### III. Sources of Information

EPA has developed lists of oil re-refiners and manufacturers of recycled building insulation products. In addition, EPA has obtained a national list of retreaders, broken down by state, from the National Tire Dealers and Retreaders Association. These lists are updated periodically as new sources are identified and product information changes. Procuring agencies should contact the manufacturers to discuss their specific needs and to obtain detailed information on the price and availability of recycled products meeting those needs. To assist procuring agencies, the lists are available at no charge by calling the Procurement Guidelines Hotline at (703) 941–4452. They also can be reviewed in the RCRA public docket, which is located at EPA headquarters in Washington, DC. The address for the docket and procedures for reviewing and copying information are described above under **ADDRESSES**. The docket numbers are F–91–RLOA–FFFFF for re-refined oil, F–91–PRTA–FFFFF for retread tires, and F–91–PIPA–FFFFF for building insulation products.

In addition to EPA's list, there are other publicly available sources of information about re-refined lubricating oils, retread tires, and building insulation products. For example, the Official Recycled Products Guide (RPG) was established in March 1989 to provide a broad range of information on recycled products. Listings include product, company name, address, contact, telephone, fax, type of company (manufacturer or distributor), and minimum recycled content. As with EPA's lists, price information is not included. The RPG is available on a subscription basis from American Recycling Market Inc., 1–800–267–0707.

State and local recycling programs are a potential source of information on local distributors, product price, and availability. In addition, state and local government purchasing offices that are contracting for recycled products may have price and availability information. A list of state purchasing/procurement officials has been placed in the RCRA public docket and will be updated periodically. Table 1 contains a list of states with recycled products purchasing programs, current as of June 1, 1991.

Information is also available from the re-refiners, retreaders, and insulation trade associations. Table 2 identifies the name, address, and telephone number of these associations.

Dated: August 27, 1991.

**Don R. Clay,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

TABLE 1.—STATES WITH RECYCLED PRODUCTS PROCUREMENT PROGRAMS AS OF JUNE 1, 1991

| State | Law | Basis of program | |
|---|---|---|---|
| | | Executive order | Resolution |
| Alaska | X | | |
| Arizona | X | | |
| Arkansas | | X | |
| California | X | | |
| Colorado | X | X | |
| Connecticut | X | | |
| Dist. of Columbia | X | | |
| Florida | X | | |
| Georgia | X | | |
| Hawaii | X | | |
| Illinois | X | X | |
| Indiana | X | | |
| Iowa | X | X | |
| Kansas | | X | |
| Kentucky | | X | |
| Louisiana | X | | |
| Maine | X | | |
| Maryland | X | | |
| Massachusetts | X | X | |
| Michigan | X | X | |
| Minnesota | X | X | |
| Mississippi | X | | |
| Missouri | X | | |
| Nebraska | | X | |
| New Hampshire | X | | |
| New Jersey | X | | |
| New Mexico | X | | |
| New York | X | X | |
| North Carolina | X | | |
| North Dakota | X | | |
| Ohio | X | X | |
| Oklahoma | X | | |
| Oregon | X | | |
| Pennsylvania | X | | |
| Rhode Island | X | | |
| Tennessee | X | | |
| Texas | X | | |
| Utah | | | X |
| Vermont | X | | |
| Virginia | X | | |
| Washington | X | | |
| West Virginia | X | | |
| Wisconsin | X | | |

Sources: American Paper Institute; Richard Keller, Northeast Maryland Waste Disposal Authority; and E.H. Pechan & Associates

TABLE 2.—TRADE ASSOCIATIONS

Oil:
Association of Petroleum Re-refiners
P.O. Box 605
Buffalo, NY 14205
716–855–2757

Tires:
American Retreaders Association
P.O. Box 17203
Louisville, KY 40217
502–361–9219

National Tire Dealers & Retreaders Association
Suite 400
1250 I Street N.W.
Washington, DC 20005
202–789–2300

Tire Retread Information Bureau
900 Weldon Grove
Pacific Grove, CA 93950
408–372–1917

Building Insulation Products:
Cellulose Insulation Standards Enforcement Program
610 Centre City Offices
Dayton, OH 45402
513–222–1024

Society of the Plastic Industry:
Polyurethane Division
355 Lexington Avenue
New York, NY 10017
212–351–5425

