substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled*Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801*et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2006.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1262 is added to subpart D to read as follows:

§ 180.1262 Sorbitol octanoate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sorbitol octanoate in or on all food commodities when used in accordance with label directions.

[FR Doc. 06–756 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1167–F]

RIN 0938–AN02

Medicare Program; Payment for Respiratory Assist Devices With Bi-Level Capability and a Backup Rate

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

ACTION: Final rule.

SUMMARY: This final rule clarifies that respiratory assist devices with bi-level capability and a backup rate must be paid as capped rental items of durable medical equipment (DME) under the Medicare program and not paid as items requiring frequent and substantial servicing (FSS), as defined in section 1834(a)(3) of the Social Security Act. Before 1999, respiratory assist devices with bi-level capability (with or without a backup rate feature) were referred to as ''intermittent assist devices with continuous positive airway pressure devices'' under the Medicare program and in the Healthcare Common Procedure Coding System (HCPCS). This final rule responds to public comments received on a proposed rule published in the **Federal Register** on August 22, 2003, and finalizes the policy in that proposed rule. The rule will ensure that respiratory assist devices are consistently and properly paid under Medicare as capped rental items.

DATES: The provisions of this final rule are effective on April 1, 2006.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority for Payment for Durable Medical Equipment (DME)

Section 1834(a) of the Social Security Act (the Act) sets forth the payment methodology and requirements for payment for the purchase or rental of new and used durable medical equipment (DME) for Medicare beneficiaries under Medicare Part B (Supplementary Medical Insurance). In accordance with section 1834(a) of the Act, payment for DME is made on a fee schedule basis. Each item of DME that is paid under Medicare Part B is classified into one of 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 (CR) items).

Each category has its own unique payment rules. With the exception of customized items, for each item of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS), a fee schedule amount is calculated. The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item.

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. 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.

Implementing regulations for these statutory provisions are located in 42 CFR part 414, subpart D.

B. Issuance of Proposed Rulemaking

On August 22, 2003, we published in the **Federal Register** (68 FR 50735) a proposed rule to clarify that one of the items of DME, a respiratory assist device with bi-level capability and a backup rate, must be paid as a CR category item under the Medicare program and not paid as an item that requires FSS. As explained below, we issued this proposal to correct coding and payment errors that have been made by some Medicare contractors that misinterpreted our statutorily prescribed policy and allowed respiratory assist devices to be paid under the category for items requiring FSS. In the August 22, 2003 proposed rule, we proposed 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. We proposed that rental claims received on or after the effective date of the final regulation would be considered claims for the initial month of rental for capped rental payment purposes.

A summary of the public comments we received on the proposed rule and our responses to those comments appear under section III of this preamble.

II. Payment for Ventilators as DME Under Medicare

A. Payment Methodology

Under section 1834(a) of the Act, payment may be made under Medicare Part B for various types of ventilators as items of DME. Section 1834(a)(3) of the Act, as amended, provides for payment for covered items of DME requiring frequent and substantial servicing such as intermittent positive pressure breathing (IPPB) machines and ventilators, excluding ventilators that are either continuous positive airway pressure (CPAP) devices or intermittent assist devices with CPAP devices (now referred to as respiratory assist devices), to avoid risk to the patient's health. Payment for an item in the FSS category is made on a monthly rental basis, and rental payments continue as long as the item remains medically necessary for the beneficiary. Section 414.222 of our regulations implements the payment provisions for the types of items of DME that are paid under the FSS category. Ventilators that are excluded from the FSS payment category are paid in accordance with section 1834(a)(7) of the Act under the CR category on a rental basis. Section 414.229 of the regulations implements the payment provisions relating to items of DME that are paid under the CR category. Payment for an item in the CR category is made on a monthly rental basis. During the 10th rental month, the supplier is required to offer the beneficiary the option to take over ownership of the item. If the beneficiary chooses this option, Medicare rental payments end after the 13th month of use and the title for the equipment transfers from the supplier to the beneficiary. After the title for the equipment has transferred to the beneficiary, Medicare will make payments for any necessary maintenance and servicing of the patient-owned equipment. If the beneficiary chooses to continue renting the equipment, Medicare rental payments end after the 15th month of use, the supplier continues to own the equipment, and the supplier must continue to supply the item to the beneficiary until the medical necessity ends or Medicare coverage ceases. Beginning 6 months after the 15th month of use, the supplier may bill and receive a semiannual maintenance and servicing payment in an amount not to exceed 10 percent of the purchase price for the equipment as determined in accordance with the statute and § 414.229(c). These maintenance and servicing payments are made regardless of whether maintenance and servicing were actually performed on the equipment during the 6-month period. Total Medicare payments made through the 13th and 15th months of rental equal 105 and 120 percent, respectively, of the statutory purchase price of the equipment.

