takes to expedite appeals and hearings.

Relative Weight of Proposed Performance Standards

Comment: One commenter suggested that we publish the weights of the performance standards.

Response: The criteria and standards reflect an evaluation of the most important functions to be performed by the DMERCs. They are not intended to evaluate every activity performed by the carriers. Thus, all performance

standards are given equal value; no points or weights are assigned to the individual standards. All standards are pass or fail, requiring the carriers to meet all performance requirements to "pass" the standard.

IV. Provisions of the Final Regulations

The provisions of this final rule that differ from the June 1992 final rule follow.

- In § 421.210(e)(2), we have identified the four DMERCs that will process DMEPOS claims for all Medicare beneficiaries residing in their respective regions (the boundaries of the four regions for processing DMEPOS claims is defined in § 421.210(c)), including those entitled to benefits under the Railroad Retirement Act. Those DMERCs will be The Travelers Insurance Company (Region A), which will be processing claims in Pennsylvania; Associated Insurance Companies, Inc.—AdminaStar (Region B), which will be processing claims in Indiana; Blue Cross and Blue Shield of South Carolina (doing business as Palmetto Government Benefits Administrators) (Region C), which will be processing claims in South Carolina; and Connecticut General Life Insurance Co. (a CIGNA Company) (Region D), which will be processing claims in Tennessee.

- In § 421.210(e)(3), we have indicated that Blue Cross and Blue Shield of South Carolina (Palmetto Government Benefits Administrators) has been selected to serve as both the National Supplier Clearinghouse and the Statistical Analysis DMERC (SADMERC).

The regionalization of DMEPOS claims processing presents the opportunity to consolidate the identification and ownership data of all DMEPOS suppliers in the Medicare program. The consolidated supplier files will allow a central entity, called the National Supplier Clearinghouse, to identify and associate suppliers which are serving multiple areas.

The SADMERC will have four primary functions:

- To coordinate the interpretation of certain DMEPOS codes and modifiers.
- To analyze and distribute national DMEPOS claims history data and store up to 3 years of those data.
- To establish and distribute to the DMERCs certain national pricing files.
- To conduct comprehensive postpayment review of national suppliers.

- We have added a new § 421.212, which states that the RRB contracts with the DMERCs.

V. Collection of Information Requirements

This final rule does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

VI. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we do not consider carriers to be small entities, therefore an RFA is not required.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. Because claims for DMEPOS submitted by hospitals will not be moved to regional carriers, there will be no impact on hospitals.

This final rule identifies the four DMERCs that will process DMEPOS claims for all Medicare beneficiaries residing in their respective regions, including those beneficiaries entitled to Medicare as Railroad Retirement beneficiaries.

We believe naming the four DMERCs will lead to more efficient and economical administration of the

Medicare program. In addition, there will be additional savings attributable to both the prevention of fraud and the more effective and timely identification of fraud.

Although we have the authority under section 1842 of the Act to select carriers non-competitively, we chose to use a competitive process. A pre-solicitation notice for comment was issued in January, 1992. An RFP was issued in May 1992. We received proposals from qualified offerors including some Medicare carriers. The offerors were not restricted to a particular region, and several did apply to be the DMERC for more than one region.

General criteria for designating the DMERCs are included in § 421.210(d); specific criteria were included in the RFP. Technical excellence was a primary consideration in the selection process. We expect to achieve a greater degree of effectiveness and efficiency of the Medicare program as measured by—

- Timeliness of claims processing;
- Cost per claim;
- Claim processing quality;
- Experience in claims processing and in establishing local medical review policy; and
- Other criteria that HCFA believes to be pertinent.

The DMERC contracts are for a 2-year period with an option for two 1-year extensions. The contracts, though they were effective January 1, 1993, allow a 9-month implementation period. Therefore, the DMERCs are scheduled to begin processing DMEPOS claims on October 1, 1993. The National Supplier Clearinghouse contract is for 1 year, with three 1-year extensions, and the Statistical Analysis DMERC contract is for 2 years, with two 1-year extensions.

Section 421.212 of this final rule states that the RRB contracts with DMERCs for processing Medicare claims for Railroad Retirement beneficiaries for the same contract periods as the contracts entered into between HCFA and the DMERCs. This arrangement will promote efficiency by subjecting claims for DMEPOS services provided to Railroad Retirement beneficiaries to the same Medicare review policy and pricing schedules. By using the DMERCs for RRB claims, suppliers furnishing services to railroad retirees will be able to submit that limited number of claims via the electronic media approved for submission for Medicare claims to the DMERCs. Claims for DMEPOS items to railroad retirees account for approximately 4 percent of the total DMEPOS claims.

This final rule will not meet the \$100 million criterion nor will it meet the other E.O. 12291 criteria. Therefore, this

final rule is not a major rule under E.O. 12291, and a regulatory impact analysis is not required.

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

List of Subjects in 42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR part 421 is amended as follows:

PART 421—INTERMEDIARIES AND CARRIERS

1. The authority citation for part 421 continues to read as follows:

Authority: Secs. 1102, 1815, 1816, 1833, 1834 (a) and (h), 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395l, 1395m (a) and (h), 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b-1.

