ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7547–8]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to delete the Resin Disposal Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region III is issuing a notice of intent to delete the Resin Disposal Superfund Site (Site) located in the Borough of Jefferson, Allegheny County, Pennsylvania, from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is found at appendix B of 40 CFR part 300 of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), have determined that all appropriate response actions under CERCLA, other than operation and maintenance and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

In the ''Rules and Regulations'' Section of today's **Federal Register**, we are publishing a direct final notice of deletion of the Resin Disposal Superfund Site without prior notice of intent to delete, because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final deletion. If we receive no adverse comment(s) on the direct final notice of deletion, we will not take further action on this notice of intent to delete. If we receive adverse comment(s), we will withdraw the direct final notice of deletion and it will not take effect. We will, as appropriate, address all public comments in a subsequent final deletion notice based on this notice of intent to delete. We will not institute a second comment period on this notice of intent to delete. Any parties interested in commenting must do so at this time. For additional information, see the direct final notice of deletion which is located in the Rules Section of this **Federal Register**.

DATES: Comments concerning this Site must be received by September 22, 2003.

ADDRESSES: Written comments should be addressed to: Trish Taylor, Community Involvement Coordinator, (3HS43), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, (215) 814–5528, *taylor.trish@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Rashmi Mathur, Remedial Project Manager (3HS22), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, (215) 814–5234, *mathur.rashmi@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information, *see* the Direct Final Notice of Deletion which is located in the Rules Section of this **Federal Register**.

Information Repositories: Comprehensive information about the Site is available for viewing and copying at the Site Information Repositories at the following locations: U.S. EPA Region III, Regional Center for Environmental Information (RCEI), 1650 Arch Street, Philadelphia, PA 19103, (215) 814–5364, Monday through Friday 8 a.m. to 4:30 p.m.; the Jefferson Borough Library (contact, Ann Reschenthaler), Municipal Building, 925 Old Clairton Road, Jefferson Borough, Pennsylvania 15025 (412) 655–7741, Monday through Thursday 11:00 a.m. to 8:30 p.m.; and the Pennsylvania Department of Environmental Protection, Pittsburgh Office, 400 Waterfront Drive, Pittsburgh, PA 15222 (412) 442–4197.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: August 4, 2003.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 03–21597 Filed 8–21–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1167–P]

RIN 0938–AL27

Medicare Program; Payment for Respiratory Assist Devices With Bi-level Capability and a Back-up Rate

AGENCY: Center for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would clarify that respiratory assist devices with bi-level capability and a back-up rate must be paid as capped rental items and not paid as items requiring frequent and substantial servicing (FSS), as defined in section 1834(a)(3) of the Social Security Act. This action would correct coding and payment errors, which began in 1994, when some Medicare contractors misinterpreted our statutorily prescribed policy and allowed these devices to be paid under the category for items requiring FSS.

DATES: *Comment Date:* Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 21, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1167–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1167–P, P.O. Box 8017, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are

encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

Copies: This **Federal Register** document is available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

A. DME Fee Schedule Payment Methodology

The Medicare Part B (Supplementary Medical Insurance) payment rules for durable medical equipment (DME) are located in section 1834(a) of the Social Security Act (the Act). In accordance with section 1834(a) of the Act, payment for DME is made on a fee schedule basis with items falling into several different payment categories, each with its own unique payment rules. The respiratory assist devices with bi-level capability would be placed in the category for other items of durable medical equipment, or capped rental items, as defined in section 1834(a)(7) of the Act.

Section 1834(a) of the Act provides that Medicare payment for DME is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. It classifies DME into the following payment categories:

- Inexpensive or other routinely purchased DME.
- Items requiring frequent and substantial servicing (FSS).
- Customized items.
- Oxygen and oxygen equipment.
- Other covered items (other than DME).
- Other items of DME (capped rental items).

There are different payment rules for each category of DME. With the exception of customized items, fee schedule amounts are calculated for each item of DME, identified by codes in the Healthcare Common Procedure Coding System (HCPCS). The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item.