Polyurethane Foam Contractors Division
1275 K Street N.W.
Suite 400
Washington, DC 20005
202–371–5313

Polystyrene Division
1275 K Street N.W.
Suite 400
Washington, DC 20005
202–371–5200

Mineral Insulation Manufacturers Association
1420 King Street
Alexandria, VA 22314
703–684–0084

Thermal Insulation Manufacturers Association
8341 S. Sangre Decristo Road
Littleton, CO 80127
303–933–9774

[FR Doc. 91–21133 Filed 9–3–91; 8:45 am]
BILLING CODE 6560–50–M

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## 40 CFR Parts 262 and 271

[SW–FRL–3987–8]

## Hazardous Waste Management System; Exports of Hazardous Waste; Final Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final Rule; Technical correction to notification of intent to export and annual reports.

**SUMMARY:** On August 8, 1986 (51 FR 28664), EPA promulgated a final rule that applies to exports of hazardous waste. Section 262.53 of these regulations requires, among other things, that exporters send to EPA's Office of

International Activities advance written notification of their plans to export hazardous waste. In addition, a "note" at the conclusion of § 271.10(e)(2) designates the Office of International Activities as recipient of export notifications required under § 262.53. Section 262.56 of the regulations also requires exporters to send annual reports to the same EPA office. This technical correction provides that such notifications and annual reports must henceforth be sent to EPA's Office of Waste Programs Enforcement.

**EFFECTIVE DATE:** September 4, 1991.

**FOR FURTHER INFORMATION CONTACT:** For general information, contact the RCRA/Superfund Hotline, toll free at (1–800) 424–9346. For specific questions on this notice, contact Ms. Angela Cracchiolo, U.S. Environmental Protection Agency, Office of Solid Waste (OS–332), 401 M Street, SW., Washington, DC 20460, (202) 382–4779.

**SUPPLEMENTARY INFORMATION:**

**I. Technical Correction**

On August 8, 1986, the U.S. Environmental Protection Agency published final regulations under the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), that apply to exports of hazardous waste (51 FR 28664). In March of 1991, the hazardous waste export and import administrative responsibilities of the Office of International Activities (OIA) were transferred to the Office of Waste Programs Enforcement (OWPE). EPA is today amending §§ 262.53, 262.56, and the "Note" contained in 271.10(e)(2) by changing the address exporters should use for Notification of Intent to Export and for submitting annual reports to: Office of Waste Programs Enforcement, RCRA Enforcement Division (OS–520), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, with "Attention: Notification to Export" prominently displayed on the front of the envelope.

EPA finds that it has good cause to make the corrections immediately effective and to promulgate the amendments without prior notice and opportunity to comment under both section 3017 of RCRA and section 553 of the Administrative Procedure Act. Comment is unnecessary because the technical correction will have no impact on the regulated community; it simply substitutes on EPA office for another as the recipient for the Notices of Intent to Export and the annual reports that must be sent to EPA by the exporter. Good cause also exists to make the corrections immediately effective. The transfer of responsibilities from OIA to OWPE has already occurred, and OIA will forward to OWPE any notifications it receives after the effective date of these corrections.

**II. Executive Order No. 12291—Regulatory Impacts**

Under Executive Order No. 12291, EPA must determine whether a regulation is "major" and is subject to the requirement to prepare a regulatory impact analysis. Major rules are defined as those which are likely to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices for consumers or individual industries, or significant adverse effects on competition, employment, investment, productivity, innovation, or international trade. Today's amendment merely corrects the address hazardous waste exporters must use to comply with the regulations and statute and does not impose new requirements, so it does not have an economic impact. Thus it is not a "major" rule.

**III. Paperwork Reduction Act**

Under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., EPA must consider the paperwork burden imposed by any information collection request in a proposed or final rule. This rule will not impose any new information collection requirements.

**IV. Regulatory Flexibility Act**

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., EPA must prepare a regulatory flexibility analysis for all rules unless the Administrator certifies that the rule will not have a significant impact on a substantial number of small entities. Accordingly, I hereby certify, pursuant to 5 U.S.C. 601(b), that this rule will not have a significant impact on a substantial number of small entities because it is merely an address change.