Suppliers of DME must meet the standards specified in regulations at § 424.57. 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 an item for which the beneficiary 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.

B. Legislative Change Relating to Types of Ventilators Payable Under the FSS Category

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 by establishing two exceptions to the previously existing statutory authority that all ventilators were classified as items requiring FSS for Medicare DME payment purposes. One category of ventilators that are excluded from the FSS payment category is ''intermittent assist devices with continuous positive airway pressure devices,'' now referred to under the Medicare program as respiratory assist devices. The legislative history of the House Report accompanying H.R. 3545 (H.R. Conf. Rep. 103–213, 1993 U.S.C.C.A.N. 1088 at 703 (1987)) states that the FSS ''category is intended to include items which require frequent servicing in order to avoid imminent danger to a beneficiary's health.'' As a result of this legislative amendment, ventilators that are excluded from the Medicare DME FSS payment category fall into the DME payment category of CR items.

C. HCPCS Coding for Intermittent Assist Devices

Effective January 1, 1992, code E0452 with the description of ''intermittent assist device with continuous positive airway pressure device (CPAP)'' was added to the HCPCS. This code was added to describe respiratory assist devices with bi-level air pressure capability, with or without a backup 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 backup rate feature enables the device to automatically switch between the two

levels of pressure at predetermined intervals. The original manufacturer of bi-level respiratory assist devices submitted documentation to us as part of our 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.

The manufacturer recommended that a performance verification be performed after each year of operation to ensure that the device is functioning properly.

The nomenclature for code E0452, intermittent assist device with continuous positive airway pressure (CPAP) device, was established to describe positive airway pressure devices with bi-level capability, with or without a backup rate feature. The term ''respiratory assist device'' is used today to refer to this exact same group of items. As indicated earlier, in accordance with OBRA of 1993, intermittent assist devices or respiratory assist devices are excluded from the FSS payment category for DME and are classified under the CR payment category under Medicare.

Effective January 1, 1992, code E0453 with the description of ''therapeutic ventilator; suitable for use 12 hours or less per day'' was added to the HCPCS. This code was added to describe ventilators that are used on a part-time basis by patients who are dependent on stationary ventilators (HCPCS code E0450) for more than 12 hours a day. The premise behind the therapeutic ventilator (code E0453) is similar to portable oxygen equipment. The stationary ventilator (code 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 because they were not one of the types of ventilators (CPAPs or intermittent assist devices) excluded from this category by OBRA of 1993.

D. Billing for Intermittent Assist Devices With a Backup Rate

Beginning as early as May 25, 1992, some Medicare carriers issued erroneous guidance to suppliers that intermittent assist devices with a backup rate should be billed to Medicare using HCPCS code E0453 for therapeutic ventilators (in the FSS payment category) instead of HCPCS code E0452, the code category established for intermittent assist devices (in the CR payment category). We are not certain to what extent carriers and suppliers were using code E0453 as opposed to code E0452 to bill for intermittent assist devices with a backup rate. However, this practice continued to some extent through 1993 and 1994, the years in which the OBRA of 1993 change in payment categories for intermittent assist devices was, respectively, 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 intermittent assist devices with a backup rate should be billed using code E0453 instead of code E0452.

The classification of intermittent assist devices or respiratory assist devices with a backup rate under the FSS payment category versus the CR payment category results in a substantial increase in Medicare payments. Total Medicare payments for one device furnished to one patient under the FSS payment category would be as much as $38,530 after 5 years as opposed to $12,201 if the device were classified under the CR payment category.[1] This difference in costs 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.

In 1998, for the first time, the DMERCs conducted an in-depth review of the use of intermittent assist devices and issued proposed medical review policies that included a recommendation to revise the nomenclature for the HCPCS codes for these devices. The term ''respiratory assist device, bi-level pressure capability'' was proposed to replace the HCPCS wording of ''intermittent assist device with continuous positive airway pressure (CPAP),'' and separate HCPCS codes were proposed to differentiate between devices with a backup rate and devices without a backup rate.