In general, the fee schedule amounts for DME are calculated on a statewide basis using average Medicare payments made in each State from 1986 and 1987 under the former reasonable charge payment methodology. The fee schedule amounts are generally adjusted annually by the change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending June 30 of the preceding year. The fee schedule amounts are limited by a ceiling (upper limit) and floor (lower limit) equal to 100 percent and 85 percent, respectively, of the median of the statewide fee schedule amounts.

Section 13543 of the Omnibus Budget Reconciliation Act of 1993 (OBRA of 1993) (Pub. L. 103–66) amended section 1834(a)(3)(A) of the Act to remove certain ventilators, namely ''intermittent assist devices with continuous airway pressure devices,'' from the DME payment category for items requiring FSS. Payment for an item in the FSS category is made on a monthly rental basis, with rental payments continuing as long as the item remains medically necessary. The conference report for OBRA of 1993 states that ''this category is intended to include items which require frequent servicing in order to avoid imminent danger to a beneficiary's health.'' Those ventilators which were excluded from the FSS category by OBRA of 1993 fall into the payment category for capped rental (CR) items. Payment for items in the CR category is made on a monthly rental basis, with rental payments being capped at 15 months or 13 months, depending on whether the beneficiary, based upon an option that must be offered by the supplier in the 10th rental month, chooses to continue renting the item or take over ownership of the item via the ''purchase option'' provided by the statute. If the beneficiary chooses the ''purchase option,'' then rental payments continue through the 13th month of use and the title for the equipment transfers from the supplier to the beneficiary. Medicare would then make payments for any necessary maintenance and servicing of the patient-owned equipment. If the beneficiary chooses to continue renting the equipment, then rental payments continue through the 15th month of use, and the supplier continues to own the equipment. The supplier must continue to supply the rented item to the beneficiary as long as medically necessary. The supplier is entitled to receive a semi-annual maintenance and servicing payment in an amount not to exceed 10 percent of the purchase price for the equipment as determined by the statute. Total Medicare payments made through the 13th and 15th months of rental equal 105 and 120 percent, respectively, of the statutory purchase price for the equipment.

Suppliers of DME must meet the standards specified in 42 CFR 414.57. These standards specify that the supplier ''must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.'' This requirement applies to items in both the FSS and CR payment categories. Therefore, for rental items in either category, the supplier is responsible for ensuring that the equipment is in good working order. In the case of items for which the patient has selected the purchase option, the patient arranges for the servicing and repair of the patient-owned equipment. Medicare payments are made as needed for maintenance and servicing of patient-owned equipment in the CR category.

It is not necessary for a respiratory therapist to perform the maintenance and servicing of respiratory assist devices. If DME suppliers perform maintenance and servicing of equipment, they are paid by Medicare for this service, regardless of whether the item is in the FSS or CR category. We are confident that this change in payment category will not result in a decrease in the current level of service being provided to the beneficiaries.

B. HCPCS Coding for Respiratory Assist Devices

On January 1, 1992, code E0452 with the description of ''intermittent assist device with continuous positive airway pressure device (CPAP)'' was added and became effective in the HCPCS. This code was added to describe respiratory assist devices with bi-level air pressure capability, with or without a back-up rate, and with the ability to switch to CPAP mode. Bi-level pressure capability means that the device can deliver a lower level of pressure when the patient exhales than when the patient inhales, as opposed to CPAP, which is the

continuous delivery of a single level of positive air pressure. A back-up rate feature enables the device to automatically switch between the two levels of pressure at pre-determined intervals. The original manufacturer of bi-level respiratory assist devices submitted documentation to us as part of its HCPCS coding recommendation. The manufacturer stated the following in the documentation:

- The word ''intermittent'' refers to devices that are designed to be used by the patient for only part of the day, usually during the hours of sleep.
- The bi-level equipment requires very little maintenance and servicing.
- Other than monthly replacement of the air inlet filter on the front of the system, there is no routine maintenance required.
- Recommends that a performance verification be performed after each year of operation to ensure that the device is functioning properly.

In accordance with OBRA of 1993, intermittent assist devices are excluded from the FSS payment category and, therefore, fall into the CR payment category.

