§ 414.92 Electronic Prescribing Incentive Program.

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(c) * * *

(2) * * *

(ii) Significant hardship exception. CMS may, on a case-by-case basis, exempt an eligible professional (or in the case of a group practice under paragraph (e) of this section, a group practice) from the application of the payment adjustment under paragraph (c)(2) of this section if, CMS determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship. Eligible professionals (or, in the case of a group practice under paragraph (e) of this section, a group practice) may request consideration for a significant hardship exemption from the 2012 eRx payment adjustment if one of the following circumstances apply:

(A) The practice is located in a rural area without high speed internet access.

(B) The practice is located in an area without sufficient available pharmacies for electronic prescribing.

(C) Registration to participate in the Medicare or Medicaid EHR Incentive Program and adoption of Certified EHR Technology.

(D) Inability to electronically prescribe due to local, State or Federal law or regulation.

(E) Limited prescribing activity.

(F) Insufficient opportunities to report the eRx measure due to limitations of the measure’s denominator.

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Subpart C—Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies

SOURCE: 66 FR 45176, Aug. 28, 2001, unless otherwise noted.

§ 414.100 Purpose.

This subpart implements fee schedules for PEN items and services as authorized by section 1842(s) of the Act.

§ 414.102 General payment rules.

(a) General rule. For items and services furnished on or after January 1, 2002, Medicare pays for the items and services as described in paragraph (b) of this section on the basis of 80 percent of the lesser of—

(1) The actual charge for the item or service; or

(2) The fee schedule amount for the item or service, as determined in accordance with § 414.104.

(b) Payment classification. (1) CMS or the carrier determines fee schedules for Parenteral and enteral nutrition (PEN) nutrients, equipment, and supplies, as specified in § 414.104.

(2) CMS designates the specific items and services in each category through program instructions.

(c) Updating the fee schedule amounts. For each year subsequent to 2002, the fee schedule amounts of the preceding year are updated by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding year.

§ 414.104 PEN Items and Services.

(a) Payment rules. Payment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented.

(b) Fee schedule amount. The fee schedule amount for payment for an item or service furnished in 2002 is the lesser of—

(i) The reasonable charge from 1995; or

(ii) The reasonable charge that would have been used in determining payment for 2002.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

[57 FR 57689, Dec. 7, 1992]

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Complex rehabilitative power-driven wheelchair means a power-driven wheelchair that is classified as—

(1) Group 2 power wheelchair with power options that can accommodate
Centers for Medicare & Medicaid Services, HHS  
§ 414.210  

§ 414.210 General payment rules.  
(a) General rule. For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—  
(1) The actual charge for the item;  
(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§414.220 through 414.232.  

(b) Payment classification. (1) The carrier determines fee schedules for the following classes of equipment and devices:  
(i) Inexpensive or routinely purchased items, as specified in §414.220.  
(ii) Items requiring frequent and substantial servicing, as specified in §414.222.  
(iii) Certain customized items, as specified in §414.224.  
(iv) Oxygen and oxygen equipment, as specified in §414.226.  
(v) Prosthetic and orthotic devices, as specified in §414.228.  
(vi) Other durable medical equipment (capped rental items), as specified in §414.229.  
(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in §414.232.  
(2) CMS designates the items in each class of equipment or device through its program instructions.  
(c) Exception for certain HHAs. Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in §413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provisions of §§414.220 through 414.230.  
(d) Prohibition on special limits. For items furnished on or after January 1, 1989 and before January 1, 1991, neither CMS nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in §405.502(g) of this chapter.  
(e) Maintenance and servicing—(1) General rule. Except as provided in paragraph (e)(3) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing
of beneficiary-owned equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer’s or supplier’s warranty. Payment is made for replacement parts in a lump sum based on the carrier’s consideration of the item. The carrier establishes a reasonable fee for labor associated with repairing, maintaining, and servicing the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for oxygen equipment described in paragraph (e)(2) of this section or for other durable medical equipment as described in §414.229(e).

(2) Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period from January 1, 2009 through June 30, 2010. The carrier makes a maintenance and servicing payment for oxygen equipment other than liquid and gaseous equipment (stationary and portable) as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with §414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for 30 minutes of labor for routine maintenance and servicing of the equipment in the beneficiary’s home (including an institution used as the beneficiary’s home).

(iii) The supplier must visit the beneficiary’s home (including an institution used as the beneficiary’s home) to inspect the equipment during the first month of the 6-month period.

(3) Exception to maintenance and servicing payments. For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in §414.222(a);

(ii) Capped rental items, as defined in §414.229(a), that are not beneficiary-owned in accordance with §414.228(d), §414.229(f)(2), or §414.229(h); and

(iv) Oxygen equipment, as described in §414.226.