E. Public Meeting on Payment for Respiratory Assist Devices

During the course of reviewing the DMERC medical review policies on intermittent assist devices (now referred to as 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 respiratory assist 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 (64 FR 30042) the convening of a public meeting on June 25, 1999, to obtain input from the supplier community regarding the appropriate DME payment category for respiratory assist devices with a backup rate. We made presentations at the June 25, 1999 public meeting. Representatives of the Food and Drug Administration (FDA) and the National Institutes of Health, respiratory assist device manufacturers, suppliers, clinicians, beneficiaries, and others also made presentations at the meeting.

Testimony was given at the public meeting to support the claim that there is a need for FSS of respiratory assist devices with bi-level capability and a backup rate. Speakers 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 regimen. The testimony pointed out that 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

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

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, that had been coded under codes E0452 and E0453 of the HCPCS since 1992. Code K0532 describes those intermittent assist devices that did not have a backup rate and were previously coded under code E0452 (the CR payment category). Codes K0533 and K0534 describe those intermittent assist devices that did have a backup rate, but had been coded under code E0453 (the 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, we delayed our decision regarding the appropriate DME payment category for devices with the backup rate (codes K0533 and K0534) to allow more time for consideration of comments made at the June 25, 1999 public meeting. Since that time, code numbers K0532, K0533, and K0534 have been replaced in the HCPCS by code numbers E0470, E0471, and E0472, respectively.

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

As a result of these conclusions (and in conjunction with the findings of the 1999 OIG report discussed in section II.F of this preamble), we issued the August 22, 2003 proposed rule. As noted above, the only regular servicing necessary for these devices is changing the filter once a year; thus, we believe that 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, Medicare pays for this service, regardless of whether the item is in the FSS or the CR category. At the time that we issued the proposed rule, we were confident that this change in payment category would not result in a decrease in the current level of service being provided to Medicare beneficiaries. After consideration of all comments, we have maintained the proposed provisions in this final rule.

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

As we explained in the August 2003 proposed rule, in 1999, the OIG began an inspection to determine if respiratory assist devices with a backup rate receive frequent and substantial servicing. To assess whether devices received frequent and substantial servicing, the OIG reviewed a stratified random sample of Medicare claims and associated supplier records. The OIG also conducted surveys of beneficiaries, suppliers, manufacturers, and accreditation agencies. In June 2001, the OIG issued its report on respiratory assist devices with a backup rate (OEI–07–99–00440) and recommended that these devices be moved from the FSS payment category to the CR payment category. The OIG made its recommendation based on information gathered from the surveys it conducted. The OIG included the following findings in its report:

- Supplier services consist primarily of routine maintenance and patient monitoring.
- For most beneficiaries, actual supplier visits do not meet the suppliers' own protocols or recommendations for frequency of visits that are developed in the absence of official guidelines regarding the number of visits that are necessary for the device.
- Contrary to supplier protocols, the number of beneficiaries receiving visits declines over time.
- Covering the respiratory assist device with backup rate in the capped rental category would have saved Medicare $11.5 million annually.

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

III. Public Comments Received on the Proposed Rule and Departmental Responses

We received 15 timely pieces of correspondence containing multiple comments on the August 22, 2003 proposed rule. A summary of these public comments and the Department's responses to those comments follow:

Comment: All of the commenters opposed the proposed change in the Medicare payment category for respiratory assist devices with backup rate capability (HCPCS code K0533 or E0471) from the FSS category to the CR category. Some commenters viewed the proposed change as a reduction in payment rather than a correction of a coding error and requested withdrawal of the proposal because the rationale was unsupportable. The commenters stated that the alleged payment error originally occurred when, they believe, CMS incorrectly relabeled what the industry now refers to as bi-level ventilators or noninvasive positive pressure ventilators (NPPVs) as respiratory assist devices. The commenters indicated that the term ''respiratory assist device'' is ambiguous and its use is inconsistent with current practice, with medical literature, and with the FDA classification of these devices. The commenters pointed out that the FDA classifies NPPVs as ventilators and, as such, their purpose and function require monitoring and servicing to avoid risk to the patient's health, and, thus, classification under the Medicare FSS payment category. The commenters added that Medicare payment policy is the only area where these ventilators are referred to as ''respiratory assist devices.''

