(j) The ozone nonattainment areas listed in this paragraph (j) are covered areas beginning on January 1, 1995, except that those areas listed in paragraphs (j)(5) (viii) and (ix), (j)(10) (i), (iii), and (v) through (xi) and (j)(11) of this section shall not be covered areas prior to EPA taking final action on the proposal to remove these areas as covered areas.

* * * * *

[FR Doc. 95–16825 Filed 7–7–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 302

[FRL–5255–5]

Reportable Quantity Adjustments; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correction to final rule.

SUMMARY: This document corrects errors in the amendatory language of a final rule published on June 12, 1995 (60 FR 30926). The final rule made changes to reportable quantities for hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act.

EFFECTIVE DATE: July 10, 1995.

FOR FURTHER INFORMATION CONTACT: The RCRA/UST, Superfund, and EPCRA Hotline at 800/424–9346 (in the Washington, DC metropolitan area, contact 703/412–9810). The Telecommunications Device for the Deaf (TDD) Hotline number is 800/553–7672 (in the Washington, DC metropolitan area, contact 703/486–3323); or Mr. Jack Arthur, Response Standards and Criteria Branch, Emergency Response Division (5202G), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, or at 703/603–8760.

Dated: June 30, 1995.

Timothy Fields, Jr.,

Acting Assistant Administrator.

For the reasons set out in the preamble, FR Doc. 95–13787, published at 60 FR 30926 (June 12, 1995) is corrected as follows:

§ 302.4 [Corrected]

1. On page 30938, column 3, amendatory instruction 4 is corrected to read as follows:

4. Table 302.4 in § 302.4 is amended by adding the following new entries in alphabetical order; and by revising the entries for ''Benzene, dimethyl'', ''Phenol, methyl-'', and ''Xylene (mixed)'' and their subentries; and by revising under the heading ''Unlisted Hazardous Wastes Characteristics: Characteristic of Toxicity:'' the entries for ''o-Cresol (D023)'', ''m-Cresol (D024)'', ''p-Cresol (D025)'', and ''Cresol (D026)''; and by revising the entries for ''F004'', ''F025'', ''F037'', ''F038'', ''K088'', ''K090'', and ''K091''; and by adding footnote ''a'' to the entry for ''Benzene''; and by removing the entries for ''Cresol(s)'' and ''Cresylic acid'' and their subentries, as set forth below:

2. On page 30944, column 1, amendatory instruction 5 is corrected to read as follows:

5. Table 302.4 in § 302.4 is also amended by revising the following entries; and by adding new entries in alphabetical order for ''Antimony Compounds'', ''Aroclors'' and its subentries, ''Arsenic Compounds (inorganic including arsine)'', ''Beryllium Compounds'', ''Cadmium Compounds'', ''Chlorinated camphene'', ''1–Chloro-2, 3-epoxypropane'', ''Chloromethane'', ''Chromium Compounds'', ''Cyanide Compounds'', ''DEHP'', ''Dibromoethane'', ''Dichloromethane'', ''1,4–Diethyleneoxide'', ''Dimethyl aminoazobenzene'', ''Ethyl chloride'', ''Hexone'', ''Hydrogen phosphide'', ''Iodomethane'', ''Lead Compounds'', ''Lindane (all isomers)'', ''MEK'', ''Mercury Compounds'', ''2–Methyl aziridine'', ''Nickel Compounds'', ''PCBs'' and its subentries, ''PCNB'', ''Quinone'', ''Quintobenzene'', ''Radionuclides (including radon)'', ''Selenium Compounds'', ''TCDD'', ''2,4–Toluene diamine'', ''2,4–Toluene diisocyanate'', and ''Urethane'', as set forth below:

3. On page 30959, preceding Appendix A to § 302.4, add the following amendatory instruction to read as follows:

5a. Appendix A to § 302.4 is amended by revising the following entries, as set forth below:

[FR Doc. 95–16754 Filed 7–7–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 414

[BPD–494–F]

RIN 0938–AD65

Medicare Program; Payment for Durable Medical Equipment and Orthotic and Prosthetic Devices

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

ACTION: Final rule.