On January 1, 1992, code E0453 with the description of ''therapeutic ventilator; suitable for use 12 hours or less per day'' was added and became effective in the HCPCS. This code was added to describe ventilators that are used on a part time basis by patients who are dependent on volume ventilators (HCPCS code E0450) for more than 12 hours a day. The premise behind the therapeutic ventilator (code E0453) is similar to the portable oxygen equipment. The stationary volume ventilator (E0450), like stationary oxygen equipment, would be the primary equipment used by the patient. The portable therapeutic ventilator, like portable oxygen equipment, would be used part of the day by the patient to move about in order to exercise muscles, prevent decubitus ulcers, and achieve other therapeutic goals. Therapeutic ventilators were properly classified in the FSS payment category.

Beginning as early as May 25, 1992, some Medicare carriers issued erroneous guidance to suppliers that intermittent assist devices with a back-up rate should be billed for using the HCPCS code E0453 for therapeutic ventilators (FSS payment category) instead of the HCPCS code E0452 for intermittent assist devices (CR payment category). We are not certain to what degree carriers and suppliers were using code E0453 as opposed to code E0452 to bill for intermittent assist devices with a back-up rate. However, this practice continued to some extent through 1993 and 1994, the respective years in which the OBRA of 1993 change in payment categories for intermittent assist devices was enacted and implemented. Responsibility for processing DME claims was transferred during this time from 34 local carriers to 4 regional carriers known as Durable Medical Equipment Regional Carriers (DMERCs). The DMERCs also issued erroneous guidance to suppliers that the intermittent assist devices with a back-up rate should be billed for using code E0453 instead of code E0452.

The classification of intermittent assist devices with a back-up rate under the FSS payment category versus the CR payment category results in a substantial increase in Medicare payments. For example, comparing cost of E0453 over 5 years using the 2000 fee schedule ceiling of $612.52, total Medicare payments under the FSS payment category would be $36,751.20 after 5 years as opposed to $7,778.99 if the device was classified under the CR payment category.[1] Based on retail prices we obtained, we determined for the year 2000, that the purchase prices for intermittent assist devices with a back-up rate range from approximately $3,000 to $6,000. This highlights the fact that the correct classification of these devices for Medicare payment purposes is a significant issue in terms of safeguarding the Medicare trust fund. That is, placing these devices in the FSS payment category instead of the CR category results in Medicare paying every 5 years approximately $36,700 rather than $7,700 for an item that can be purchased for $6,000 or less.

In 1998, for the first time, the DMERCs conducted an in-depth review of the use of intermittent assist devices with CPAP. As a result, in July 1998, the DMERCs issued proposed medical review policies on intermittent assist devices with CPAP, which called for a revision to the HCPCS codes for these devices and the adoption of more specific nomenclature to describe respiratory assistance technology. The term ''respiratory assist device, bi-level pressure capability'' was proposed to replace the HCPCS wording of ''intermittent assist device with CPAP,'' and separate HCPCS codes were proposed to differentiate between devices with a back-up rate and devices without a back-up rate.

[1] The CR payment of $7,778.99 includes the 15 monthly rental payments plus 7 payments of $61.25 for maintenance and servicing that can be billed every 6 months beginning 6 months after the 15th rental payment has been made.

C. Public Meeting on Payment for Respiratory Assist Devices

During the course of reviewing the DMERC medical review policies on respiratory assist devices, we became aware that the carriers and DMERCs had been allowing HCPCS code E0453 to be used primarily for the billing of respiratory assist devices with a back-up rate. As a result, we intended to take action to clarify that these devices belonged in the CR payment category. Because of concerns raised by the industry on the appropriate coding and payment classification for these devices, we announced in the **Federal Register** on June 4, 1999 that a public meeting would be held on June 25, 1999 to get input from the supplier community regarding the appropriate DME payment category for respiratory assist devices with a back-up rate. We made presentations at the June 25, 1999 public meeting, in addition to the Food and Drug Administration, the National Institutes of Health, respiratory assist device manufacturers, suppliers, clinicians, beneficiaries, and others.