Response: Respiratory assist devices with bi-level capability and a backup rate, or NPPVs as they are referred to by suppliers and manufacturers of these devices, are a type of intermittent assist device with CPAP and, therefore, are excluded from the FSS payment category by law. CPAP devices and intermittent assist devices with CPAP are indeed referred to as ventilators in the statute, but are nonetheless excluded from the FSS category under section 1834(a)(3) of the Act. This statutory provision does not allow us to exempt certain types of intermittent assist devices (that is, those with backup rate features). The terms ''intermittent assist device'' and ''respiratory assist device'' describe the same general category of bi-level positive airway pressure device technology that was brought onto the market under the trade name of BiPAP® and that still exists today. While some bi-level devices include a backup rate feature and some do not, the term ''intermittent assist devices'' was developed for HCPCS code E0452 to describe all bi-level devices, and this is the statutory language that was used to exclude

certain ventilators from the FSS payment category. Therefore, the law requires this change.

We note that FDA classification of devices for the purpose of clearing products for market distribution does not determine Medicare coverage and payment rules or our policy development. Likewise, our definitions and classification of devices under the Medicare program have no direct effect on FDA classification of drugs and devices. The process of clearing devices for marketing and determining coverage and payment of devices under Medicare are two different programs with different parameters.

Comment: A number of commenters stated that CMS does not have the legal authority under the plain meaning of the language in the statute to change the payment category for NPPVs or respiratory assist devices with bi-level capability and backup rate. In addition, they believed CMS is taking too narrow a view of the term ''servicing'' in the language of the 1993 statutory amendments to the Act and the legislative history. The commenters stated that the House Report language clarifies that ''frequent and substantial servicing'' refers more broadly to the servicing, monitoring, and adjustments needed to make certain that these ventilators are both functioning properly and being used properly by the patient, not just to the equipment itself. Further, one commenter indicated that the House Report further states that these items are typically quite expensive and often subject to relatively rapid technological changes. Therefore, the commenters pointed out, NPPV ventilators fit the statutory definition for the FSS payment category.

Response: As indicated above, respiratory assist devices with bi-level capability and a backup rate, or NPPVs as they are referred to by suppliers and manufacturers of these devices, are a type of intermittent assist device with CPAP and, therefore, are excluded from the FSS payment category by section 1834(a)(3) of the Act. This statutory provision does not allow us to exempt certain types of intermittent assist devices (that is, those with backup rate features). Therefore, we do not have the discretion to place these items in the FSS category. Even assuming arguendo that the items did require frequent and substantial servicing, which we believe they do not, based on information we have received, including the OIG report on this subject, the law excludes them from this category of items.

Comment: A number of commenters suggested that if CMS wanted to take corrective action against suppliers who are noncompliant with established protocols pertaining to the FSS category, the better approach would be to sanction those providers for inappropriate or fraudulent billing practices, not to reduce payments for the devices. Another commenter who agreed with the OIG report believed that CMS must protect beneficiaries and take action when suppliers of DME fail to properly set up, adjust incrementally, and provide careful followup on the use of the equipment. The commenter believed that corrective action would be proper, but disagreed with the lowering of the payment for the services needed.

Response: Section 1834(a)(20) of the Act, as added by section 302(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), requires us to establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. We expect to implement this statutory provision in the near future, at which point suppliers of respiratory assist devices will not be allowed to bill Medicare for furnishing these devices if they do not meet the established quality standards. In addition, we will continue to implement and refine our procedures for identifying and sanctioning fraudulent and abusive suppliers under Medicare.

With regard to the lowering of overall Medicare payments for the device that would result from implementation of this rule, it is not the intent of this rule to lower payments in order to take corrective action against suppliers who fail to provide necessary services. This rule would place respiratory assist devices with bi-level capability and a backup rate feature in the CR category in order to comply with section 1834(a)(3) of the Act.

Comment: Several commenters believed that the OIG study investigating the impact of the proposed policy was flawed in design, interpretation of results and conclusions, and they challenged the four major findings cited in the proposed rule (see also section II.D of this final rule). The commenters believed that there were (1) Inconsistent interpretation of the statute and intent of the Congress; (2) disregard for FDA's regulatory classification of NPPVs as ventilators; (3) conclusions regarding the nature and frequency of services to patients using NPPVs that are inconsistent with the underlying data (data that they believed were incorrect and misleading); and (4) recommendations that were in conflict with published medical views of NPPVs that pose health risks and prevent access to devices by beneficiaries.