SUMMARY: This final rule addresses comments received on an interim final rule with comment period published on December 7, 1992. The interim final rule implemented section 4062(b) of the Omnibus Budget Reconciliation Act of 1987. It specified that payment under the Medicare program for durable medical equipment (DME), prosthetics, and orthotics furnished on or after January 1, 1989 is limited to the lower of the actual charge for the equipment or the fee schedule amount established by the carrier. This final rule describes amendments to the methods for computing fee schedules covering the six classes of DME and how they are updated in subsequent years in accordance with sections 13542 through 13546 of the Omnibus Budget Reconciliation Act of 1993.

DATES: These final regulations are effective August 9, 1995.

FOR FURTHER INFORMATION CONTACT:

Sharon Hippler—(410) 966–4633 (Coverage Issues)

William Long—(410) 966–5655 (Payment Issues)

SUPPLEMENTARY INFORMATION:

I. Background

The provisions of sections 1833 and 1842 of the Social Security Act (the Act) set forth the general payment authority for most physician and other medical and health services furnished under Part B of the Medicare program. Section 1834 sets forth the 6 classes of DME and specifies that payment for these items is limited to 80 percent of the lesser of the actual charge or a fee schedule amount established by each Medicare carrier.

We published an interim final rule on December 7, 1992 (57 FR 57675) that set forth the methods for computing fee schedules for the six classes of DME effective for services furnished on or after January 6, 1993. The interim rule also described how the fee schedules are updated. The December 1992 rule explained in detail the various legislative changes that led to its publication (57 FR 57676).

On August 10, 1993, the Omnibus Budget Reconciliation Act of 1993 (OBRA 93, Public Law 103–66), revised the statutory provisions upon which the DME payment rules that appeared in the December 1992 final rule were based. We are including these provisions in this final rule since the revisions are not discretionary but follow the explicit language contained in sections 13542 through 13546.

A summary of the provisions of these sections of OBRA 93 follows :

- Section 13542 amends sections 1834(a)(2), (a)(3), (a)(8), and (a)(9) of the

Act by providing that for 1994 and subsequent years, the national limited payment amount for (1) inexpensive or routinely purchased DME, (2) items requiring frequent and substantial servicing, (3) oxygen, and (4) other DME (capped rental) is equal to one of the following amounts:

- If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.
- If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.
- If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.
- Section 13543(a) amends section 1834(a)(3)(A) of the Act by deleting nebulizers and aspirators from the statutory list of items that require frequent and substantial servicing. It also clarifies that ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices are excluded from the frequent and substantial servicing class.
- Section 13543(b) amends section 1834(a)(2)(A) of the Act by specifying that accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from the frequent and substantial servicing class are included in the inexpensive or routinely purchased equipment class.
- Section 13544(a) amends section 1834(h)(1) of the Act by providing that payment for ostomy supplies, tracheostomy supplies, and urologicals be made using the methodology for inexpensive or routinely purchased equipment.
- Section 13544(b) adds a new paragraph (i) to section 1834 of the Act to provide that payment for surgical dressings must be made using the methodology for inexpensive or routinely purchased equipment. It further specifies the national limited payment amount for surgical dressings must be based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992 increased by the covered item updates for 1993 and 1994.
- Section 13545 amends section 1834(a)(1)(D) of the Act by providing that the reduced payment amount for transcutaneous electrical nerve stimulator (TENS) devices, furnished on or after January 1, 1994, be based on the payment amount effective April 1, 1990, reduced by 45 percent.
- Section 13546 amends section 1834(h)(4)(A) of the Act by specifying that the term ''applicable percentage increase'' used for computing the local purchase price for prosthetic and orthotic devices is ''0'' percent for 1994 and 1995. It also specifies that for subsequent years that term means the percentage increase in the consumer price index for all urban consumers for the 12-month period ending with June of the previous year.

II. Summary of Public Comments and Responses for the December 1992 Final Rule

We received comments from seven groups representing the industry and one State agency. We have summarized the comments related to the fee schedule payment methodology and have presented them below along with our responses.

Several comments were received that concerned other issues related to medical equipment (for example, refining the coverage definitions of medical equipment and updating the HCFA Common Procedure Coding System (HCPCS)) but did not pertain to the subject matter of the interim final rule, which dealt only with the six classes of DME and the corresponding fee schedule methodologies. We are not responding in this final rule to any comments unrelated to the fee schedule payment methodologies.