**List of Subjects in 40 CFR Parts 262 and 271**

Administrative practice and procedure, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Water pollution control, and Water supply.

Dated: August 12, 1991.

**Don R. Clay,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

For the reasons set out in the preamble, title 40 of the Code of Federal Regulations is amended as follows:

## PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

1. The authority citation for part 262 is revised to read as follows:

**Authority:** 42 U.S.C. 6906, 6912(a), 6922, 6923, 6924, 6925, 6937 and 6938.

2. Section 262.53 is amended by revising paragraph (b) to read as follows:

**§ 262.53 Notification of intent to export.**

* * * * *

(b) Notification shall be sent to the Office of Waste Programs Enforcement, RCRA Enforcement Division (OS–520), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460 with "Attention: Notification to Export" prominently displayed on the front of the envelope.

* * * * *

3. Section 262.56 is amended by revising paragraph (b) to read as follows:

**§ 262.56 Annual reports.**

* * * * *

(b) Reports shall be sent to the following address: Office of Waste Programs Enforcement, RCRA Enforcement Division (OS–520), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

## PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

1. The authority citation for Part 271 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), and 6926.

2. Section 271.10(e)(2) is amended by revising the note to read as follows:

**§ 271.10 Requirements for generators of hazardous wastes.**

* * * * *

**Note:** Such notices shall be mailed to the Office of Waste Programs Enforcement, RCRA Enforcement Division (OS–520), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

* * * * *

[FR Doc. 91–21137 Filed 9–3–91; 8:45 am]

BILLING CODE 6560–50–M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**42 CFR Parts 405, 410, 413, and 414**

**[BPD-737-IFC]**

**RIN 0938-AE52**

# Medicare Program; Coverage of Erythropoietin (EPO) Used by Competent Home Dialysis Patients

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

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This final rule—

- Provides for Medicare coverage of EPO used by ESRD beneficiaries who dialyze at home and are competent to use the drug without medical or other supervision; and
- Establishes criteria for selection of patients that can be considered "competent" and for monitoring of the patients who are selected.

This rule is necessary to implement section 4201(d)(1) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). The purpose is to facilitate use of EPO at home, while ensuring that such use of the drug is safe and effective.

**DATES:** *Effective date:* These rules are effective September 4, 1991. *Comment date:* We will consider comments received by November 4, 1991.

**ADDRESSES:** Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-737-IFC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC,
or
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept audio or video comments or facsimile (FAX) copies of comments. In commenting, please refer to file code BPD-737-IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 245-7890).

**COPIES:** To order copies of the **Federal Register** containing this comment, send your request to: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 275-6802. The cost for each copy (in paper or microfiche form) is $1.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. The order desk operator will be able to tell you the location of the U.S. Government Depository Library nearest to you.

**FOR FURTHER INFORMATION CONTACT:** Anne Marie Hummel, (301) 966-4637.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Chronic renal failure (CRF) is a progressive and usually irreversible decline in kidney function that does not always require regular dialysis. However, CRF patients who have end-stage renal disease do require a regular course of dialysis or kidney transplantation in order to sustain life.

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603) established the Medicare ESRD benefit by extending coverage to any individual who requires either dialysis or transplantation, and meets the following requirements:

- Is fully or currently insured or entitled to monthly benefits under title II of the Social Security Act; or
- Is the spouse or dependent child of the insured or entitled individual.

The methods and amounts of payment for services to ESRD patients have changed over the years and are currently set forth in §§ 410.50 and 413.170-413.179 of the HCFA rules. Law and program policy have moved over the years towards encouraging greater use of self-dialysis and home dialysis.

On June 1, 1989, the Food and Drug Administration approved the drug erythropoietin (EPO). EPO is a sterile, colorless, preservative-free, liquid, biologically engineered protein that stimulates the bone marrow to make new red blood cells. EPO may be covered under the Medicare program when used to treat anemia associated with chronic renal failure. Most chronic renal failure patients are anemic because their kidneys are unable to produce sufficient amounts of erythropoietin.

Patients with this condition include those who require renal dialysis and are eligible for Medicare under the endstage renal disease (ESRD) provisions of the law. EPO may be administered either intravenously or subcutaneously for the treatment of anemia associated with chronic renal failure. Individuals with chronic renal failure use the drug to elevate or maintain the red blood cell level (as measured by the hematocrit or hemoglobin level) and to decrease the need for blood transfusions. Chronic renal patients considered for EPO therapy should generally have a hematocrit of less than 30 percent.

