
42 U.S. Code § 1395m

Special payment rules for particular items and services

(a) Payment for durable medical equipment

(1) General rule for payment

(A) In general

With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

- (i) the actual charge for the item, or
- (ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item; except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) Exclusive payment rule

Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for covered items under this part or under part A to a home health agency.

(D) Reduction in fee schedules for certain items

With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) Clinical conditions for coverage

(i) In general

The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements

The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1395x(r) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) and a prescription for the item.

(iii) Priority of establishment of standards

In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) Standards for power wheelchairs

Effective on December 8, 2003, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x(r)(1) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items

Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) Application of competitive acquisition; limitation of inherent reasonableness authority

In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1395w-3(a) of this title—

- (i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;
- (ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1395w-3 of this title and in the case of such adjustment, paragraph (10)(B) shall not be applied; and
- (iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1395w-3 of this title are recomputed in accordance with section 1395w-3(b)(3)(B) of this title.

(G) Use of information on competitive bid rates

The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas. In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1395u(s)(3)(B) of this title, the Secretary shall—

- (i) solicit and take into account stakeholder input; and
- (ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:
 - (I) The average travel distance and cost associated with furnishing items and services in the area.
 - (II) The average volume of items and services furnished by suppliers in the area.

(III) The number of suppliers in the area.

(H) Diabetic supplies

(i) In general

On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1395w-3 of this title.

(ii) Date described

The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1395w-3 of this title.

(I) Treatment of vacuum erection systems

Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1395x(s)(8) of this title shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1395w-102(e)(2)(A) of this title.

(2) Payment for inexpensive and other routinely purchased durable medical equipment

(A) In general

Payment for an item of durable medical equipment (as defined in paragraph (13))—

- (i) the purchase price of which does not exceed \$150,
 - (ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,
 - (iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or
 - (iv) in the case of devices furnished on or after October 1, 2015, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,
- shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

- (i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;
- (ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;
- (iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and
- (iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose

testing strip furnished after 1997 for an individual with diabetes).

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) Payment for items requiring frequent and substantial servicing

(A) In general

Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device

computed under subparagraph (C)(ii) for that year.

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) Payment for certain customized items

Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this subchapter, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item.

(5) Payment for oxygen and oxygen equipment

(A) In general

Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) Add-on for portable oxygen equipment

When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) Volume adjustment

When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) Limit on adjustment

When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) Recertification for patients receiving home oxygen therapy

In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) Rental cap

(i) In general

Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) Payments and rules after rental cap

After the 36th continuous month during which payment is made for the equipment under this paragraph

—
(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) Payment for other covered items (other than durable medical equipment)

Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) Payment for other items of durable medical equipment

(A) Payment

In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) Rental

(I) In general

Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) Payment amount

Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) Special rule for power-driven wheelchairs

For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting “15 percent” and “6 percent” for “10 percent” and “7.5 percent”, respectively.

(ii) Ownership after rental

On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) Purchase agreement option for complex, rehabilitative power-driven wheelchairs

In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) Maintenance and servicing

After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier’s or manufacturer’s warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) Range for rental amounts

(i) For 1989

For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) For 1990

For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) Replacement of items

(i) Establishment of reasonable useful lifetime

In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) Payment for replacement items

If the reasonable lifetime of such an item, as so established, has been reached during a continuous period

of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

- (I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or
- (II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) Length of reasonable useful lifetime

The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this subchapter, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) Purchase price recognized for miscellaneous devices and items

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price

Each carrier under section 1395u of this title shall compute a base local purchase price for the item as follows:

- (i) The carrier shall compute a base local purchase price, for each item described—
 - (I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or
 - (II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.
- (ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—
 - (I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,
 - (II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased 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 items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; ¹¹ or
 - (III) in 1992, 1993, and 1994, equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) Computation of national limited purchase price

With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

- (i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

- (ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;
- (iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and
- (iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) Purchase price recognized

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

- (i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);
- (ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;
- (iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and
- (iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) Monthly payment amount recognized with respect to oxygen and oxygen equipment

For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an “item”).

(A) Computation of local monthly payment rate

Each carrier under this section shall compute a base local payment rate for each item as follows:

- (i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this subchapter.
- (ii) The carrier shall compute a local average monthly payment rate for the item applicable—
 - (I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or
 - (II) to 1991, 1992, 1993, and 1994, equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) Computation of national limited monthly payment rate

With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

- (i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the

year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) Monthly payment amount recognized

For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(D) Authority to create classes

(i) In general

Subject to clause (ii), the Secretary may establish separate classes for any item of oxygen and oxygen equipment and separate national limited monthly payment rates for each of such classes.

(ii) Budget neutrality

The Secretary may take actions under clause (i) only to the extent such actions do not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken. The requirement of the preceding sentence shall not apply beginning with the second calendar quarter beginning on or after December 27, 2020.

(10) Exceptions and adjustments

(A) Areas outside continental United States

Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) Adjustment for inherent reasonableness

The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1395u(b) of this title to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) Transcutaneous electrical nerve stimulator (TENS)

In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) Improper billing and requirement of physician order

(A) Improper billing for certain rental items

Notwithstanding any other provision of this subchapter, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1395u(j)(2) of this title in the same manner such sanctions may apply with respect to a physician.

(B) Requirement of physician order

(i) In general

The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1395cc(j) of this title or an eligible professional under section 1395w-4(k)(3)(B) of this title that is enrolled under section 1395cc(j) of this title has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) Requirement for face to face encounter

The Secretary shall require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) Regional carriers

The Secretary may designate, by regulation under section 1395u of this title, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) “Covered item” defined

In this subsection, the term “covered item” means durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title, but not including implantable items for which payment may be made under section 1395l(t) of this title.

(14) Covered item update

In this subsection, the term “covered item update” means, with respect to a year—

- (A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;
- (B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;
- (C) for each of the years 1998 through 2000, 0 percentage points;
- (D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;
- (E) for 2002, 0 percentage points;
- (F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;
- (G) for 2004 through 2006—
- (i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) for the year involved; and
 - (ii) in the case of covered items not described in clause (i), 0 percentage points;
- (H) for 2007—
- (i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and
 - (ii) in the case of covered items not described in clause (i), 0 percentage points;
- (I) for 2008—
- (i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and
 - (ii) in the case of covered items not described in clause (i), 0 percentage points;
- (J) for 2009—
- (i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1395w-3(a)(1)(B)(i)(I) of this title before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or
 - (ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;
- (K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and
- (L) for 2011 and each subsequent year—
- (i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—
 - (ii) the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title.
- The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.
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(15) Advance determinations of coverage for certain items

(A) Development of lists of items by Secretary

The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) Development of lists of suppliers by Secretary

The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

- (i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1395y(a)(1) of this title; or
- (ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) Determinations of coverage in advance

A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1395y(a)(1) of this title if—

- (i) the item is included on the list developed by the Secretary under subparagraph (A);
- (ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or
- (iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) Disclosure of information and surety bond

The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

- (i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1320a-3(a)(3) of this title) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and
- (ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1320a-3(a)(2) of this title) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1395u(b)(18)(C) of this title) who furnish items or services under this part.

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