Inexpensive and Routinely Purchased DME (Section 414.220(a))

Comment: One commenter suggested that we not change to a State-by-State methodology for classifying an item as inexpensive even if the local submitted purchase price is less than $150. The commenter stated that changing the status of an item from State to State would be hopelessly confusing to suppliers and would contribute to increased claims processing costs.

Response: We agree with the commenter. Classifying items by State would create inconsistencies among carrier jurisdictions and would be inconsistent with the thrust of the national limited payment amounts that went into effect in 1991. For example, a capped rental item in one jurisdiction could be considered inexpensive in an adjacent jurisdiction. Therefore, we intend to continue using the national weighted mean submitted charge for purchase of an item (whose price did not exceed $150 during the period from July 1, 1986 through June 30, 1987) for classifying the item as inexpensive.

Frequently Serviced DME (Section 414.222(a))

Comment: One commenter agreed that we should add or delete items in the frequently serviced class by making modifications to this class on a simplified basis. Another commenter suggested that we not change the methodology for adding or deleting items in the frequently serviced class. The commenter argued that, since some items in this class are mandated by the Act, any attempt by us to administratively restructure this class would violate congressional intent.

Response: We believe that the second commenter may have misunderstood our intent in this matter. Section 1834(a)(3) of the Act specifically mandates that certain DME be included in the class of items that require frequent and substantial servicing. In § 414.222(a) of the interim final rule, we announced our intention to specify other items requiring frequent and substantial servicing. It was, and continues to be, our intention to delete only those items that we previously added administratively. Section 414.222(a) permits us and the carriers to define those items needing frequent and substantial servicing.

We will not delete any of the statutorily mandated items from this class of items absent a change in the Act. However, we will add or delete items we previously added in this class by announcing additions and deletions in an administrative instruction rather than in the regulations.

Comment: One commenter suggested that the following items belong in the frequently serviced class: continuous passive motion machines, memory monitors, powered air flotation beds, air fluidized beds, and alternating pressure mattresses. Conversely, the commenter believed that nebulizers and aspirators do not belong in the frequently serviced class. Two commenters suggested that infusion pumps should be placed in the frequently and substantially serviced class. The commenters stated that few infusion pumps last 5 years without major servicing and that pumps more than a few years old may not be serviceable because of a lack of replacement parts. They also stated that infusion pump manufacturers often stop producing cassettes once the pumps are no longer in production and the Food and Drug Administration believes that infusion pumps should be tracked because the risk of failure presents the potential for serious adverse health consequences.

Response: Continuous passive motion machines currently appear in the class of items that require frequent and substantial servicing (§ 414.222(a)). We will consider whether memory monitors, powered air flotation beds, air fluidized beds, alternating pressure

mattresses, and infusion pumps should also be added. If after our review, we agree that these items belong in this class, we will add them through an administrative instruction.

Section 1834(a)(3) of the Act specifically mandated that aspirators, nebulizers and ventilators be included in the frequent and substantial servicing class. However, section 13543 of OBRA 93 deleted aspirators, nebulizers and some ventilators from this class effective January 1, 1994. Consequently, we have revised § 414.222(a) to remove aspirators, nebulizers, and certain ventilators from the frequent and substantial servicing class. (Depending on changes in the data, items may be moved into any of the other classes, for example, inexpensive or routinely purchased, or capped rental).

Capped Rental DME (Section 414.229)

Comment: Three commenters suggested that we provide a new 15-month rental period if a beneficiary moves outside the supplier's service area or changes suppliers, even though there would be additional cost and a potential for abuse. One commenter suggested giving the second supplier a 12-month rental period.

Response: We agree that these proposals would result in additional program cost and have the potential for abuse. We also believe that we are precluded by section 1834(a)(7)(A) of the Act from providing a new rental period beyond the original 15-month rental period. This section provides that ''* * * payments under this clause may not extend over a period of continuous use of longer than 15 months * * *.'' Therefore, if the beneficiary changes suppliers during or after the 15-month rental period, that change would not result in a new rental period.

In asking for comments regarding this provision, we specifically requested comments on which supplier would be responsible for furnishing the capped rental equipment to the beneficiary if the beneficiary changes suppliers during or after the 15-month rental period. In the December 1992 rule (57 FR 57683), we indicated our initial position that the supplier that provided the item in the fifteenth month of the rental period would be responsible for supplying the equipment and for maintenance and servicing after the 15-month period.