Response: The overriding issue addressed by the proposed rule and this final rule is the fact that the statute excludes intermittent assist devices or respiratory assist devices from the FSS category. Although the OIG report indicates that suppliers of respiratory assist devices are not performing frequent and substantial servicing of the devices, the report itself cannot affect the legal mandate to exclude these items from the FSS payment category.

Comment: A number of commenters recommended that CMS establish a standard for payment of respiratory care services for patients who require the use of NPPV, as well as guidelines specific to ventilator treatment of patients with amyotrophic lateral sclerosis (ALS). The commenters believed that switching NPPV to the category of capped rental items without simultaneously covering the cost of respiratory care services that the comments state that ventilator dependent patients need would eliminate followup care by clinical personnel for these patients and would endanger the lives of many patients who suffer from respiratory insufficiency due to such diseases as ALS and post-polio syndrome.

Response: As mentioned in an earlier response, section 1834(a)(20) of the Act, as added by section 302(a) of Public Law 108–173, requires us to establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. We expect to implement this provision in the near future.

With regard to the services of a respiratory therapist and other clinical services related to the care of a patient using a respiratory assist device, these services do not fall within the scope of the DME benefit. The overall clinical care of a beneficiary who receives DME is the responsibility of the beneficiary's treating physician. Therefore, payment under the DME benefit does not include payment for the clinical services of a respiratory therapist or other clinicians that relate to the care of the patient. Further clarification of this issue will be provided through the DME supplier quality standards.

Comment: A number of commenters believed that the proposed change (1) would have a significant adverse impact on beneficiaries' access to ventilator therapy (for people with neuromuscular diseases such as ALS, post-polio syndrome, and multiple sclerosis); (2) would jeopardize the health and safety of disabled beneficiaries with neuromuscular diseases; and (3) would

create additional costs to the Medicare program through an increase in the number of hospitalizations and urgent care visits. Some of the commenters believed that these issues were not adequately addressed in the proposed rule, despite their presentation at the 1999 public meeting.

Commenters acknowledged that there is no provision in the Medicare statute that authorizes coverage and payment for services of a health care professional who provides ''hands-on'' care for a home ventilator patient. However, the commenters pointed out that, in the real world, a professional who is attempting to provide FSS to the equipment invariably also interacts with and may provide care to the patient, a service that would be eliminated if the category payment change is made. One commenter indicated that loss of payment resulting from the change in payment category means loss of service to needy individuals.

Response: The proposed rule and this final rule pertain only to respiratory assist devices, not to ventilator therapy. They do not affect coverage of ventilators, which continue to be covered under the DME benefit. We disagree that the proposed rule and this final rule will significantly affect beneficiary access to respiratory assist devices. The law requires that intermittent assist devices or respiratory assist devices be excluded from the DME FSS payment category under Medicare. We believe the payments for these respiratory assist devices as capped rental items will cover the costs of medically necessary equipment and services.

Comment: One commenter pointed out that a DME company has no obligation to provide any services for a beneficiary who selects the purchase option and that this creates a hazard to some beneficiaries. The commenter added that it will not be cost-effective to provide necessary services to beneficiaries with severe respiratory problems if the device is moved to the CR payment category.

Response: We do not believe that the provisions of the proposed rule and this final rule will create a hazard for beneficiaries. Medicare will make rental payments for respiratory assist devices as DME under the provisions of the statute and will make payments for any necessary maintenance and servicing of patient-owned equipment if the beneficiary selects the purchase option during the 10th rental month of the 15-month rental. In addition, as we have indicated earlier, we are in the process of developing rules that will establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. These standards will implement provisions of section 1834(a)(20) of the Act as added by section 302(a) of Pub. L. 108–173.

Comment: A number of commenters believed that the proposed rule would have a disproportionate adverse economic effect on small businesses, given the estimated significant reductions in payments that would occur if the proposed rule were finalized, that is, a 78-percent reduction in payments over a 5-year period. The commenters pointed out the limited number of suppliers of NPPV ventilators nationally and that, of the top 30 suppliers cited by CMS in the proposed rule, 83 percent are probably small businesses. The commenters agreed with CMS' assessment in the proposed rule that the top 30 suppliers account for 50 percent of the use of code K0533 and that 5 of these suppliers account for 40 percent of expenditures for the code. One commenter indicated that as a result of the revised DMERC policy, many companies have already stopped offering respiratory assist services. This commenter believed that most companies would not offer to provide NPPV at all under the proposed change in the payment category.