(4) Supplier replacement of beneficiary-owned equipment based on accumulated repair costs. A supplier that transfers title to a capped rental item to a beneficiary in accordance with §414.229(f)(2) is responsible for furnishing replacement equipment at no cost to the beneficiary or to the Medicare program if the carrier determines that the item furnished by the supplier will not last for the entire reasonable useful lifetime established for the equipment in accordance with §414.210(f)(1). In making this determination, the carrier may consider whether the accumulated costs of repair exceed 60 percent of the cost to replace the item.

(5) Maintenance and servicing payment for certain oxygen equipment furnished after the 36-month rental period and on or after July 1, 2010. For oxygen equipment other than liquid and gaseous equipment (stationary and portable), the carrier makes payment as follows:

(i) For the first 6-month period following the date on which the 36-month rental period ends in accordance with §414.226(a)(1) of this subpart, no payments are made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period for routine maintenance and servicing of the equipment in the beneficiary’s home (including an institution used as the beneficiary’s home).

(iii) Payment for maintenance and servicing is made based on a reasonable fee not to exceed 10 percent of the purchase price for a stationary oxygen concentrator. This payment includes payment for maintenance and servicing of all oxygen equipment other than liquid or gaseous equipment (stationary or portable).

(iv) The supplier must visit the beneficiary’s home (including an institution used as the beneficiary’s home) to inspect the equipment during the first month of the 6-month period.

(f) Payment for replacement of equipment. If an item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by
the patient for the equipment’s reasonable useful lifetime or if the carrier determines that the item is lost, stolen, or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement oxygen equipment, payment is made in accordance with §414.226(a).

(3) If the beneficiary elects to obtain a replacement capped rental item, payment is made in accordance with §414.229(a)(2) or (a)(3).

(4) For all other beneficiary-owned items, if the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

§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.

(c) Fee schedule amount for 1989 and 1990. The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier’s allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI-U for the 6-month period ending December 1987.

(d) Updating the local payment amounts for years after 1990. For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) Calculating the fee schedule amounts for years after 1990. For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

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

(1) The 1991 national limited payment amount is equal to:

(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
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weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(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) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average;

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(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.

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the median.

(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.

[57 FR 57689, Dec. 7, 1992, as amended at 60 FR 35497, July 10, 1995]

§ 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 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”).

(2) Continuous and intermittent positive pressure breathing machines.

(3) Continuous passive motion machines.

(4) Other Items specified in CMS program instructions.

(5) Other items identified by the carrier.

(b) Payment rule. Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) Fee schedule amount for 1989 and 1990. The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through
§ 414.226 Oxygen and oxygen equipment.

(a) Payment rules—(1) Oxygen equipment. Payment for rental of oxygen equipment is made based on a monthly fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 36 months. A period of continuous use is determined under the provisions in §414.230.

(2) Oxygen contents. Payment for purchase of oxygen contents is made based on a monthly fee schedule amount until medical necessity ends.

(b) Monthly fee schedule amount for items furnished prior to 2007. (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(A) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(B) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the

§ 414.224 Customized items.

(a) Criteria for a customized item. To be considered a customized item for payment purposes under paragraph (b) of this section, a covered item (including a wheelchair) must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

(b) Payment rule. Payment is made on a lump sum basis for the purchase of a customized item based on the carrier’s individual consideration and judgment of a reasonable payment amount for each customized item. The carrier’s individual consideration takes into account written documentation on the costs of the item including at least the cost of labor and materials used in customizing an item.

change in the CPI-U for the six-month period ending December 1987.

(3) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(iii) and (iv) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(4) For 1991 through 2006, the fee schedule amounts for items described in paragraphs (b)(1)(i) and (ii) of this section are determined using the methodology contained in §414.220(d), (e), and (f).

(5) For 2005 and 2006, the fee schedule amounts determined under paragraph (b)(4) of this section are reduced using the methodology described in section 1834(a)(21)(A) of the Act.

(c) Monthly fee schedule amount for items furnished for years after 2006. (1) For 2007, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable equipment only (gaseous or liquid tanks).

(iii) Oxygen generating portable equipment only.

(iv) Stationary oxygen contents only.

(v) Portable oxygen contents only.

(2) The national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section is equal to the weighted average fee schedule amount established under paragraph (b)(5) of this section reduced by $1.44.

(3) The national limited monthly payment rate for items described in paragraph (c)(1)(ii) of this section is equal to the weighted average fee schedule amounts established under paragraph (b)(5) of this section.