In July, 1989, we issued instructions in the Provider Reimbursement Manual-Part 1 (Chapter 27, Transmittal 11) authorizing Medicare contractors to start paying for the drug EPO, as of June 1, 1989. Coverage instructions were issued in November 1989 in the Intermediary Manual-Part 3 (Transmittal 1449), Carriers Manual-Part 3 (Transmittal 1329), Hospital Manual (Transmittal 576) and the Renal Dialysis Facility Manual (Transmittal 42). The effective date of the coverage instructions was also June 1, 1989. The Medicare regulations were not amended at that time.

Before enactment of Public Law 101-508 (OBRA '90), home use of EPO was not covered. For patients who dialyzed at home to receive Medicare payment for EPO, the drug had to be administered either in an ESRD facility or as a service "incident to" a physician's professional services.

## II. Statutory Provisions

Section 4201(d)(1) of OBRA '90 amended section 1861(s)(2) of the Act by adding a new subparagraph (Q) that—

- Provides for coverage of EPO that is used by home dialysis patients who are competent to use the drug without medical or other supervision and for coverage of items related to administration of the drug;
- Requires the Secretary to establish by regulation methods and standards for the safe and effective use of the drug at home.

Section 4201(c) of OBRA '90 (Pub. L. 101-508) provides that EPO furnished to ESRD patients by Medicare approved dialysis facilities will be made at the rate of $11 per 1,000 units, rounded to the nearest 100 units, effective 1-1-91. After applying the part B coinsurance

requirement, payment will be made at the rate of $8.80 per 1,000 units.

A facility furnished EPO as follows:

EXAMPLE

| | Units |
|---|---|
| 2/1 | 3,000 |
| 2/4 | 3,000 |
| 2/6 | 3,000 |
| 2/8 | 3,000 |
| 2/11 | 2,500 |
| 2/13 | 2,500 |
| 2/15 | 2,500 |
| 2/18 | 2,500 |
| 2/20 | 2,560 |
| 2/22 | 2,500 |
| 2/25 | 2,000 |
| 2/27 | 2,000 |

A total of 31,060 units were furnished during February. In determining payment, the facility's intermediary would round total units to 31,100. The total allowance would be $342.10 (31.1×$11).

Typically, EPO is administered at the end of the dialysis treatment. Unless medical documentation shows that it is necessary to administer EPO at a time other than during a dialysis treatment, only a dialysis facility is paid for EPO administered to patients who are dialyzing on an infacility basis.

For home use of EPO supplied to a home dialysis patient competent to administer the drug without medical supervision, the program may pay only a Medicare approved dialysis facility (for Method I or Method II patients) or a supplier of home dialysis equipment and supplies (for Method II patients only). In any case, payment for home use of EPO is made at the facility rate described above.

If a home patient is NOT competent to use EPO without supervision, and the drug has been prescribed, generally the patient's dialysis facility would administer it. If a physician administers EPO to the patient, it should be the physician who receives the Monthly Capitation Payment (MCP) for furnishing all of the renal-related services that the beneficiary may need. In this latter case Medicare pays on a reasonable charge basis for the drug, but no additional payment is made to the physician for administration.

After the current fiscal year, HCFA will announce annually, for public comment, whether an update in the EPO allowance is appropriate. By statute, any increase will not exceed the percentage increase (if any) in the implicit price deflator for the gross national product for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

Because of our concern as to the safety and efficacy of EPO used in the home, we consulted with the HCFA Physicians Panel, which suggested that we refer the matter to the Office of Health Technology Assessment (OHTA). The OHTA's response after consultation with FDA, indicated that EPO can be administered safely and effectively in the home by properly trained patients who are subject to regular monitoring of blood pressure and hemoglobin or hematocrit measurements. In addition, some professional medical organizations gave us their protocols and guidelines for home use of EPO. We consulted those guidelines in developing these regulations.