Response: We agree that some small suppliers may be adversely affected by this rule. However, given that the current monthly fee schedule ceiling for this device is $642.17 and is very generous compared to the monthly fee schedule ceiling of $256.60 for the device without the back-up rate feature, we do not believe that many of the current suppliers of respiratory assist devices will be significantly affected. In addition, we do not anticipate problems with beneficiary access to respiratory assist devices as a result of this rule given this generous payment schedule. We refer readers to a further discussion of the impact of this final rule on small suppliers in section VI of this final rule.

Comment: One commenter believed that the rapid rise in Medicare expenditures for use of ventilators was due to the fact that the benefits of NPPV were relatively unknown until 1995, not to the misuse of the device and coding. The commenter indicated that CMS also failed to consider the cost savings from decreased hospitalizations among the groups of patients receiving NPPVs.

Response: The reasons for the growth in expenditures for respiratory assist devices are not relevant to this final rule. The law requires that these devices be excluded from the DME FSS payment category under Medicare.

Comment: One commenter believed that CMS failed to meet the statutory requirement to analyze options for regulatory relief under the Regulatory Flexibility Act when over half of the small businesses would be seriously impacted by the proposed rule (16 of 25). The commenter wanted to know where and how it could seek relief. This commenter also disagreed with CMS' determination that the costs and benefits of the proposed rule would be economically insignificant, that is, less than $100 million.

Response: The statute specifically excludes intermittent assist devices (now referred to as respiratory assist devices) from the DME FSS payment category under Medicare. The only relief from this statutory exclusion would be a legislative change. As we discuss in detail under section VI of this preamble, we estimate that this final rule will result in total expenditures of less than the $100 million threshold per year defined in the Executive Order as economically significant.

IV. Provisions of the Final Rule

After consideration of the public comments received, we are adopting as final the proposed clarification of the payment category policy for respiratory assist devices under Medicare Part B. In this final rule, we are specifying that respiratory assist devices with bi-level capability and a backup rate must be paid as capped rental items under the Medicare program and not paid as items requiring frequent and substantial servicing. In cases where beneficiaries are currently receiving these items, the capped rental period will begin for claims with dates of service on or after April 1, 2006.

V. Collection of Information Requirements

This final rule does not impose information collection and recordkeeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. 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 19, 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.

A. Executive Order 12866

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). Based on the OIG study (OEI–07–99–00440), moving these devices to the CR payment category will result in annual savings of approximately 27 percent. Based on 2004 expenditures of approximately $70 million for this device, below are the estimated 5-year savings for this regulation.

Fiscal year	Savings * (million)
2006	$0
2007	20
2008	20
2009	20
2010	20

* Rounded to the nearer $10 million.

Since we estimate that this final rule will result in reductions in total expenditures of less than $100 million per year, this final 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.

B. Regulatory Flexibility Analysis

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 because of their nonprofit status or because they have 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 will be minimal because most companies supply more than this one type of equipment. We estimate that total Medicare expenditures for DME are approximately $7 billion per year.

As indicated above, we estimate that the overall impact on Medicare revenue associated with moving respiratory assist devices with a backup rate to the CR payment category will be payment reductions that range from approximately $15 million in FY 2005 to $45 million in FY 2009. Therefore, the overall impact on the total industry annual receipts will be small, that is, less than a 1-percent reduction in Medicare revenue. However, while the overall impact is small, some suppliers will 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 will be seriously affected by this final rule. We have reviewed data from the statistical analysis conducted by DMERCs for the top 30 suppliers of respiratory assist devices with backup rate that were furnished during the period of October through December 2003 and billed using HCPCS code K0533. These suppliers accounted for over 66 percent of the total allowed charges in that quarter for code K0533. For these suppliers, the percentage of total DME allowed charges that were made up by allowed charges for code K0533 was 22.5 percent on average. The top 3 DME suppliers of code K0533 accounted for over 50 percent of the total allowed charges for code K0533 and are not small suppliers based on Medicare allowed charges attributed to these suppliers. For these 3 suppliers, the percentage of total DME allowed charges that were made up by allowed charges for code K0533 ranged from 1.4 percent to 2.9 percent. All but one of the other 30 suppliers would be considered small suppliers based on Medicare allowed charge data alone (we are not certain what revenue sources these entities may have other than Medicare). The percentage of total DME allowed charges that were made up by allowed charges for code K0533 was over 50 percent for only 6 of the top 30 suppliers, and the total allowed charges for code K0533 that were associated with these 6 suppliers accounted for only 4.4 percent of total allowed charges for code K0533 during that quarter. Based on these data, we conclude that most small suppliers of respiratory assist devices with backup rate will not be significantly affected by this final rule.