(4) The national limited monthly payment rate for items described in paragraphs (c)(1)(iv) and (c)(1)(v) of this section is equal to 50 percent of the weighted average fee schedule amounts established under paragraph (b)(3) of this section for items described in paragraph (b)(1)(iii) of this section.

(5) Beginning in 2008, CMS makes an annual adjustment to the national limited monthly payment rates for each class of items described in paragraph (c)(1) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) Application of monthly fee schedule amounts. (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (e)(2) of this section, the fee schedule amount for items described in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (c)(1)(iv) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (c)(1)(v) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in (c)(1)(i) of this section; or

(ii) Rents portable oxygen equipment described in paragraph (c)(1)(ii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for an item described in paragraph (c)(1)(v) of this section is adjusted as follows:

(e) Volume adjustments. (1) The fee schedule amount for items described in paragraph (c)(1)(i) of this section is adjusted as follows:
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(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (e)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (c)(1)(i) and (c)(1)(ii) or (c)(1)(iii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (e)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

(f) Furnishing oxygen and oxygen equipment after the 36-month rental cap.

(1) The supplier that furnishes oxygen equipment for the first month during which payment is made under this section must continue to furnish the equipment for the entire 36-month period of continuous use, unless medical necessity ends or—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain oxygen equipment from a different supplier prior to the expiration of the 36-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) Oxygen equipment furnished under this section may not be replaced by the supplier prior to the expiration of the reasonable useful lifetime established for the equipment in accordance with § 414.210(f)(1) unless:

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the order is based on medical necessity, the order must indicate why the equipment initially furnished is no longer medically necessary and the
§ 414.228 Prosthetic and orthotic devices.

(a) Payment rule. Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

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

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

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

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(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 the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

(3) CMS determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) CMS determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, CMS determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) CMS determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(c) Payment for therapeutic shoes. The payment rules specified in paragraphs (a) and (b) of this section are applicable to custom molded and extra depth shoes, modifications, and inserts (therapeutic shoes) furnished after December 31, 2004.

§ 414.229 Other durable medical equipment—capped rental items.

(a) General payment rule. Payment is made for other durable medical equipment that is not subject to the payment provisions set forth in §414.220 through §414.228 as follows:

(1) For items furnished prior to January 1, 2006, payment is made on a rental or purchase option basis in accordance with the rules set forth in paragraphs (b) through (e) of this section.

(2) For items other than power-driven wheelchairs furnished on or after January 1, 2006, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(3) For power-driven wheelchairs furnished on or after January 1, 2006 through December 31, 2010, payment is made in accordance with the rules set forth in paragraphs (f) or (h) of this section.

(4) For power-driven wheelchairs that are not classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(5) For power-driven wheelchairs classified as complex rehabilitative power-driven wheelchairs, furnished on or after January 1, 2011, payment is made in accordance with the rules set forth in paragraph (f) of this section.

(b) Fee schedule amounts for rental. (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under §405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI-U for the 6-month period ending December 1987.

(2) For 1991. (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in §414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as determined using the methodology contained in §414.220(f).

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

(d) Purchase option. Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. On or after January 1, 2011, this option is available only for complex rehabilitative power-
driven wheelchairs. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in paragraph (c) of this section.

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in §414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) Payment for maintenance and servicing.

(1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made on the basis of reasonable and necessary charges.

(f) Rules for capped rental items furnished beginning on or after January 1, 2006.

(1) For items furnished on or after January 1, 2006, payment is made based on a monthly rental fee schedule amount during the period of medical need, but for no longer than a period of continuous use of 13 months. A period of continuous use is determined under the provisions in §414.230.

(2) The supplier must transfer title to the item to the beneficiary on the first day that begins after the 13th continuous month in which payments are made under paragraph (f)(1) of this section.

(3) Payment for maintenance and servicing of beneficiary-owned equipment is made in accordance with §414.210(e).

(g) Additional supplier requirements for capped rental items that are furnished beginning on or after January 1, 2007. (1) The supplier that furnishes an item for the first month during which payment is made using the methodology described in paragraph (f)(1) of this section must continue to furnish the equipment until medical necessity ends, or the 13-month period of continuous use ends, whichever is earlier, unless—

(i) The item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;

(ii) The beneficiary relocates to an area that is outside the normal service area of the supplier that initially furnished the equipment;

(iii) The beneficiary elects to obtain the equipment from a different supplier prior to the expiration of the 13-month rental period; or

(iv) CMS or the carrier determines that an exception should apply in an individual case based on the circumstances.

(2) A capped rental item furnished under this section may not be replaced by the supplier prior to the expiration of the 13-month rental period unless—

(i) The supplier replaces an item with the same, or equivalent, make and model of equipment because the item
§ 414.230 Determining a period of continuous use.