For health and safety reasons, we are allowing only the patient's dialysis facility, or the physician responsible for furnishing all dialysis-related services to the patient to participate in patient selection, training, and monitoring. Suppliers may not select, train, or monitor patients for this purpose. Suppliers are not subject to conditions of participation, nor to other health and safety requirements. Furthermore, this policy is consistent with the provisions of section 6203 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239), which require that the renal dialysis facility or an approved provider of services be responsible for all self-care home dialysis support services. Nonetheless, suppliers may furnish EPO to home dialysis patients who have been trained and are routinely monitored by a dialysis facility or physician.

## III. Provisions of the Regulations

We have amended subpart U of part 405 of the HCFA rules, which sets forth the conditions for coverage of services furnished to ESRD beneficiaries, as discussed below.

### *A. Patient Selection*

To ensure the safe and effective use of EPO by home dialysis patients, we have amended § 405.2163 to require that the patient's dialysis facility or the physician responsible for all dialysis-related services make a comprehensive assessment of the patient and the patient's needs at the time of selection for EPO therapy.

We believe and emphasize that proper patient selection is necessary for a safe, effective program of EPO therapy at home. In considering EPO therapy in the home setting, it is important for the dialysis facility or the physician responsible for all dialysis-related services to assess the degree of self-care that is feasible, that is, whether the patient will actually be able to administer the drug, and if not, whether the patient would have available the necessary assistance from a care-giver. We believe that patient compliance with certain elements is necessary for successful EPO therapy. Accordingly, we are requiring that, in order to be selected for home use of EPO, a patient must—

- Be a home dialysis patient (either peritoneal or hemodialysis method).
- Have a hematocrit (or comparable hemoglobin) of less than 30 percent unless medical documentation justifies a patient's need for EPO with a hematocrit higher than 30 percent. For example, a patient with severe angina, severe pulmonary disease, or severe hypotension may require EPO to prevent adverse symptoms even though the patient has a higher hematocrit
- Be under the care of the physician who is responsible for the dialysis-related services and who prescribes EPO, and under the care of the renal dialysis facility that establishes the plan of care for the services and monitors the progress of the home EPO therapy.
- Be trained by the facility to inject EPO or have an appropriate caregiver who is trained to inject EPO.

In addition, the following requirements must be met:

1. Prior to the determination that the patient is a candidate for use of EPO in the home, the patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

2. The patient's physician or facility must develop an appropriately designed protocol to provide to the patient for the safe and effective use of the drug. The protocol must include monitoring of blood pressure.

3. The patient must be capable of performing self-administration of EPO, be able to learn aseptic technique, and be able to read the drug labeling, or must have a primary care-giver who can perform these tasks.

4. The patient must be able to adhere to a disciplined medical regimen.

### *B. Patient Care Plan*

To ensure adequate monitoring of home EPO therapy, we have amended § 405.2137(b), to add a new paragraph (b)(7) which requires that the patient plan for a home dialysis patient who uses EPO in the home include the following:

- Review of diet and fluid modifications to monitor iron stores and hyperkalemia related to dietary indiscretion or elevated blood pressure.
- Reevaluation of the patient's dialysis prescription taking into account

the patient's increased appetite and red blood cell volume.

- A method of teaching the patient to identify the signs and symptions of hypotension and hypertension.
- The decrease or discontinuance of EPO if hypertension is uncontrolled.
- A method of followup on blood work and a means to keep the physician informed of the results.

*C. Other Concerns*

We understand that this drug may be abused. In order to minimize possible abuse, we have revised § 405.2163(g)(4) to require that the physician or facility ensure that "on hand" EPO is limited to a two-month supply. We request the public's views and suggestions regarding this policy, and any other issues including whether it is necessary to impose special storage requirements for safe-keeping of EPO, considering that the drug contains no preservatives, and that its presence might entail possible risks to any children in the household.

*D. Other Minor Changes*

The following minor changes were also required, to codify in the rules the coverage of EPO and to reflect the expansion of that coverage to include EPO used by home dialysis patients. As explained in the "Background" section of this preamble, previous coverage of EPO was implemented through general instructions issued by HCFA, but not reflected in the rules.

*Section 410.10.*

We have amended this section to show that EPO used at home by home-dialysis patients is now covered as one of the services included in "Medical and other health services", as defined in section 1861(s) of the Social Security Act.

*Section 410.29.*

We have amended this section to show that EPO may be covered as an exception to the general exclusion of drugs that may be self-administered.