C. Impact on Rural Areas

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 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 100 beds. We are not preparing a rural impact analysis because we have determined that this final rule will not have a significant economic impact on the operation of a substantial number of small rural hospitals.

D. Unfunded Mandates

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 final rule will not have an effect on the governments mentioned, and private sector costs will be less than the $110 million threshold.

E. Executive Order 13132

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.

F. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final 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 is amending 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 frequent and substantial servicing.

(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 backup 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 7, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 10, 2005.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register January 24, 2006.

[FR Doc. 06–798 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–21; MB Docket No. 05–16; RM–11143, RM–11295]

Radio Broadcasting Services; La Grange, Shallotte, Swansboro, Topsail Beach, and Wrightsville Beach, NC

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a *Notice of Proposed Rule Making,* 70 FR 7220 (February 11, 2005), this *Report and Order* upgrades Channel 279C3, Station WBNU(FM), Shallotte, North Carolina, to Channel 279C2, reallots Channel 279C2 to Wrightsville Beach, North Carolina, and modifies the license of Station WBNU(FM) accordingly. The coordinates for Channel 279C2 at Wrightsville Beach are 33–59–56 NL and 77–54–35 WL, with a site restriction of 25.4 kilometers (15.8 miles) southwest of Wrightsville Beach. The *Report and Order* also upgrades Channel 229A, Station WBNE(FM, Wrightsville Beach, to Channel 229C3, reallots Channel 229C3 to Topsail Beach and modifies the license of Station WBNE(FM) accordingly. The coordinates for Channel 229C3 at Topsail Beach are 34–25–37 NL and 77–38–33 WL, with a site restriction of 7.0 kilometers (4.3 miles) north of Topsail Beach. In addition, the *Report and Order* downgrades Channel 280C3, Station WWTB(FM), Topsail Beach, North Carolina, to Channel 281A, reallots Channel 281A to Swansboro, North Carolina, and modifies the license of Station WWTB(FM) accordingly. The coordinates for Channel 281A at Swansboro are 34–42–41 NL and 77–16–07 WL, with a site restriction of 13.9 kilometers (8.7 miles) west of Swansboro. Lastly, the Report and Order upgrades Channel 284C3, Station WZUP(FM), La Grange, North Carolina, to Channel 284C2. The coordinates for Channel 284C2 at LaGrange are 35–07–39 NL and 77–42–59 WL, with a site restriction of 20.9 kilometers (13.0 miles) south of La Grange.

DATES: Effective February 21, 2006.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 05–16, adopted January 4, 2006, and released January 6, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

Part 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 reads as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under North Carolina, is amended by removing Channel 284C3 and adding Channel 284C2 at La Grange; by removing Channel 279C3 at Shallotte, by adding Swansboro, Channel 281A, by removing Channel 280C3 and adding Channel 229C3 at Topsail Beach and by removing Channel 229A and by adding Channel 279C2 at Wrightsville Beach.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 06–800 Filed 1–26–06; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–13; MB Docket No. 03–147, RM–10722; MB Docket No. 03–148, RM–10724; MB Docket No. 03–177, RM–10749; MB Docket No. 03–178; RM–10750; and MB Docket No. 03–180, RM 10753]

Radio Broadcasting Services; Anacoco, LA; Barstow, CA; Erie, PA, Greenfield, CA; and Newcastle, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Linda A. Davidson, allots Channel 267A at Barstow, California, as the community's third local FM transmission service. *See* 68 FR 42664, July 18, 2003. Channel 267A can be allotted to Barstow in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 267A at Barstow are 34–53–55 North Latitude and 117–01–19 West Longitude. Because Barstow is located within 320 kilometers (199 miles) of the U.S.-Mexican border, Mexican concurrence has been requested. However, concurrence of the Mexican government has not yet been received. If a construction permit for Channel 267A at Barstow is granted prior to the Commission's receipt of formal concurrence in the allotment by the Mexican Government, the construction permit will include the following condition: ''Use of this allotment is subject to suspension, modification, or termination without right to hearing, if found by the Commission to be necessary in order to conform to the 1992 USA-Mexico FM Broadcast Agreement or if specifically objected to