We mentioned that, as an alternative position, we considered requiring the supplier that had furnished the item for the longest portion of the rental period to be responsible for the period of continuous use of the equipment after the 15-month period expired. However, we were concerned about the possible inconveniences to the beneficiary and the initial supplier; for example, the longest term supplier may be located some distance from the beneficiary's residence at the end of the 15-month period. In addition, we did not believe it was appropriate to require a supplier to service equipment that it did not furnish and with which it may not be familiar.

We also mentioned that we considered requiring the last supplier of an item to be responsible for a period of continuous use after the 15-month period but only if the supplier furnished the item for 3 consecutive months. However, based on advice received from the DME industry, we rejected this option because of the possible inconveniences similar to those discussed in the option set forth above.

Other than the comments suggesting that we provide for an additional rental period if the beneficiary changes suppliers, which is precluded by the Act, we received no comments regarding this provision. Further, since this provision became effective on January 1, 1989, we received no significant correspondence from Medicare beneficiaries or the DME industry indicating that this rule presents a problem. This corroborates what representatives of the DME industry indicated to us after the passage of section 4062 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203) (OBRA 1987). At that time, they indicated that suppliers would be able to accommodate beneficiaries who change suppliers (for example, because of a change of residence or dissatisfaction with a supplier). They further indicated that the DME industry preferred making the supplier that rents the item in the last (that is, fifteenth) month of the rental period responsible for supplying the equipment after the last month of rental payments and for continued maintenance and servicing of the equipment.

Therefore, the rules governing this class of equipment will remain the same. Responsibility for supplying equipment in the capped-rental class that has been rented for 15-consecutive months remains with the supplier that rented the item in the last month of the rental period. Responsibility for maintenance and service of the item also remains with that supplier. A move by the Medicare beneficiary does not relieve the supplier that rented the item in the last rental month of either responsibility.

Of course, we will not object to the responsible supplier establishing an arrangement with a supplier located nearer to the beneficiary's new residence to furnish the actual maintenance and service of the equipment.

Reasonable Useful Life (Section 414.229(f))

Comment: One commenter suggested that we should establish reasonable useful lifetime guidelines for equipment but did not offer specific suggestions for these guidelines. Other commenters suggested that a 5-year useful life was too long and that the useful life should be considered to end 12 months after the period identified in the manufacturer's warranty. Another commenter suggested that we meet with manufacturers of medical equipment, especially manufacturers of orthotic devices, to develop specific standards regarding the useful life of equipment.

Response: While we specifically solicited comments regarding the useful life of DME, prosthetics, orthotics, and supplies (DMEPOS), we received only one comment indicating what that useful life should be (which was 12 months after the date indicated in the manufacturer's warranty) for any item of medical equipment. We selected a 5-year useful life because that is the useful life of capped rental DME established in section 1834(a)(7)(C)(iii) of the Act. We continue to believe that a minimum useful life of 5 years is reasonable for payment purposes and should be applied to other items of DME, prosthetics, and orthotics.

We believe that establishing a useful life of 12 months beyond a manufacturer's warranty is unsupported and arbitrary. We would welcome meeting with manufacturers of medical equipment to discuss information that supports considering an alternative to the 5-year useful lifetime of equipment. We will maintain the minimum 5-year useful lifetime provision for payment purposes for all medical equipment unless we receive evidence that supports some other timeframe.

Implementation of the Fee Schedule Methodology Through Program Instructions

Comment: One commenter suggested that implementation of the fee schedule payment methodology has decreased payments and increased regulatory and paperwork burdens, significantly affecting small suppliers of medical equipment. The commenter asserted that since we have implemented the fee schedule methodology through Medicare Carrier Manual issuances, the industry's opportunity to present its case in the public forum of rulemaking has been denied.

Response: We disagree with the commenter. While the December 1992 interim final rule became effective 30 days after it was published, it provided an opportunity for public comment and potential reconsideration of the policies it set forth. We usually implement legislation by following the rulemaking process that affords all parties an opportunity to comment before we implement the legislation. The Congress, in mandating the OBRA 87 changes establishing the DME fee schedule methodology, expressly authorized the Secretary to issue the implementing regulations on an interim basis. However, because of the need to implement the fee schedule as soon as possible, it was necessary that we issue instructions in the Medicare Carriers Manual while developing the interim rule.