*Section 410.50.*

We have amended this section to snow that medically necessary drugs and biologicals are covered as part of institutional dialysis services furnished in a dialysis facility. (EPO covered as a dialysis facility service is paid as add-on to the facility payment rate.)

*Section 410.52.*

We have amended this section to show that EPO for use by competent patients in the home is now included in the scope of ESRD services furnished in the patient's home.

*Section 413.170(a)(1).* We have amended this section to update the cross references to the ESRD program coverage provisions in the regulations.

*Section 413.170(c).* We have added a new paragraph (c)(6) to describe reimbursement for EPO when it is furnished by a Medicare approved dialysis facility or a supplier of home dialysis equipment and supplies.

*Section 414.300 and 414.335.* We have added a new paragraph (d) to § 414.300 and a new § 414.335 to describe reimbursement for EPO when the beneficiary deals directly with a supplier of home dialysis equipment and supplies (method II).

## IV. Waiver of Proposed Rulemaking and of Delayed Effective Date

In adopting substantive rules, we ordinarily publish a notice of proposed rulemaking with a 60-day period for public comment as required under section 1871(b)(1) of the Act. The notice of proposed rulemaking identifies the legal authority or the administrative necessity for the proposed rule. It also discusses the substance and the reasons for the particular provisions being proposed. However, section 4207(j) of OBRA '90 authorizes issuance of interim final regulations (without prior notice and comment) to implement any of the OBRA provisions that affect the Medicare and Medicaid programs. We are using that authority to publish this as an interim final rule, since coverage of EPO for use at home by home dialysis patients cannot be implemented properly without the criteria for selection of patients and the rules and procedures necessary to ensure that the treatment is safe and effective. Since Congress provided that coverage of EPO for home use go into effect on July 1, 1991, we find that, once these rules are published, to further delay the effective date would serve no useful purpose. Medicare will pay for services furnished on and after that date that meet the requirements of this regulation.

## V. Response to Comments

Although this is a final rule, we will consider all timely comments and discuss those comments when we amend the rule or make it permanent without changes.

## VI. Regulatory Impact Statement

*A. Executive Order 12291*

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any regulation that is likely to have an annual impact of $100 or meet other thresholds specified in section 1(b) of the order.

We have determined that a regulatory impact analysis is not required for these rules because they will not have an annual impact of $100 million or more or meet any of the other threshold criteria. However, in the formulation of a final rule, we will prepare a benefit and cost analysis. In this analysis, we will consider the social benefits to Medicare beneficiaries who use EPO at home, and attempt to place a dollar value on the benefits accruing from this provision. Examples of benefits might be savings in travel previously required to obtain EPO, or the ability of the beneficiary to resume employment. To assist us in this analysis, we request public comment on benefits and costs that may be anticipated as a result of this regulation.

*B. Regulatory Flexibility Act*

Consistent with the Regulatory Flexibility Act (RFA) and section 1102(b) of the Social Security Act, we prepare a regulatory flexibility analysis for each rule, unless the Secretary certifies that particular rule will not have a significant economic impact on substantial number of small entities, or a significant impact on the operation of a substantial number of small rural hospitals.

The RFA defines "small entity" as a small business, a nonprofit enterprise, or a governmental jurisdiction (such as a county, city, or township) with a population of less than 50,000. We also consider all providers and suppliers of services to be small entities. For purposes of section 1102(b) of the Act, we define small rural hospital as a hospital that has fewer than 50 beds, and is located anywhere but in a metropolitan statistical area.

We have not prepared a regulatory flexibility analysis because we have determined, and the Secretary certifies, that these rules will not have a significant economic impact on a substantial number of small entities or a significant impact on the operation of a substantial number of small rural hospitals.

*Paperwork Reduction Act*

This rule contains no information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

**List of Subjects**

*42 CFR Part 405*

Administrative practice and procedure, Health facilities, Health professions, Kidney disease,

Laboratories, Medicare, Reporting and record keeping requirements, Rural areas, X-rays.

*42 CFR Part 410*

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

*42 CFR Part 413*

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

*42 CFR Part 414*

End-stage renal (ESRD), Health professions, Laboratories, Medicare.