2. In § 421.210, paragraph (e)(2) is revised, and new paragraphs (e)(3) and (e)(4) are added to read as follows:

§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

* * * * *

(e) *Carrier designation.*

* * * * *

(2) The regional carriers designated to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated in paragraph (c) of this section), including those entitled under the Railroad Retirement Act, are the following:

(i) The Travelers Insurance Company (Region A), which will be processing claims in Pennsylvania.

(ii) Associated Insurance Companies, Inc.—AdminaStar (Region B), which will be processing claims in Indiana.

(iii) Blue Cross and Blue Shield of South Carolina (doing business as Palmetto Governments Benefits Administrators) (Region C), which will be processing claims in South Carolina.

(iv) Connecticut General Life Insurance Co. (a CIGNA Company) (Region D), which will be processing claims in Tennessee.

(3) Blue Cross and Blue Shield of South Carolina (Palmetto Government Benefits Administrators) has been

selected to serve as the National Supplier Clearinghouse and the Statistical Analysis DME regional carrier.

(4) The contracts for the four DME regional carriers will be periodically recomputed. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier do not constitute separate contracts, but are contract amendments to one of the DME regional carrier contracts. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier contract amendments will also be periodically recomputed.

* * * * *

3. A new § 421.212 is added to read as follows:

§ 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by HCFA, as set forth in § 421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between HCFA and the DMEPOS regional carriers.

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

Dated: August 13, 1993.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: September 30, 1993.

Donna E. Shalala,
Secretary.

[FR Doc. 93-28160 Filed 11-17-93; 8:45 am]
BILLING CODE 4120-01-P

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1035

[Ex Parte No. 495]

Bills of Lading

AGENCY: Interstate Commerce Commission (ICC).

ACTION: Final rule.

SUMMARY: The Commission revises its regulations pertaining to railroad and water carrier uniform bills of lading and livestock contracts. The purpose of the revision is to clarify the terms, to remove obsolete references and to permit railroads and shippers mutually to make changes to the language on the front of the bill of lading, as set forth

below. The intended effect is to make the rules understandable and to bring information requirements into conformity with modern billing and accounting practice.

EFFECTIVE DATE: December 18, 1993.

FOR FURTHER INFORMATION CONTACT:

Joseph H. Dettmar (202) 927-5660 or Andrew J. Nosacek (202) 927-5318; TDD for hearing impaired: (202) 927-5721.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was published in the Federal Register, (58 FR 34775) on June 29, 1993. Additional information is contained in the Commission's decision served November 18, 1993. To obtain a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289-4357/4329. (Assistance for the hearing impaired is available through TDD services (202) 927-5721.)

We reaffirm our initial finding that this action will not significantly affect either the quality of the human environment or the conservation of energy resources.

We reaffirm our initial conclusion that our action in this proceeding will not have a significant economic impact on a substantial number of small entities. The purpose of this action is to clarify language in the existing regulations and to reduce a regulatory burden. The economic impact on small entities, if any, is not likely to be significant within the meaning of the Regulatory Flexibility Act.

List of Subjects in 49 CFR Part 1035

Bills of lading, Railroads, Water carriers.

Decided: November 3, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,
Secretary.

For the reasons set out in the preamble and the Commission's decision, the Interstate Commerce Commission amends title 49, chapter X, part 1035 of the Code of Federal Regulations as follows:

Part 1035 is revised to read as follows:

PART 1035—BILLS OF LADING

Sec.

1035.1 Requirement for certain forms of bills of lading.

1035.2 Modification of front of uniform bill of lading.

Sec.

Appendix A to Part 1035—Uniform Straight Bill of Lading.

Appendix B to part 1035—Contract Terms and Conditions.

Authority: 49 U.S.C. 10321 and 5 U.S.C. 553.

§ 1035.1 Requirement for certain forms of bills of lading.

(a) All common carriers, except express companies, engaged in the transportation of property other than livestock and wild animals, by rail or by water subject to the Interstate Commerce Act are required to use straight bills of lading as prescribed in Appendix A and B to this part, or order bills of lading as prescribed in Appendix A and B to this Part, except that order bills of lading shall:

(1) Be entitled "Uniform Order Bill of Lading" and be designated as "Negotiable" on the front (appendix A to this part);

(2) Indicate consignment "to the order of * * *" on the front (appendix A to this part); and

(3) Provide for endorsement on the back portion (appendix B to this part).

(b) All such bills of lading:

(1) May be either documented on paper or issued electronically;

(2) May be a copy, reprographic or otherwise, of a printed bill of lading, free from erasure and interlineation;

(3) May vary in the arrangement and spacing of the printed matter on the face of the form.

§ 1035.2 Modification of front of uniform bill of lading.

Notwithstanding any other provision of § 1035.1(a), with respect to the information called for, the front portion only (appendix A to this part) of a bill of lading may deviate from the language prescribed in this part so long as the deviation conforms with approved national standards for the electronic data interchange or other commercial requirements for bill of lading information; *provided* that no such deviation in the language shall affect the obligations of any shipper to provide information absent the consent of such shipper nor shall such deviation be deemed to alter any rights or obligations conferred by statute or regulation on either carriers or shippers with respect to the preparation or issuance of bills of lading.

Appendix A to Part 1035

Uniform Straight Bill of Lading

Original—Not Negotiable

Shipper's No _____

Agent's No _____

Company _____