Access to Common Working File

Comment: Two commenters suggested that suppliers need access to our Common Working File to determine if a beneficiary has previously rented a piece of equipment and, if so, for what period of time.

Response: There are always privacy considerations concerning the release of beneficiary information contained in the Common Working File systems. However, we intend to investigate the effects of disclosing beneficiary information to DME suppliers. Nevertheless, the option to furnish equipment rests with the supplier. Since the supplier is able to communicate with the beneficiary before furnishing medical equipment, we believe that the supplier should be responsible for determining whether a beneficiary has ever rented equipment. We are responsible for ensuring that we do not pay for services furnished to a patient who is not entitled to Medicare benefits and that we do not pay for equipment after the appropriate rental period.

Budget Savings Resulting From the DME Fee Schedule Methodology

Comment: Two commenters noted that budget savings associated with the interim rule continue to remain elusive, noting that while the fee schedule methodology was estimated to save Medicare more than $2 billion, a study by the General Accounting Office (GAO) issued in July 1992 found that the fee schedule methodology actually cost more than the reasonable charge system it replaced.

Response: The GAO found that for the first 2 years after implementation of the fee schedule methodology, Medicare program expenditures increased by 16 percent compared to what the costs would have been under the reasonable charge system. The GAO also projected that when fully implemented in 1993, the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508, enacted on November 5, 1990) (OBRA 90) would offset the program cost increases that occurred when the fee schedule methodology was implemented. The savings generated would save the Medicare program more than $2 billion over 5 years beginning in 1992.

Uniform Payment, Coverage, and Utilization Criteria

Comment: One commenter suggested that we adopt national uniform payment, coverage, and utilization criteria for prosthetic and orthotic devices. The commenter also suggested that the term ''region'' should encompass geographic areas as large as possible, preferably dividing the nation into four areas that comport with the four new regions of the DMEPOS regional carriers.

Response: The December 1992 interim rule defined ''region'' as those carrier service areas administered by the ten HCFA regional offices (57 FR 57689). This was the longstanding definition of ''region'' in use when legislation established a fee schedule methodology for prosthetic and orthotic devices that was to be calculated on a regional basis.

We believe it was the intent of the Congress that we recognize differences in the costs of supplying prosthetic and orthotic devices among the ten geographic regions then in use. Since this was the definition of region that we used when the Congress passed the fee schedule methodology, we will continue to group States together by the ten HCFA regions for pricing purposes.

Effective October 1, 1993, we contracted with four ''regional'' carriers that process all DMEPOS claims nationally. We expect that having the four carriers will result in more uniform payment, coverage, and utilization of Medicare services. However, we continue to believe that using a ten region structure for pricing of services is appropriate. We believe that a larger number of regions gives more recognition to local variations in the cost of providing equipment.

Reducing the number of regions to four rather than the current ten would give less emphasis to local variation. If we based the pricing of services on a four region system, each region would cover a greater number of suppliers, which could produce greater disparity in suppliers' costs throughout the region. Having a larger supplier pool could dilute the impact of outlying suppliers whose labor, material, and overhead costs are significantly higher than the median.

By retaining a pricing system based on ten regions, we expect that, for any item of DME, the costs of suppliers within each region would be more similar to each other and the resulting fee schedule more reflective of costs in the local supplier population.

Comment: One commenter asked if we intend that the regional purchase price be determined State-by-State.

Response: As described in the interim final rule (57 FR 57691), regional pricing is based on local prices within a carrier area, which usually is an entire State. Specifically, our methodology for computing the regional purchase price is to first calculate a local purchase price, then calculate a regional purchase price by averaging the local purchase prices for the region (weighted by the relative volume of all claims among the carriers in the region).

Use of the Term ''Durable Medical Equipment''

Comment: One commenter suggested using the term ''home'' to define medical equipment used in the home rather than the term ''durable.'' Another commenter suggested that we expand the definition of DME in § 414.202 to include coverage of equipment not used in the home and provide for coverage of additional items of disposable equipment.