42 CFR chapter IV is amended as set forth below:

## A. PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

### Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

1. The authority citation for subpart U continues to read as follows:

**Authority:** Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1295hh, 1395kk, and 1395rr), unless otherwise noted.

2. Section 405.2137 is amended to add a new paragraph (b)(7), to read as follows:

**§ 405.2137 Condition: Patient long-term program and patient care plan.**

* * * * *

(b) *Standard: Patient care plan.* * * *

(7) For a home dialysis patient who uses EPO in the home, the plan for monitoring home use of EPO must include the following:

(i) A review of diet and fluid modifications to monitor for adequate iron stores and hyperkalemia related to dietary indiscretions or elevated blood pressure.

(ii) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(iii) A method for followup on blood tests and a mechanism for keeping the physician informed of the results.

(iv) A method for teaching the patient to identify the signs and symptoms of hypotension and hypertension.

(v) The decrease or discontinuance of EPO if hypertension is uncontrollable.

3. Section 405.2163 is amended to add a new paragraph (g), to read as follows:

**§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.**

* * * * *

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment of the patient that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The patient must meet the following conditions:

(i) Be a home dialysis patient.

(ii) Have a hematocrit (or comparable hemoglobin level) of less than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) of higher than 30 percent. (Severe angina, severe pulmonary disease, or severe hypotension may require EPO to prevent adverse symptoms despite higher hematocrit or hemoglobin levels.)

(iii) Be able to adhere to a disciplined medical regime.

(iv) Be under the care of a physician who is responsible for all dialysis-related services, who prescribes the EPO and monitors the EPO home therapy, and be under the care of a renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The patient or a caregiver who assists the patient in performing self-dialysis, must meet the following conditions:

(i) Be trained by the facility to inject EPO and capable of carrying out the procedure.

(ii) Be capable of reading and understanding drug labelling.

(iii) Be trained in, and capable of observing, aseptic techniques.

(4) *Protocol.* The patient's physician or facility must develop an appropriate protocol to give to the patient to ensure safe and effective home use of EPO. The protocol must include monitoring of blood pressure. The physician or facility must ensure that "on hand" EPO is limited to a two-month supply.

## B. PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

**Authority:** Secs. 1102, 1832, 1833, 1835, 1861(r), (s), and (cc), 1871, and 1881 of the Social Security Act. (42 U.S.C. 1302, 1395k, 13951, 1395n, 1395x(r), (s), and (cc), 1395hh, and 1395rr).

### Subpart B—Medical and Other Health Services

**§ 410.10 [Amended]**

2. In § 410.10, paragraph (k), the phrase "erythropoietin (EPO) for home dialysis patients competent to use the drug," is inserted immediately after "equipment,".

**§ 410.29 [Amended]**

3. In § 410.29, paragraph (a), the phrase "and except for EPO," is added immediately after "factors."

4. In § 410.50, the introductory text is republished, paragraph (a) is revised, and a new paragraph (d) is added, to read as follows:

**§ 410.50 Institutional dialysis services and supplies: Scope and conditions.**

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary in the treatment of the patient for ESRD.

* * * * *

(d) Erythropoietin (EPO) and its administration.

5. In § 410.52, the introductory text of paragraph (a) is republished, and a new paragraph (a)(4) is added, to read as follows:

**§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.**

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

* * * * *

(4) Erythropoietin (EPO) for use at home by a home dialysis patient if it has been determined, in accordance with § 405.2163 of this chapter, that the patient is competent to use the drug safely and effectively.

* * * * *

## C. PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT

1. The authority citation for part 413 is revised to read as follows:

**Authority:** Secs. 1102, 1122, 1814(b), 1815, 1833(a), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1320a–1, 1395f(b), 1395g, 13951(a), 1395x(5), 1395hh, 1395rr, 1395tt, and 1395ww).

**§ 413.170 [Amended]**

2. Section 413.170 is amended as follows:

a. In paragraph (c), a new paragraph (c)(6) is added, to read as follows:

(c) *Prospective rates for hospital-based and independent ESRD facilities.* * * *

(6) *Erythropoietin (EPO).* (i) When EPO is furnished to an ESRD patient by a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies, payment is based on the amount specified in § 413.170(c)(5)(iii).

(ii) The payment is made only on an assignment basis, that is, directly to the facility or supplier, which must accept, as payment in full, the amount that HCFA determines.