The testimony at the public meeting that was given to support the claim that there is a need for FSS of respiratory devices with bi-level capability and a back-up rate described the need to have a respiratory therapist visit the beneficiary to make sure that the device is being used appropriately by the beneficiary and that the beneficiary is complying with the treatment. After the respiratory therapist performs an assessment of the beneficiary and has consulted with the beneficiary's physician, it may be determined that the pressure setting on the equipment needs to be adjusted. However, no information was presented at the public meeting that would indicate that the equipment itself requires FSS as required by section 1834(a)(3)(A) of the Act.

The DMERC medical review policies on respiratory assist devices were implemented on October 1, 1999. The following HCPCS codes were added as part of these new policies:

K0532 Respiratory Assist Device, Bi-Level Pressure Capability, Without Back-up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)

K0533 Respiratory Assist Device, Bi-Level Pressure Capability, With Back-up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)

K0534 Respiratory Assist Device, Bi-Level Pressure Capability, With Back-up Rate Feature, Used With Invasive Interface, E.G., Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device)

These codes were added to better describe those respiratory assist devices, or intermittent assist devices with CPAP, that had been coded under codes E0452 and E0453 of the HCPCS since 1992. Code K0532 describes those intermittent assist devices with CPAP that did not have a back-up rate and were previously coded under code E0452 (CR payment category). Codes K0533 and K0534 describe those intermittent assist devices with CPAP that did have a back-up rate but had been coded under code E0453 (FSS payment category). It was also decided that no code was needed for therapeutic ventilators, the devices originally intended to fall under code E0453. Although the DMERC medical review policies were implemented on October 1, 1999, the decision regarding the appropriate DME payment category for devices with the back-up rate (codes K0533 and K0534) was delayed until now to allow more time for consideration of comments made at the June 25, 1999 public meeting.

After reviewing all of the information presented at the June 25, 1999 public meeting, we conclude that respiratory assist devices with bi-level pressure capability and a back-up rate do not require FSS payment. We also conclude that these devices are a type of intermittent assist device with CPAP and are therefore excluded from the FSS payment category by section 1834(a)(3)(A) of the Act. We conclude that all payments made for these devices in the past under the FSS payment category were erroneous.

D. Office of Inspector General (OIG) Report on Respiratory Assist Devices

In 1999, the OIG began an inspection to determine if respiratory assist devices with a back-up rate receive FSS. During the course of their inspection, the OIG conducted surveys of beneficiaries, suppliers, manufacturers, and accreditation agencies. In June 2001 (OEI–07–99–00440), the OIG issued their report on respiratory assist devices with a back-up rate, recommending that these devices be moved from the FSS payment category to the CR payment category. This recommendation is based on information gathered from the surveys conducted by the OIG that resulted in the following findings listed in the report:

- Supplier services consist primarily of routine maintenance and patient monitoring.
- For most beneficiaries, visits (from suppliers) do not meet supplier protocols for frequency.
- Contrary to supplier protocols, the number of beneficiaries receiving visits declines over time.
- Covering the respiratory assist device with back-up rate under capped rental would have saved Medicare $11.5 million annually.

Therefore, the OIG, after conducting a detailed inspection, has determined that respiratory assist devices with a back-up rate do not receive FSS.

II. Provisions of the Proposed Regulations

For the reasons stated above, we propose to include respiratory assist devices billed using HCPCS codes K0533 and K0534 in the DME fee schedule payment category for other items of DME, or capped rental items, as defined in section 1834(a)(7) of the Act. Rental claims received on or after the effective date of this provision would be claims considered for the initial month of rental for capped rental payment purposes.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Collection of Information Requirements