Response: Section 1861(n) of the Act defines ''durable medical equipment.'' We are bound by the definition of DME contained in the law.

Applicability to Medicaid

Comment: One commenter suggested that the Medicare payment methodology should also be applicable to State Medicaid programs.

Response: The statute does not authorize us to impose the Medicare payment methodology on States, therefore, the Congress must pass legislation to authorize us to do so.

Fraud and Abuse

Comment: One commenter noted that the rules regarding TENS, seat lift mechanisms, and electric wheelchairs should help eliminate fraud and abuse.

Response: We agree.

III. Provisions of This Final Rule

To implement the requirements of sections 13542 through 13546 of OBRA 93, we are revising part 414, subpart D.

We expand the list of inexpensive or routinely purchased items in § 414.220(a) to include, effective January 1, 1994—

• 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

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 50 beds.

C. General Effects

Since beneficiary copayments are linked to the level of allowed payments for DME, the reduction in fee schedule amounts will reduce costs to beneficiaries. The magnitude of savings to beneficiaries will coincide with the reduction in payment levels for DME. Section 13543 of OBRA '93 limited payment for aspirators, nebulizers, and certain ventilators by deleting them from the group for items requiring frequent and substantial servicing. Beneficiaries who had been renting these items for an unlimited period will in the future be required to pay copayment fees on payment up to only the allowed purchase price or rental cap amount of the device.

Section 13545 reduces the payment amount for TENS devices furnished on or after January 1, 1994 by 45 percent from the payment amount effective April 1, 1990. As the payment for the TENS device will be reduced, the beneficiaries copayment portion will also be reduced.

From the perspective of manufacturers and distributors, the reductions in Medicare payments for certain DME, nebulizers and aspirators, TENS devices, and orthotics, prosthetics, and prosthetic devices will result in some revenue losses. Manufacturers and suppliers that do not specialize in these items may see minimal reductions in their revenues. We do not have detailed data that will enable us to predict the economic impact on individual suppliers and manufacturers. Considering that the total DME sales in CY 1993 equaled an estimated $2.4 billion and the limited reductions we are making at this time, we do not believe the impact on DME manufacturers and suppliers will significantly affect the quantity or quality of DME available to Medicare beneficiaries.

The provisions of this rule conform the regulations to legislative provisions. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this rule was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Durable medical equipment, Medicare, Prosthetic and orthotic devices.

42 CFR part 414, subpart D, is amended as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

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

Authority: Secs. 1102, 1833(a), 1834 (a) and (h), 1848, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395l(a), 1395m (a) and (h), 1395w–4, 1395hh, and 1395rr).

2. In § 414.220, the introductory text for paragraph (f) is republished, paragraphs (a), (b), and (f)(3) introductory text, (f)(3)(i), and (f)(3)(ii) are revised, and new paragraphs (f)(4) and (g) are added, to read as follows:

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions*—(1) *Inexpensive equipment* means equipment the average purchase price of which did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(3) *Accessories.* Effective January 1, 1994, accessories used in conjunction with a nebulizer, aspirator, or ventilator excluded from § 414.222 meet the definitions of ''inexpensive equipment'' and ''routinely purchased equipment'' in paragraphs (a)(1) and (a)(2) of this section, respectively.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(3) of this section, payment for inexpensive and routinely purchased items is made on a rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount.

(2) Effective January 1, 1994, payment for ostomy supplies, tracheostomy supplies, urologicals, and surgical dressings not furnished as incident to a physician's professional service or furnished by an HHA is made using the methodology for the inexpensive and routinely purchased class.

(3) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

* * * * *

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

* * * * *

(3) For 1993, the national limited payment amount is equal to one of the following:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts.

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts.

* * * * *

(4) For 1994 and subsequent years, the national limited payment amount is equal to one of the following:

(i) If the local payment amount is not in excess of the median, nor less than 85 percent of the median, of all local payment amounts—100 percent of the local payment amount.

(ii) If the local payment amount exceeds the median—100 percent of the median of all local payment amounts.

(iii) If the local payment amount is less than 85 percent of the median—85 percent of the median of all local payment amounts.

(g) *Payment for surgical dressings.* For surgical dressings furnished after December 31, 1993, the national limited payment amount is computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates for 1993 and 1994.

