

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