• Accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222.

• Ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by a home health agency.

We add a new paragraph (f)(4) to § 414.220 to reflect that, for 1994 and subsequent years, the national limited payment amounts are calculated using the median rather than the weighted average. We make conforming changes to paragraph (f)(3).

We add a new paragraph (g) to § 414.220 to state that payment for surgical dressings effective January 1, 1994 is based on the national limited payment amount increased by the covered item updates for 1993 and 1994.

We revise § 414.222(a) to delete aspirators, nebulizers, and certain ventilators from the list of items requiring frequent and substantial servicing.

We add a new paragraph (e) to § 414.222 to set forth the following transition rules that apply to rental of DME that was paid for under the frequent and substantial servicing class but is no longer paid for under that payment class. For purposes of calculating the 15-month rental period, beginning January 1, 1994, if payment is subsequently made under the other DME (capped rental) payment class for an item that formerly required frequent and substantial servicing, the period begins with the first month of continuous rental, even if that rental period began before January 1, 1994.

For example, if the rental period began on July 1, 1993, the carrier must use this date as beginning the first month of rental. Section 1834(a)(7)(A)(i) limits total rental payments to 15 months (or 13 months if the beneficiary elects the purchase option). If we calculated the 15-month period beginning on January 1, 1994 instead of July 1, 1993 (the first month of rental), rental payments would be made for an additional 6 months beyond the 15-month limit. We do not believe that this would be consistent with the law. Thus, under this final rule, if the beneficiary reached the purchase price limitation on a rental claim before January 1, 1994, no further rental or purchase payments would be made.

Likewise, for purposes of calculating the 10-month purchase option, the rental period also begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August of 1993, the 10-month purchase option must be offered to the beneficiary in May of 1994, the 10th month of continuous rental.

Likewise, for purposes of calculating the purchase ceiling, if an item that is paid under the frequent and substantial servicing class is subsequently paid under the inexpensive or routinely purchased payment class, the rental period begins with the first month of continuous rental under the frequent and substantial servicing class, even if that period began before January 1, 1994.

The transition rules for items previously in the frequent and substantial servicing class are the same as those (§ 414.229(f)) that were promulgated for use in computing the 10- and 15-month periods for capped rental DME. We believe that these transitional requirements are necessary to carry out the statutory intent, to limit capped rental equipment payments to 15 months, or 13 months if the beneficiary elects the purchase option, and to limit rental payments, for inexpensive and routinely purchased items to the purchase price. For example, if we were to begin calculating the 15-month period on January 1, 1994 instead of the first month of rental, payments would be incurred for up to 15 additional months beyond the 15-month limit. For inexpensive or routinely purchased DME, if we were to begin calculating the purchase price limitation on January 1, 1994 instead of the first month of rental, we could pay twice the purchase price. We believe that such a result would be contrary to the direction of the law.

We revise § 414.228(b)(2) to reflect that the applicable percentage increase in the purchase price for prosthetic and orthotic devices is 0 percent for 1994 and 1995.

We revise § 414.232(a) to reflect that the payment amount for TENS computed under § 414.220 was reduced by 15 percent by OBRA 87, effective April 1, 1990. The payment amount originally reduced by 15 percent was further reduced by an additional 15 percent, effective January 1, 1991, by OBRA 90. Effective January 1, 1994, OBRA 93 changed the percent of reduction mandated by OBRA 90 from 15 percent to 45 percent.

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 1980 (44 U.S.C. 3501 et seq.).

V. Regulatory Impact Statement

A. Introduction

This final rule implements changes required by sections 13542 through 13546 of OBRA 93. Section 13543 removed aspirators and nebulizers and certain ventilators from the class of DME items requiring frequent and substantial servicing. These aspirators, nebulizers, and ventilators are now considered to be either capped rental or inexpensive/routinely purchased items. Also, section 13545 provides that the payment amount for TENS devices furnished on or after January 1, 1994 be based on the payment amount effective April 1, 1990, reduced by 45 percent. The Medicare program had expenditures of approximately $5.6 million for an estimated 34,000 TENS units furnished in calendar year (CY) 1993.

Section 13546 provides that there will be no percentage increase in payment in CYs 1994 and 1995 for orthotics, prosthetics, and prosthetic devices. The percentage increase in the consumer price index is expected to resume for payment in subsequent years.

Listed below is a table showing the estimated savings as a result of the various OBRA 93 changes.

ESTIMATE OF MEDICARE SAVINGS OBRA 93 (IN MILLIONS)*

FY 1995	FY 1996	FY 1997	FY 1998	FY 1999
$45	$75	$85	$90	$100

*Rounded to the nearest $5 million.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, most manufacturers and suppliers of DME and orthotic and prosthetic devices are considered to be small entities. Some manufacturers and suppliers, however, clearly have substantial regional or national sales, and do not, therefore, meet the definition of a small entity. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section