3. In § 414.222, paragraph (a) is revised and paragraph (e) is added to read as follows:

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators (except those that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices).

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other items specified in HCFA program instructions.

(5) Other items identified by the carrier.

* * * * *

(e) *Transition to other payment classes.* For purposes of calculating the

15-month rental period, beginning January 1, 1994, if an item has been paid for under the frequent and substantial servicing class and is subsequently paid for under another payment class, the rental period begins with the first month of continuous rental, even if that 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. Likewise, for purposes of calculating the 10-month purchase option, the rental period begins with the first month of continuous rental without regard to when that period started. For example, if the rental period began in August 1993, the 10-month purchase option must be offered to the beneficiary in May 1994, the tenth month of continuous rental.

4. In § 414.228, the introductory text for paragraphs (b) and (b)(2) are republished, paragraph (b)(2)(ii) is revised, and new paragraphs (b)(2)(iii) and (b)(2)(iv) are added, to read as follows:

§ 414.228 Prosthetic and orthotic devices.

* * * * *

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

* * * * *

(2) The carrier determines a local purchase price equal to the following:

* * * * *

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991. For 1992 and 1993, the applicable percentage increase is equal to the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

(iii) For 1994 and 1995, the applicable percentage increase is 0 percent.

(iv) For all subsequent years the applicable percentage increase is equal to the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

* * * * *

5. In § 414.229, the section heading is revised, the introductory text for paragraph (c) is republished and paragraph (c)(3) is revised, to read as follows:

§ 414.229 Other durable medical equipment—capped rental items.

* * * * *

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

* * * * *

(3) *For years after 1991.* The purchase price is determined using the methodology contained in paragraphs (d) through (f) of § 414.220.

* * * * *

6. In § 414.232, paragraph (a) is revised to read as follows:

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule.* Except as provided in paragraph (b) of this section, payment for TENS is made on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. The payment amount for TENS computed under § 414.220(c)(2) is reduced according to the following formula:

(1) Effective April 1, 1990—the original payment amount is reduced by 15 percent.

(2) Effective January 1, 1991—the reduced payment amount in paragraph (a)(1) is reduced by 15 percent.

(3) Effective January 1, 1994—the reduced payment amount in paragraph (a)(1) is reduced by 45 percent.

* * * * *

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

Dated: June 28, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 95–16805 Filed 7–7–95; 8:45 am]

BILLING CODE 4120–01–P

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42 CFR Part 433

[MB–39–F]

RIN: 0938–AF11

Medicaid Program; Third Party Liability (TPL) Cost-Effectiveness Waivers

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

ACTION: Final rule.

SUMMARY: This final rule revises regulations concerning Medicaid agencies' actions where third party liability (TPL) may exist for expenditures for medical assistance covered under the State plan. It allows the Medicaid agencies to request waivers from certain procedures in our regulations that are not expressly required by the Social Security Act. We will consider waiving nonstatutorily required procedures relating to identifying possible TPL where the agency finds that following a given required procedure is not cost-effective and is duplicative of another State activity. A nonstatutorily required activity is eligible for a waiver if the cost of the required activity exceeds the TPL recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the States. This change gives States greater flexibility in managing their Medicaid programs.

EFFECTIVE DATE: This final rule is effective September 8, 1995.

FOR FURTHER INFORMATION CONTACT: Mel Schmerler, (410) 966–5942.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902(a)(25) of the Social Security Act (the Act) requires that State or local Medicaid agencies take all reasonable measures to ascertain the legal liability of third parties to pay for care and services furnished to Medicaid recipients. A third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan. Medicaid is intended to be the payer of last resort; that is, other available resources must be used before Medicaid pays for the care and services of a Medicaid-eligible individual. These other resources are known as third party liability, or TPL.

Further, provisions under section 1902(a)(25)(A)(i) of the Act specify that the Medicaid State plan must provide for the collection of sufficient information to enable the State to pursue claims against third parties. Examples of liable third parties include commercial insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payments received directly from an individual who has either voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients; and fraternal groups, union, or State workers' compensation commissions. TPL also includes medical support provided by a parent under a court or administrative order.

Statutory provisions (sections 1137 and 1902(a)(25) of the Act) require States to obtain health insurance information at eligibility intake and redetermination interviews, perform the State Wage Information Collection