(iii) HCFA determines the payment amount in accordance with the following rules:

(A) The amount is prospectively determined.

(B) HCFA publishes annually a Federal Register notice, indicating whether an update in the EPO payment amount is appropriate and requesting public comment.

(C) Any increase in this amount does not exceed the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(D) HCFA sets a single amount to be paid nationwide to hospital-based and independent dialysis facilities and to suppliers of home dialysis equipment and supplies, regardless of the location of the facility, supplier, or patient.

(E) The Medicare payment is subject to the Part B deductible and coinsurance.

## D. PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

**Authority:** Secs. 1102, 1833(a), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 13951(a), 1395hh, and 1395).

2. Section 414.300 is amended to add a new paragraph (d) to read as follows:

**§ 414.300 Scope of subpart.**

* * * * *

(d) Erythropoietin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

3. A new § 414.335 is added, to read as follows:

**§ 414.335 Payment for EPO furnished to a home dialysis patient for use in the home.**

(a) Payment for EPO used at home by a home dialysis patient is made only to either a Medicare approved ESRD facility or a supplier of home dialysis equipment and supplies.

(b) Payment is made in accordance with the rules set forth in § 413.170 of this chapter.

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

Dated: June 25, 1991.

**Gail R. Wilensky,**

*Administrator, Health Care Financing Administration.*

Approved: July 24, 1991.

**Louis W. Sullivan,**

*Secretary.*

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL 3992-5]**

**48 CFR Parts 1516 and 1552**

**Acquisition Regulation**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** This document finalizes a rule on the payment of fee on cost-reimbursement, term-form contracts. The effect of this action is to change, in many instances, the current procedure of making provisional payments of fee as a percentage of costs incurred, to a method of payment based on the number of direct hours performed in relation to the total level of effort in the contract. This action provides for a more equitable procedure for the provisional payment of fee.

**EFFECTIVE DATE:** This rule is effective October 4, 1991.

**FOR FURTHER INFORMATION CONTACT:** Joe Nemargut at (202) 382-5019 or FTS 382-5019.

**SUPPLEMENTARY INFORMATION:**

### A. Background

This regulation was published as a proposed rule in the Federal Register on December 29, 1989. Three comments were received. Those comments and the EPA response are summarized below.

Two commenters stated the proposed rule would increase contractor costs without commensurate benefits to EPA. The EPA believes there should be no additional costs to a contractor in implementing the rule, which will require only a minor change to a contractor's method of calculating the fee payable.

Two commenters stated the rule conflicts with the intent of the Federal Acquisition Regulation (FAR) to promote uniform policies and procedures for acquisition of goods and services not unique to an agency. While the EPA agrees that the use of cost-reimbursement type contracts is not unique to EPA, existing FAR guidance does not prescribe the methods for contractors to receive provisional fee payments. Therefore, this regulation provides policies and procedures necessary for EPA to implement the FAR, as permitted under FAR 1.302.

One commenter asserted this rule contradicts the prompt payment initiatives of the Congress and the Office of Management and Budget by delaying payments to contractors. Under many cost-reimbursement contracts, the Agency has contracted for a specified level-of-effort stated as an estimated number of hours. This rule will assure that provisional payments of fee are made on the same basis as the contract terms. This rule should in no way delay a contractor's timely receipt of contract financing payments.

A commenter contends the rule would act as a roadblock to improving contractor performance by penalizing the use of labor-saving devices. This should not be the case. Prior to contract award, contractors are evaluated on their technical approach, which may include their use of labor-saving methods. For award-fee contracts, the amount of fee awarded is based on the overall quality of contractor performance. This generally includes an evaluation of the contractor's use of innovative approaches designed to reduce the overall cost to the Government. However, in response to this comment, the final rule permits the Contracting Officer to omit this clause if its inclusion might be detrimental to overall contractor performance.

One commenter suggested that a provision be added to this rule requiring that fixed fee be settled at the end of the contract base year and for each option period thereafter, with the withholding provisions modified accordingly. This is outside the scope of the proposed changes.

### B. Executive Order 12291

OMB Bulletin No. 85-7, dated December 14, 1984, establishes the requirements for Office of Management and Budget (OMB) review of agency procurement regulations. This regulation does not fall within any of the categories cited in the Bulletin requiring OMB review.