This document 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 1995.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that the reductions in annual expenditures that would occur as a result of moving respiratory assist devices with a back-up rate to the CR payment category will be approximately $10 million, based on the payment differential between the CR and FSS payment categories. This estimate is based on estimated annual savings of $11.5 million from the OIG report, rounded to the nearest $10 million. The OIG found that the average number of months a beneficiary used the device between January 1996 and September 1999 was 16 months. We estimate that Medicare beneficiaries utilize 10,000 to 12,000 devices each year. Since this rule would result in reductions in total expenditures of less than $100 million per year, this rule is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities either by nonprofit status or by having revenues of $6 million to $29 million or less in any 1 year. For purposes of the RFA, approximately 98 percent of suppliers of DME and prosthetic devices are considered small businesses according to the Small Business Administration's (SBA) size standards. Individuals and States are not included in the definition of a small entity. We estimate that 106,000 entities bill Medicare for DME, prosthetics, orthotics, surgical dressings, and other equipment and supplies each year. We believe the impact on the DME industry and small businesses in general would be minimal because most companies supply many different types of equipment. Total Medicare expenditures for DME are approximately $7 billion per year.

The OIG estimates that moving respiratory assist devices with a back-up rate to the CR payment category would result in payment reductions of

approximately $11.5 million per year. Therefore, the overall impact on the total industry annual receipts would be small, that is, less than 1 percent reduction in Medicare revenue. However, while the overall impact is small, some suppliers would be seriously affected as a result of the mix of DME that they furnish to Medicare beneficiaries. Namely, suppliers who specialize in furnishing respiratory assist devices would be seriously affected by this rule. To estimate how many suppliers could be seriously affected by this rule, we analyzed data for the top 30 suppliers of RADs with a back-up rate, which account for approximately 50 percent of Medicare expenditures for code K0533. Total allowed charges for code K0533 were $77 million in 2002. Therefore, a $10 million reduction in annual expenditures resulting from this proposed rule equates to a 13 percent reduction in revenue for suppliers for code K0533. These top 30 suppliers were ranked in terms of total allowed charges attributed to them for claims received for HCPCS code K0533 from October 1, 2002 through December 31, 2002. Five of the top 30 suppliers would not be considered small entities by SBA standards. These 5 suppliers account for approximately 40 percent of total expenditures for K0533. Twenty-five suppliers in the top 30 could be considered small entities if such a determination was based solely on Medicare expenditures (data on revenue attributed to sources other than Medicare has not been obtained for these companies as part of this analysis). Therefore, the total reduction in revenue for potential small entities as a result of this proposed rule would be approximately $6 million. The percentage of Medicare DME business that K0533 devices represent for 9 of the 25 potential small entities is 5 percent or less. For the remaining 16 potential small entities, the percentage of Medicare DME business that K0533 devices represent ranges from 17 to 98 percent. Therefore, these 16 suppliers would be seriously affected by this rule. Other K0533 suppliers not in the list of top 30 suppliers could also be small entities and could be seriously affected by this rule. The total allowed charges per year for these suppliers for code K0533 are less than $250,000.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing a rural impact analysis since we have determined that this rule would not have a significant economic impact on the operation of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal government, in the aggregate, or by the private sector of $110 million. This rule would not have an effect on the governments mentioned, and private sector costs would be less than the $110 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule does not significantly affect State or local governments.

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

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 414 as follows:

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, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr (b)(1)).

2. In § 414.222 paragraph (a)(1) is revised to read as follows:

§ 414.222 Items requiring FSS.

(a) *Definition.* * * *

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a back-up rate, previously referred to as intermittent assist devices with continuous airway pressure devices).

* * * * *

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

Dated: April 15, 2003.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 24, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–21443 Filed 8–21–03; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 2

[ET 03–158; MB 03–159; FCC 03–165]

Use of Television Channel 16 by the New York Police Department and NYMAC for Public Safety Services

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the rules of the Federal Communications Commission (FCC) to reallocate television channel 16 to the land mobile service in order to permit the New York Police Department and New York Metropolitan Advisory Committee (NYMAC) to utilize the channel for public safety services.

DATES: Submit comments on or before September 22, 2003. Reply comments are due on or before October 6, 2003.

ADDRESSES: Federal Communications Commission, 445 12th St. SW., Washington, DC 20554. See **SUPPLEMENTARY INFORMATION** for filing instructions.

FOR FURTHER INFORMATION CONTACT: Dave Roberts (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a summary of the FCC's Notice of Proposed Rulemaking, (NPRM) FCC 03–165, adopted on July 7, 2003, and released on July 10, 2003. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the FCC's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by