(a) Scope. This section sets forth the rules that apply in determining a period of continuous use for rental of durable medical equipment.

(b) Continuous use. (1) A period of continuous use begins with the first month of medical need and lasts until a beneficiary’s medical need for a particular item of durable medical equipment ends.

(2) In the case of a beneficiary receiving oxygen equipment on December 31, 2005, the period of continuous use for the equipment begins on January 1, 2006.

(c) Temporary interruption. (1) A period of continuous use allows for temporary interruptions in the use of equipment.

(2) An interruption of not longer than 60 consecutive days plus the days remaining in the rental month in which use ceases is temporary, regardless of the reason for the interruption.

(3) Unless there is a break in medical necessity that lasts longer than 60 consecutive days plus the days remaining in the rental month in which use ceases, medical necessity is presumed to continue.

(d) Criteria for a new rental period. If an interruption in the use of equipment continues for more than 60 consecutive days plus the days remaining in the rental month in which use ceases, a new rental period begins if the supplier submits all of the following information—

(1) A new prescription.

(2) New medical necessity documentation.

(3) A statement describing the reason for the interruption and demonstrating that medical necessity in the prior episode ended.

(e) Beneficiary moves. A permanent or temporary move made by a beneficiary does not constitute an interruption in the period of continuous use.

(f) New equipment. (1) If a beneficiary changes equipment or requires additional equipment based on a physician’s prescription, and the new or additional equipment is found to be necessary, a new period of continuous use begins for the new or additional equipment. A new period of continuous use does not begin for base equipment that is modified by an addition.

(2) A new period of continuous use does not begin when a beneficiary

initially furnished was lost, stolen, irreparably damaged, is being repaired, or no longer functions;

(ii) A physician orders different equipment for the beneficiary. If the need for different equipment is based on medical necessity, then the order must indicate why the equipment initially furnished is no longer medically necessary and the supplier must retain this order in the beneficiary’s medical record;

(iii) The beneficiary chooses to obtain a newer technology item or upgraded item and signs an advanced beneficiary notice (ABN); or

(iv) CMS or the carrier determines that a change in equipment is warranted.

(3) Before furnishing a capped rental item, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of all monthly rental claims for the duration of the rental period. A supplier’s intentions could be expressed in the form of a written agreement between the supplier and the beneficiary.

(4) No later than two months before the date on which the supplier must transfer title to a capped rental item to the beneficiary, the supplier must disclose to the beneficiary whether it can maintain and service the item after the beneficiary acquires title to it. CMS or its carriers may make exceptions to this requirement on a case-by-case basis.

(h) Purchase of power-driven wheelchairs furnished on or after January 1, 2006. (1) Suppliers must offer beneficiaries the option to purchase power-driven wheelchairs at the time the equipment is initially furnished.

(2) Payment is made on a lump-sum purchase basis if the beneficiary chooses this option.

(3) On or after January 1, 2011, this option is available only for complex rehabilitative power-driven wheelchairs.

[57 FR 57691, Dec. 7, 1992, as amended at 60 FR 35498, July 10, 1995; 71 FR 65934, Nov. 9, 2006; 75 FR 73622, Nov. 29, 2010]
§ 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.

(b) Exception. In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

Subpart E—Determination of Reasonable Charges Under the ESRD Program

§ 414.300 Scope of subpart.

This subpart sets forth criteria and procedures for payment of the following services furnished to ESRD patients:

(a) Physician services related to renal dialysis.
(b) Physician services related to renal transplantation.
(c) Home dialysis equipment, supplies, and support services.
(d) Epoetin (EPO) furnished by a supplier of home dialysis equipment and supplies to a home dialysis patient for use in the home.

§ 414.310 Determination of reasonable charges for physician services furnished to renal dialysis patients.

(a) Principle. Physician services furnished to renal dialysis patients are subject to payment if the services are otherwise covered by the Medicare program and if they are considered reasonable and medically necessary in accordance with section 1862(a)(1)(A) of the Act.

(b) Scope and applicability—(1) Scope. This section pertains to physician services furnished to the following patients:

(i) Outpatient maintenance dialysis patients who dialyze—
(A) In an independent or hospital-based ESRD facility, or
(B) At home.
(ii) Hospital inpatients for which the physician elects to continue payment under the monthly capitation payment (MCP) method described in § 414.314.

(2) Applicability. These provisions apply to routine professional services of physicians. They do not apply to administrative services performed by physicians, which are paid for as part of a prospective payment for dialysis services made to the facility under § 413.170 of this chapter.

(c) Definitions. For purposes of this section, the following definitions apply: