payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the transtelephonic monitoring of cardiac pacemakers. Such revised guidelines shall include provisions regarding the specifications for and frequency of transtelephonic monitoring procedures which will be found to be reasonable and necessary.

''(2)(A) Except as provided in subparagraph (B), if the guidelines required by paragraph (1) have not been issued and put into effect by October 1, 1984, and until such guidelines have been issued and put into effect, payment may not be made under part B of title XVIII of the Social Security Act for transtelephonic monitoring procedures, with respect to a single-chamber cardiac pacemaker powered by lithium batteries, conducted more frequently than—

''(i) weekly during the first month after implantation,

''(ii) once every two months during the period representing 80 percent of the estimated life of the implanted device, and

''(iii) monthly thereafter.

''(B) Subparagraph (A) shall not apply in cases where the Secretary determines that special medical factors (including possible evidence of pacemaker or lead malfunction) justify more frequent transtelephonic monitoring procedures.''

PAYMENT FOR PREADMISSION DIAGNOSTIC TESTING PERFORMED IN PHYSICIAN'S OFFICE

Pub. L. 98–369, div. B, title III, §2305(f), July 18, 1984, 98 Stat. 1070, provided that: ''The amendments made by this section [amending this section and enacting provisions set out above] shall not be construed as prohibiting payment, subject to the applicable copayments, under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for preadmission diagnostic testing performed in a physician's office to the extent such testing is otherwise reimbursable under regulations of the Secretary.''

PROVIDERS OF SERVICES TO CALCULATE AND REPORT LESSER-OF-COST-OR-CHARGES DETERMINATIONS SEPARATELY WITH RESPECT TO PAYMENTS UNDER PARTS A AND B OF THIS SUBCHAPTER; ISSUANCE OF REGULATIONS

For provision directing the Secretary to issue regulations requiring providers of services to calculate and report the lesser-of-cost-or-charges determinations separately with respect to payments for services under parts A and B of this subchapter other than diagnostic tests under subsec. (h) of this section, see section 2308(a) of Pub. L. 98–369, set out as a note under section 1395f of this title.

DETERMINATION OF NOMINAL CHARGES FOR APPLYING NOMINALITY TEST

For provision directing the Secretary to provide, in addition to other rules deemed appropriate, that charges representing 60 percent or less of costs be considered nominal for purposes of applying the nominality test under subsec. (a)(2)(B)(ii) of this section, see section 2308(b)(1) of Pub. L. 98–369, set out as a note under section 1395f of this title.

STUDY OF MEDICARE PART B PAYMENTS; COMPILATION OF CENTRALIZED CHARGE DATA BASE; REPORT TO CONGRESS

Pub. L. 98–369, div. B, title III, §2309, July 18, 1984, 98 Stat. 1074, directed Director of Office of Technology Assessment to conduct a study of physician reimbursement under the Medicare program and make a report not later than Dec. 31, 1985, covering findings and recommendations on methods by which payment amounts and other program policies under the program might be modified, and directed that Secretary of Health and Human Services compile a centralized Medicare part B charge data base to aid in the study.

MONITORING PROVISION OF HEPATITIS B VACCINE; REVIEW OF CHANGES IN MEDICAL TECHNOLOGY

Pub. L. 98–369, div. B, title III, §2323(e), July 18, 1984, 98 Stat. 1086, provided that: ''The Secretary shall monitor the provision of hepatitis B vaccine under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], and shall review any changes in medical technology which may have an effect on the amounts which should be paid for such service.''

REPORT ON PREADMISSION DIAGNOSTIC TESTING EXPENSES

Pub. L. 96–499, title IX, §932(b), Dec. 5, 1980, 94 Stat. 2635, required a report to Congress, no later than one year after Dec. 5, 1980, on the policy respecting expenses incurred for preadmission diagnostic testing furnished to an individual at a hospital within seven days of an individual's admission to another hospital.

STUDY OF FEASIBILITY AND DESIRABILITY OF IMPOSING COPAYMENT REQUIREMENT ON RURAL HEALTH CLINIC VISITS; REPORT NOT LATER THAN DECEMBER 13, 1978

Pub. L. 95–210, §1(c), Dec. 13, 1977, 91 Stat. 1485, directed Secretary of Health, Education, and Welfare to conduct a study of the feasibility and desirability of imposing a copayment for each visit to a rural health clinic for rural health clinic services under this part and that Secretary report to appropriate committee of Congress, not later than one year after Dec. 13, 1977, on such study.

PROHIBITION AGAINST PAYMENTS IN CASES OF NONENTITLEMENT TO MONTHLY BENEFITS UNDER SUBCHAPTER II OR SUSPENSION OF BENEFITS OF ALIENS OUTSIDE THE UNITED STATES

Pub. L. 89–97, title I, §104(b)(1), July 30, 1965, 79 Stat. 334, provided that: ''No payments shall be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to expenses incurred by an individual during any month for which such individual may not be paid monthly benefits under title II of such Act [42 U.S.C. 401 et seq.] (or for which such monthly benefits would be suspended if he were otherwise entitled thereto) by reason of section 202(t) of such Act [42 U.S.C. 402(t)] (relating to suspension of benefits of aliens who are outside the United States).''

§ 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 recompeted 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;[1] 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

[1] So in original. The semicolon probably should be a comma.

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.

(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 1395*l*(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.

(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.

(17) Prohibition against unsolicited telephone contacts by suppliers

(A) In general

A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) Prohibiting payment for items furnished subsequent to unsolicited contacts

If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) Exclusion from program for suppliers engaging in pattern of unsolicited contacts

If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this chapter, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1320a–7 of this title.

(18) Refund of amounts collected for certain disallowed items

(A) In general

If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) Sanctions

If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1395u(j)(2) of this title.

(C) Notice

Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) Timely basis defined

A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) Certain upgraded items

(A) Individual's right to choose upgraded item

Notwithstanding any other provision of this subchapter, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) Payments to supplier

In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) Consumer protection safeguards

Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) Identification of quality standards

(A) In general

Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this subchapter.

(B) Designation of independent accreditation organizations

Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1395bb(a) of this title, the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) Quality standards

The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) Items and services described

The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in subsection (h)(4).

(iii) Items and services described in section 1395u(s)(2) of this title.

(E) Implementation

The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) Application of accreditation requirement

In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1395w–4(k)(3)(B) of this title), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) Application of accreditation requirement to certain pharmacies

(i) In general

With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) Pharmacies described

A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this

subchapter are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1395cc(j) of this title as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) Special payment rule for specified items and supplies

(A) In general

Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, as identified in the column entitled ''Median FEHP Price'' in the table entitled ''SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS'' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) Specified item or supply described

For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) Application of update to special payment amount

The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1395w–3 of this title.

(22) Special payment rule for diabetic supplies

Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after January 2, 2013, and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking ''but only if furnished through mail order''.

(b) Fee schedules for radiologist services

(1) Development

The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) Consultation

In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) Considerations

In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) Savings

(A) Budget neutral fee schedules

The Secretary shall develop preliminary fee schedules for 1989, which are designed to

result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1395*l*(a)(1)(J) and 1395*l*(b) of this title) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) Initial savings

The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under the preliminary fee schedules developed under subparagraph (A).

(C) 1990 fee schedules

For radiologist services (other than portable X-ray services) furnished under this part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 fee schedules

For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) National weighted average conversion factor

The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) Reduced national weighted average

The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) Computation of 1990 locality index relative to national average

The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) Adjusted conversion factor

The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the locally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) Locally-adjusted amount

For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-adjusted amount

For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1395u(b)(14)(C)(iv) of this title for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) Limits on conversion factor

The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) Rule for certain scanning services

In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) Subsequent updating

For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year.

(G) Nonparticipating physicians and suppliers

Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1395u(b)(4)(A)(iv) of this title) of the payment rate recognized for participating physicians and suppliers.

(5) Limiting charges of nonparticipating physicians and suppliers

(A) In general

In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an indi-

vidual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) "Limiting charge" defined

In subparagraph (A), the term ''limiting charge'' means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) Enforcement

If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1395u(j)(2) of this title in the same manner as such sanctions may apply to a physician.

(6) "Radiologist services" defined

For the purposes of this subsection and section 1395*l*(a)(1)(J) of this title, the term ''radiologist services'' only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) Payment and standards for screening mammography

(1) In general

With respect to expenses incurred for screening mammography (as defined in section 1395x(jj) of this title), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 263b of this title.

(2) Frequency covered

(A) In general

Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) Revision of frequency

(i) Review

The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) Revision of frequency

The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) Frequency limits and payment for colorectal cancer screening tests

(1) Screening fecal-occult blood tests

(A) Payment amount

The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1395*l*(h) of this title.

(B) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) Screening flexible sigmoidoscopies

(A) Fee schedule

With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1395w–4 of this title shall be consistent with payment under such section for similar or related services.

(B) Payment limit

In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395*l* of this title, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions

If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) Screening colonoscopy

(A) Fee schedule

With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1395w–4 of this title shall be consistent with payment amounts under such section for similar or related services.

(B) Payment limit

In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395*l* of this title, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions

If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) Accreditation requirement for advanced diagnostic imaging services

(1) In general

(A) In general

Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1395w–4(b) of this title and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).[2]

(B) Advanced diagnostic imaging services defined

In this subsection, the term ''advanced diagnostic imaging services'' includes—

[2] So in original. Subpar. (B) of par. (2) does not contain clauses.

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1395w–4(b)(4)(B) of this title (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) Supplier defined

In this subsection, the term ''supplier'' has the meaning given such term in section 1395x(d) of this title.

(2) Accreditation organizations

(A) Factors for designation of accreditation organizations

The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i)[2] and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) Designation

Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) Review and modification of list of accreditation organizations

(i) In general

The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations

In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) Criteria for accreditation

The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) Recognition in standards for the evaluation of medical directors and supervising physicians

The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) Rule for accreditations made prior to designation

In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) Reduction in payments for physician pathology services during 1991

(1) In general

For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) Limitation

The prevailing charge for the technical and professional components of an[3] physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) Payment for outpatient critical access hospital services

(1) In general

The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) Election of cost-based hospital outpatient service payment plus fee schedule for professional services

A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1395cc(a)(2)(A) of this title:

(A) Facility fee

With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) Fee schedule for professional services

With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1395*l* of this title shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) Disregarding charges

The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) Treatment of clinical diagnostic laboratory services

No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this subchapter shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1395x(mm)(3) of this title, clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) Coverage of costs for certain emergency room on-call providers

In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this subchapter and are not on-call at any other provider or facility.

(h) Payment for prosthetic devices and orthotics and prosthetics

(1) General rule for payment

(A) In general

Payment under this subsection for prosthetic devices and orthotics and prosthetics

[3] So in original. Probably should be ''a''.

shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) Exception for certain public home health agencies

Subparagraph (B)(i) shall not apply to an item 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.

(D) Exclusive payment rule

Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) Exception for certain items

Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of subsection (a)(2).

(F) Special payment rules for certain prosthetics and custom-fabricated orthotics

(i) In general

No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) Description of custom-fabricated item

(I) In general

An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) List of items

The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) Qualified practitioner defined

In this subparagraph, the term ''qualified practitioner'' means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) Qualified supplier defined

In this subparagraph, the term ''qualified supplier'' means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) Replacement of prosthetic devices and parts

(i) In general

Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) Confirmation may be required if device or part being replaced is less than 3 years old

If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1395y(a)(1)(A) of this title;

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) Application of competitive acquisition to orthotics; limitation of inherent reasonableness authority

In the case of orthotics described in paragraph (2)(C) of section 1395w–3(a) of this title furnished on or after January 1, 2011, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) subject to subsection (a)(1)(G), the Secretary may 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, paragraphs (8) and (9) of section 1395u(b) of this title shall not be applied.

(2) Purchase price recognized

For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics 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 equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(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 (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) Computation of regional purchase price

With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) Purchase price recognized

For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) Range on amount recognized

The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) Applicability of certain provisions relating to durable medical equipment

Paragraphs (12), (15), and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) Definitions

In this subsection—

(A) the term ''applicable percentage increase'' means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, 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;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, 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;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) 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;

(vii) for 2002, 1 percent;

(viii) for 2003, 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;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for[4] each of 2007 through 2010, 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; and

(xi) 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 (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) 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.

(B) the term ''prosthetic devices'' has the meaning given such term in section 1395x(s)(8) of this title, except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1395*l*(t) of this title; and

(C) the term ''orthotics and prosthetics'' has the meaning given such term in section 1395x(s)(9) of this title (and includes shoes described in section 1395x(s)(12) of this title), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title.

(5) Documentation created by orthotists and prosthetists

For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1395w–4(k)(3)(B) of this title.

(i) Payment for surgical dressings

(1) In general

Payment under this subsection for surgical dressings (described in section 1395x(s)(5) of this title) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially 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 described in such subsection for 1993 and 1994).

(2) Exceptions

Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) Requirements for suppliers of medical equipment and supplies

(1) Issuance and renewal of supplier number

(A) Payment

Except as provided in subparagraph (C), no payment may be made under this part after October 31, 1994, for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number

A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after October 31, 1994, and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

[4] So in original.

(C) Exception for items furnished as incident to a physician's service

Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) Prohibition against multiple supplier numbers

The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) Prohibition against delegation of supplier determinations

The Secretary may not delegate (other than by contract under section 1395u of this title) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity

(A) Limitation on information provided by suppliers on certificates of medical necessity

(i) In general

Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges

If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty

Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(B) "Certificate of medical necessity" defined

For purposes of this paragraph, the term ''certificate of medical necessity'' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria

The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability

If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1395y(a)(1) of this title;

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) "Medical equipment and supplies" defined

The term ''medical equipment and supplies'' means—

(A) durable medical equipment (as defined in section 1395x(n) of this title);

(B) prosthetic devices (as described in section 1395x(s)(8) of this title);

(C) orthotics and prosthetics (as described in section 1395x(s)(9) of this title);

(D) surgical dressings (as described in section 1395x(s)(5) of this title);

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1395x(s)(2)(F) of this title),

(ii) immunosuppressive drugs (as described in section 1395x(s)(2)(J) of this title),

(iii) therapeutic shoes for diabetics (as described in section 1395x(s)(12) of this title),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1395x(s)(2)(Q) of this title), and

(v) self-administered erythropoetin (as described in section 1395x(s)(2)(P) of this title).

(k) Payment for outpatient therapy services and comprehensive outpatient rehabilitation services

(1) In general

With respect to services described in section 1395*l*(a)(8) or 1395*l*(a)(9) of this title for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) Payment in 1998 based upon adjusted reasonable costs

The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) Applicable fee schedule amount

In this subsection, the term ''applicable fee schedule amount'' means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1395w–4 of this title for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) Adjusted reasonable costs

In paragraph (2), the term ''adjusted reasonable costs'' means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1395*l*(a)(8)(B) of this title (relating to services provided by hospitals).

(5) Uniform coding

For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) Restraint on billing

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(7) Adjustment in discount for certain multiple therapy services

In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

***(l)* Establishment of fee schedule for ambulance services**

(1) In general

The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5 and in accordance with the requirements of this subsection.

(2) Considerations

In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) Savings

In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to 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 in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by 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 in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title.

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) Consultation

In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) Restraint on billing

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(7) Coding system

The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) Services furnished by critical access hospitals

Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1395x(mm)(1) of this title), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) Transitional assistance for rural providers

In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) Phase-in providing floor using blend of fee schedule and regional fee schedules

In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1395ww(d)(2) of this title) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) Adjustment in payment for certain long trips

In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule estab-

lished under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) Assistance for rural providers furnishing services in low population density areas

(A) In general

In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2023, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) Identification of qualified rural areas

(i) Determination of population density in area

Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) Ranking of areas

The Secretary shall rank each such area based on such population density.

(iii) Identification of qualified rural areas

The Secretary shall identify those areas (in subparagraph (A) referred to as ''qualified rural areas'') with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) Rural area

For purposes of this paragraph, the term ''rural area'' has the meaning given such term in section 1395ww(d)(2)(D) of this title. If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395*oo* of this title, or otherwise, respecting the identification of an area under this subparagraph.

(13) Temporary increase for ground ambulance services

(A) In general

After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2023,,[4] for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023).

(B) Application of increased payments after applicable period

The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) Providing appropriate coverage of rural air ambulance services

(A) In general

The regulations described in section 1395x(s)(7) of this title shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) Satisfaction of requirement of medically necessary

The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival

or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) Rural air ambulance service defined

For purposes of this paragraph, the term ''rural air ambulance service'' means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) Limitation

(i) In general

Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) Exception

Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1395xx of this title) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) Payment adjustment for non-emergency ambulance transports for ESRD beneficiaries

The fee schedule amount otherwise applicable under the preceding provisions of this subsection shall be reduced by 10 percent for ambulance services furnished during the period beginning on October 1, 2013, and ending on September 30, 2018, and by 23 percent for such services furnished on or after October 1, 2018, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1395rr(b)(14)(B) of this title) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) Prior authorization for repetitive scheduled non-emergent ambulance transports

(A) In general

Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1315a(c) of this title, then the Secretary shall expand such model to all States.

(B) Funding

The Secretary shall use funds made available under section 1395ddd(h)(10) of this title to carry out this paragraph.

(C) Clarification regarding budget neutrality

Nothing in this paragraph may be construed to limit or modify the application of section 1315a(b)(3)(B) of this title to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(17) Submission of cost and other information

(A) Development of data collection system

The Secretary shall develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services (in this paragraph referred to as ''providers'') and suppliers of ground ambulance services. Such system shall be designed to collect information—

(i) needed to evaluate the extent to which reported costs relate to payment rates under this subsection;

(ii) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1320a(a) of this title; and

(iii) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in paragraph (12).

(B) Specification of data collection system

(i) In general

The Secretary shall—

(I) not later than December 31, 2019, specify the data collection system under subparagraph (A); and

(II) identify the providers and suppliers of ground ambulance services that would be required to submit information under such data collection system, including the representative sample described in clause (ii).

(ii) Determination of representative sample

(I) In general

Not later than December 31, 2019, with respect to the data collection for the first year under such system, and for each subsequent year through 2024, the

Secretary shall determine a representative sample to submit information under the data collection system.

(II) Requirements

The sample under subclause (I) shall be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas).

(III) Limitation

The Secretary shall not include an individual provider or supplier of ground ambulance services in the sample under subclause (I) in 2 consecutive years, to the extent practicable.

(C) Reporting of cost information

For each year, a provider or supplier of ground ambulance services identified by the Secretary under subparagraph (B)(i)(II) as being required to submit information under the data collection system with respect to a period for the year shall submit to the Secretary information specified under the system. Such information shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) Payment reduction for failure to report

(i) In general

Beginning January 1, 2022, subject to clause (ii), a 10 percent reduction to payments under this subsection shall be made for the applicable period (as defined in clause (ii)) to a provider or supplier of ground ambulance services that—

(I) is required to submit information under the data collection system with respect to a period under subparagraph (C); and

(II) does not sufficiently submit such information, as determined by the Secretary.

(ii) Applicable period defined

For purposes of clause (i), the term ''applicable period'' means, with respect to a provider or supplier of ground ambulance services, a year specified by the Secretary not more than 2 years after the end of the period with respect to which the Secretary has made a determination under clause (i)(II) that the provider or supplier of ground ambulance services failed to sufficiently submit information under the data collection system.

(iii) Hardship exemption

The Secretary may exempt a provider or supplier from the payment reduction under clause (i) with respect to an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the provider or supplier of ground ambulance services to submit such information in a timely manner for the specified period.

(iv) Informal review

The Secretary shall establish a process under which a provider or supplier of ground ambulance services may seek an informal review of a determination that the provider or supplier is subject to the payment reduction under clause (i).

(E) Ongoing data collection

(i) Revision of data collection system

The Secretary may, as the Secretary determines appropriate and, if available, taking into consideration the report (or reports) under subparagraph (F), revise the data collection system under subparagraph (A).

(ii) Subsequent data collection

In order to continue to evaluate the extent to which reported costs relate to payment rates under this subsection and for other purposes the Secretary deems appropriate, the Secretary shall require providers and suppliers of ground ambulance services to submit information for years after 2024 as the Secretary determines appropriate, but in no case less often than once every 3 years.

(F) Ground ambulance data collection system study

(i) In general

Not later than March 15, 2023, and as determined necessary by the Medicare Payment Advisory Commission thereafter, such Commission shall assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system under subparagraph (A), the adequacy of payments for ground ambulance services under this subsection, and geographic variations in the cost of furnishing such services.

(ii) Contents

A report under clause (i) shall contain the following:

(I) An analysis of information submitted through the data collection system.

(II) An analysis of any burden on providers and suppliers of ground ambulance services associated with the data collection system.

(III) A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised under subparagraph (E)(i).

(IV) Other information determined appropriate by the Commission.

(G) Public availability

The Secretary shall post information on the results of the data collection under this paragraph on the Internet website of the Centers for Medicare & Medicaid Services, as determined appropriate by the Secretary.

(H) Implementation

The Secretary shall implement this paragraph through notice and comment rulemaking.

(I) Administration

Chapter 35 of title 44 shall not apply to the collection of information required under this subsection.

(J) Limitations on review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the data collection system or identification of respondents under this paragraph.

(K) Funding for implementation

For purposes of carrying out subparagraph (A), the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2018. Amounts transferred under this subparagraph shall remain available until expended.

(m) Payment for telehealth services

(1) In general

The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1395x(r) of this title) or a practitioner (described in section 1395u(b)(18)(C) of this title) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) Payment amount

(A) Distant site

The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this subchapter had such service been furnished without the use of a telecommunications system.

(B) Facility fee for originating site

(i) In general

Subject to clause (ii) and paragraph (6)(C), with respect to a telehealth service, subject to section 1395*l*(a)(1)(U) of this title, there shall be paid to the originating site a facility fee equal to—

(I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(II) for a subsequent year, the facility fee specified in subclause (I) or this subclause for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year.

(ii) No facility fee if originating site is the home

No facility fee shall be paid under this subparagraph to an originating site described in paragraph (4)(C)(ii)(X).

(C) Telepresenter not required

Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) Limitation on beneficiary charges

(A) Physician and practitioner

The provisions of section 1395w–4(g) of this title and subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) Originating site

The provisions of section 1395u(b)(18) of this title shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) Definitions

For purposes of this subsection:

(A) Distant site

The term ''distant site'' means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) Eligible telehealth individual

The term ''eligible telehealth individual'' means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) Originating site

(i) In general

Except as provided in paragraphs (5), (6), and (7), the term ''originating site'' means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 254e(a)(1)(A) of this title;

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) Sites described

The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1395x(mm)(1) of this title).

(III) A rural health clinic (as defined in section 1395x(aa)(2) of this title).

(IV) A Federally qualified health center (as defined in section 1395x(aa)(4) of this title).

(V) A hospital (as defined in section 1395x(e) of this title).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1395i–3(a) of this title).

(VIII) A community mental health center (as defined in section 1395x(ff)(3)(B) of this title).

(IX) A renal dialysis facility, but only for purposes of section 1395rr(b)(3)(B) of this title.

(X) The home of an individual, but only for purposes of section 1395rr(b)(3)(B) of this title or telehealth services described in paragraph (7).

(D) Physician

The term ''physician'' has the meaning given that term in section 1395x(r) of this title.

(E) Practitioner

The term ''practitioner'' has the meaning given that term in section 1395u(b)(18)(C) of this title.

(F) Telehealth service

(i) In general

The term ''telehealth service'' means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) Yearly update

The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) Treatment of home dialysis monthly ESRD-related visit

The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1395rr(b)(3)(B) of this title, at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii).

(6) Treatment of stroke telehealth services

(A) Non-application of originating site requirements

The requirements described in paragraph (4)(C) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, as determined by the Secretary.

(B) Inclusion of certain sites

With respect to telehealth services described in subparagraph (A), the term ''originating site'' shall include any hospital (as defined in section 1395x(e) of this title) or critical access hospital (as defined in section 1395x(mm)(1) of this title), any mobile stroke unit (as defined by the Secretary), or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.

(C) No originating site facility fee for new sites

No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (A) if the originating site does not otherwise meet the requirements for an originating site under paragraph (4)(C).

(7) Treatment of substance use disorder services furnished through telehealth

The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after July 1, 2019, to an eligible telehealth individual with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, as determined by the Secretary, at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph).

(n) Authority to modify or eliminate coverage of certain preventive services

Notwithstanding any other provision of this subchapter, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1395x(ddd)(3) of this title to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this subchapter for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

***(o)* Development and implementation of prospective payment system**

(1) Development

(A) In general

The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this

subchapter. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) Collection of data and evaluation

By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) Implementation

(A) In general

Notwithstanding section 1395*l*(a)(3)(A) of this title, the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this subchapter in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) Payments

(i) Initial payments

The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1395*l*(a)(1)(Z) of this title) under this subchapter for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1395cc(a)(2)(A)(ii) of this title) that would have occurred for such services under this subchapter in such year if the system had not been implemented.

(ii) Payments in subsequent years

Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved.

(C) Preparation for PPS implementation

Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(3) Additional payments for certain FQHCS with physicians or other practitioners receiving data 2000 waivers

(A) In general

In the case of a Federally qualified health center with respect to which, beginning on or after January 1, 2019, Federally qualified health center services (as defined in section 1395x(aa)(3) of this title) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in subparagraph (C), the Secretary shall, subject to availability of funds under subparagraph (D), make a payment (at such time and in such manner as specified by the Secretary) to such Federally qualified health center after receiving and approving an application submitted by such Federally qualified health center under subparagraph (B). Such a payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in subparagraph (C)(ii). Such a payment may be made only one time with respect to each such physician or practitioner.

(B) Application

In order to receive a payment described in subparagraph (A), a Federally qualified health center shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A Federally qualified health center may apply for such a payment for each physician or practitioner described in subparagraph (A) furnishing services described in such subparagraph at such center.

(C) Requirements

For purposes of subparagraph (A), the requirements described in this subparagraph, with respect to a physician or practitioner, are the following:

(i) The physician or practitioner is employed by or working under contract with a Federally qualified health center described in subparagraph (A) that submits an application under subparagraph (B).

(ii) The physician or practitioner first receives a waiver under section 823(g) of title 21 on or after January 1, 2019.

(D) Funding

For purposes of making payments under this paragraph, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $6,000,000, which shall remain available until expended.

(p) Quality incentives to promote patient safety and public health in computed tomography

(1) Quality incentives

In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) Applicable computed tomography services defined

In this subsection, the term ''applicable computed tomography service'' means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).[5]

(3) Applicable payment system defined

In this subsection, the term ''applicable payment system'' means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1395w–4(b) of this title.

(B) The prospective payment system for hospital outpatient department services under section 1395*l*(t) of this title.

(4) Consistency with CT equipment standard

In this subsection, the term ''not consistent with the CT equipment standard'' means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management''. Through rulemaking, the Secretary may apply successor standards.

(5) Applicable percentage defined

In this subsection, the term ''applicable percentage'' means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) Implementation

(A) Information

The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under subsection (e) and hospitals under section 1395bb(a) of this title.

(B) Administration

Chapter 35 of title 44 shall not apply to information described in subparagraph (A).

(q) Recognizing appropriate use criteria for certain imaging services

(1) Program established

(A) In general

The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) Appropriate use criteria defined

In this subsection, the term ''appropriate use criteria'' means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) Applicable imaging service defined

In this subsection, the term ''applicable imaging service'' means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) Applicable setting defined

In this subsection, the term ''applicable setting'' means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) Ordering professional defined

In this subsection, the term ''ordering professional'' means a physician (as defined in section 1395x(r) of this title) or a practitioner described in section 1395u(b)(18)(C) of this title who orders an applicable imaging service.

(F) Furnishing professional defined

In this subsection, the term ''furnishing professional'' means a physician (as defined in section 1395x(r) of this title) or a practitioner described in section 1395u(b)(18)(C) of this title who furnishes an applicable imaging service.

[5] So in original. The period probably should be preceded by another closing parenthesis.

(2) Establishment of applicable appropriate use criteria

(A) In general

Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) Considerations

In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) Revisions

The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) Treatment of multiple applicable appropriate use criteria

In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) Mechanisms for consultation with applicable appropriate use criteria

(A) Identification of mechanisms to consult with applicable appropriate use criteria

(i) In general

The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) Consultation

The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) Inclusion of certain mechanisms

Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1395w–4(*o*)(4) of this title).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) Qualified clinical decision support mechanisms

(i) In general

For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) Requirements

The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) List of mechanisms for consultation with applicable appropriate use criteria

(i) Initial list

Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) Periodic updating of list

The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) Consultation with applicable appropriate use criteria

(A) Consultation by ordering professional

Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applica-

ble imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) Reporting by furnishing professional

Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) Exceptions

The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) Emergency services

An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1395dd(e)(1) of this title).

(ii) Inpatient services

An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) Significant hardship

An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) Applicable payment system defined

In this subsection, the term ''applicable payment system'' means the following:

(i) The physician fee schedule established under section 1395w–4(b) of this title.

(ii) The prospective payment system for hospital outpatient department services under section 1395*l*(t) of this title.

(iii) The ambulatory surgical center payment systems under section 1395*l*(i) of this title.

(5) Identification of outlier ordering professionals

(A) In general

With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) Outlier ordering professionals

The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) Use of two years of data

The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) Process

The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) Consultation with stakeholders

The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) Prior authorization for ordering professionals who are outliers

(A) In general

Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) Appropriate use criteria in prior authorization

In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) Funding

For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) Construction

Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) Payment for renal dialysis services for individuals with acute kidney injury

(1) Payment rate

In the case of renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) furnished under this part by a renal dialysis facility or provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) Individual with acute kidney injury defined

In this subsection, the term ''individual with acute kidney injury'' means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1395rr(b)(14) of this title.

(s) Payment for applicable disposable devices

(1) Separate payment

The Secretary shall make a payment (separate from the payments otherwise made under section 1395fff of this title) in the amount established under paragraph (3) to a home health agency for an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1395fff(b) of this title.

(2) Applicable disposable device

In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) Payment amount

The separate payment amount established under this paragraph for an applicable disposable device for a year shall be equal to the amount of the payment that would be made under section 1395*l*(t) of this title (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

(t) Site-of-service price transparency

(1) In general

In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this subchapter, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1395*l* of this title and the ambulatory surgical center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) Calculation of estimated beneficiary liability

For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1395ss of this title or any other supplemental insurance coverage is responsible.

(3) Implementation

In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1395b–2(a) of this title a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on December 13, 2016, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

(4) Funding

For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.

(u) Payment and related requirements for home infusion therapy

(1) Payment

(A) Single payment

(i) In general

Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement

a payment system under which a single payment is made under this subchapter to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1395x(iii)(2))[6] of this title furnished by a qualified home infusion therapy supplier (as defined in section 1395x(iii)(3)(D) of this title) in coordination with the furnishing of home infusion drugs (as defined in section 1395x(iii)(3)(C) of this title) under this part.

(ii) Unit of single payment

A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

(iii) Limitation

The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1395w–4 of this title for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

(B) Required adjustments

The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1395x(iii)(1) of this title to reflect other factors such as—

(i) a geographic wage index and other costs that may vary by region; and

(ii) patient acuity and complexity of drug administration.

(C) Discretionary adjustments

(i) In general

Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

(ii) Requirement of budget neutrality

Any adjustment under this subparagraph shall be made in a budget neutral manner.

(2) Considerations

In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

(3) Annual updates

(A) In general

Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by 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 preceding year.

(B) Adjustment

For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

(4) Authority to apply prior authorization

The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1395x(iii)(1) of this title.

(5) Accreditation of qualified home infusion therapy suppliers

(A) Factors for designation of accreditation organizations

The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(iv) Such other factors as the Secretary determines appropriate.

(B) Designation

Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) Review and modification of list of accreditation organizations

(i) In general

The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the

[6] So in original. The second closing parenthesis probably should not appear.

factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations

In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(D) Rule for accreditations made prior to designation

In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

(6) Notification of infusion therapy options available prior to furnishing home infusion therapy

Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1395x(iii)(1) of this title for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

(7) Home infusion therapy services temporary transitional payment

(A) Temporary transitional payment

(i) In general

The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1395x(iii)(2))[6] of this title furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

(ii) Period specified

For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

(iii) Transitional home infusion drug defined

For purposes of this paragraph, the term ''transitional home infusion drug'' has the meaning given to the term ''home infusion drug'' under section 1395x(iii)(3)(C))[6] of this title, except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of February 9, 2018.

(B) Payment methodology

For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

(ii) assign drugs to such categories, in accordance with such clauses;

(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category.

(C) Payment categories

(i) Payment category 1

The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

(ii) Payment category 2

The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J1555 JB, J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

(iii) Payment category 3

The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J9000, J9039,

J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

(iv) Infusion drugs not otherwise included

With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

(II) billed under any code that is implemented after February 9, 2018, and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

(D) Payment amounts

(i) In general

Under the payment methodology, the Secretary shall pay eligible home infusion suppliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1395w–4 of this title for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of the geographic adjustment under subsection (e) of such section.

(ii) Payment amount for category 1

For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus three units of HCPCS code 96366 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iii) Payment amount for category 2

For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus three units of HCPCS code 96370 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iv) Payment amount for category 3

For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus three units of HCPCS code 96415 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(E) Clarifications

(i) Infusion drug administration day

For purposes of this subsection, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier or a qualified home infusion therapy supplier, a reference to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1395x(iii)(2)(A) of this title) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

(ii) Treatment of multiple drugs administered on same infusion drug administration day

In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual's home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual's home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

(F) Eligible home infusion suppliers

In this paragraph, the term ''eligible home infusion supplier'' means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

(G) Implementation

Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(v) Payment for outpatient physical therapy services and outpatient occupational therapy services furnished by a therapy assistant

(1) In general

In the case of an outpatient physical therapy service or outpatient occupational therapy service furnished on or after January 1, 2022, for which payment is made under section 1395w–4 of this title or subsection (k), that is furnished in whole or in part by a therapy assistant (as defined by the Secretary), the amount of payment for such service shall be an amount equal to 85 percent of the amount of payment otherwise applicable for the service under this part. Nothing in the preceding sentence shall be construed to change applicable requirements with respect to such services.

(2) Use of modifier

(A) Establishment

Not later than January 1, 2019, the Secretary shall establish a modifier to indicate (in a form and manner specified by the Secretary), in the case of an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined), that the service was furnished by a therapy assistant.

(B) Required use

Each request for payment, or bill submitted, for an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined) on or after January 1, 2020, shall include the modifier established under subparagraph (A) for each such service.

(3) Implementation

The Secretary shall implement this subsection through notice and comment rulemaking.

(w) Opioid use disorder treatment services

(1) In general

The Secretary shall pay to an opioid treatment program (as defined in paragraph (2) of section 1395x(jjj) of this title) an amount that is equal to 100 percent of a bundled payment under this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.

(2) Considerations

The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine[7] appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under subchapter XIX or under the TRICARE program under chapter 55 of title 10.

(3) Annual updates

The Secretary shall provide an update each year to the bundled payment amounts under this subsection.

(Aug. 14, 1935, ch. 531, title XVIII, §1834, as added and amended Pub. L. 100–203, title IV, §§4049(a)(2), 4062(b), Dec. 22, 1987, 101 Stat. 1330–91, 1330–100; Pub. L. 100–360, title II, §§202(b)(4), 203(c)(1)(F), 204(b), title IV, §411(a)(3)(A), (B)(ii), (C)(ii), (f)(8)(A), (B)(ii), (D), (g)(1)(A), (B), July 1, 1988, 102 Stat. 704, 722, 726, 768, 779, 781; Pub. L. 100–485, title VI, §608(d)(21)(C), (22)(A), Oct. 13, 1988, 102 Stat. 2420; Pub. L. 101–234, title II, §201(a), title III, §301(b)(1), (c)(1), Dec. 13, 1989, 103 Stat. 1981, 1985; Pub. L. 101–239, title VI, §§6102(f)(1), 6105(a), 6112(a), (c), (d)(1), (e)(2), 6116(b)(2), 6140, Dec. 19, 1989, 103 Stat. 2188, 2210, 2214–2216, 2220, 2224; Pub. L. 101–508, title IV, §§4102(a), (d), (f), 4104(a), 4152(a)(1), (b), (c)(1)–(4)(B)(i), (e), (f)(1), (g)(1), 4153(a)(1), (2)(D), 4163(b), Nov. 5, 1990, 104 Stat. 1388–55, 1388–57, 1388–59, 1388–74, 1388–77 to 1388–81, 1388–83, 1388–97; Pub. L. 103–66, title XIII, §§13542(a), 13543(a), (b), 13544(a)(1), (2), (b)(1), 13545(a), 13546, Aug. 10, 1993, 107 Stat. 587, 589, 590; Pub. L. 103–432, title I, §§102(e), 126(b)(1), (2), (4), (5), (g)(1), (10)(B), 131(a), 132(a), (b), 133(a)(1), 134(a)(1), 135(a)(1), (b)(1), (3), (d)(1), (e)(2)–(5), 145(a), 156(a)(2)(C), Oct. 31, 1994, 108 Stat. 4403, 4414–4416, 4419, 4421–4424, 4427, 4440; Pub. L. 105–33, title IV, §§4101(a), (c), 4104(b)(1), 4105(b)(2), 4201(c)(5), 4312(a), (c), 4316(b), 4531(b)(2), 4541(a)(2), 4551(a), (c)(1), 4552(a), (b), Aug. 5, 1997, 111 Stat. 360, 363, 367, 374, 386, 387, 392, 451, 455, 457–459; Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(e)(2), title III, §321(k)(3), title IV, §403(d)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A–340, 1501A–366, 1501A–371; Pub. L. 106–554, §1(a)(6) [title I, §§103(b), 104(b), title II, §§201(a), 202(a), 204(a), 205(a), 221(a), 223(b), title IV, §§423(a)(1), (b)(1), 425(a), 426(a), 427(a), 428(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–468, 2763A–469, 2763A–481, 2763A–482, 2763A–486, 2763A–487, 2763A–518 to 2763A–520, 2763A–522; Pub. L. 108–173, title III, §302(a), (c)(1)(A), (2), (3), (d)(1), (2), title IV, §§405(a)(1), (b)(1), (d)(1), 414(a)–(c)(1), (d), 415(a), title VI, §627(b)(1), title VII, §736(b)(4), (5), Dec. 8, 2003, 117 Stat. 2223, 2230–2232, 2266, 2267, 2278–2281, 2321, 2356; Pub. L. 109–171, title V, §§5101(a)(1), (b)(1), 5113(b), Feb. 8, 2006, 120 Stat. 37, 38, 44; Pub. L. 110–275, title I, §§125(b)(5), 135(a)(1), 144(b)(1), 146(a), (b)(2)(A), 148(a), 149(a), 154(a)(2)(A), (3), (4), (b)(1)(A), (d)(2), July 15, 2008, 122 Stat. 2519, 2532, 2547–2549, 2563, 2564, 2567; Pub. L. 111–72, §1(a), Oct. 13, 2009, 123 Stat. 2059; Pub. L. 111–148, title III, §§3105(a), (c), 3109(a), 3128(a), 3136(a), (b), 3401(j), (m), (n), title IV, §4105(a), title V, §§5501(a)(2), (b)(2), 5502(b), title VI, §§6402(g)(1), 6405(a), 6407(b), 6410(b), title X, §§10311(a), (c), 10501(i)(1), (3)(A), Mar. 23, 2010, 124 Stat. 417, 418, 426, 437, 438, 486, 487, 558, 653, 654, 759, 768, 770, 773, 942, 943, 997; Pub. L. 111–309, title I, §106(a), (c), Dec. 15, 2010, 124 Stat. 3287; Pub. L. 112–78, title III, §306(a), (c), Dec. 23, 2011, 125 Stat. 1285; Pub. L. 112–96, title III, §3007(a), (c), Feb. 22, 2012, 126 Stat. 190; Pub. L. 112–240, title VI, §§604(a), (c), 633(b), 636, 637, Jan. 2, 2013, 126 Stat. 2347, 2348, 2355–2357; Pub. L. 113–67, div. B, title I, §1104, Dec. 26, 2013, 127 Stat. 1196; Pub. L. 113–93, title I, §104, title II, §218(a)(1), (b)(1), Apr. 1, 2014, 128 Stat. 1042, 1063, 1065; Pub. L. 113–295, div. B, title II, §203, Dec. 19, 2014, 128 Stat. 4065; Pub. L. 114–10, title II, §203, title V, §§504(a), 515(b), Apr. 16, 2015, 129 Stat. 144, 165, 174; Pub. L. 114–27, title VIII, §808(b), June 29, 2015, 129 Stat. 418; Pub. L. 114–40, §3, July 30, 2015, 129 Stat. 441; Pub. L. 114–113, div. O, title V, §504(a), Dec. 18, 2015, 129 Stat. 3021; Pub. L. 114–255, div. A, title IV, §4011, title V, §5012(b), div. C, title XVI,

[7] So in original. Probably should be ''determines''.

§ 16008(a), (b)(1), Dec. 13, 2016, 130 Stat. 1186, 1199, 1329; Pub. L. 115–123, div. E, title II, § 50203, title III, §§ 50302(b), 50325, title IV, §§ 50401(a), 50402, 50411, title XII, §§ 53107, 53108, Feb. 9, 2018, 132 Stat. 178, 191, 205, 214, 217, 220, 303; Pub. L. 115–271, title II, §§ 2001(a), 2005(c)(2), title VI, § 6083(a), Oct. 24, 2018, 132 Stat. 3924, 3929, 3994.)

APPLICABILITY OF AMENDMENT

Amendment of section by section 5012(b) of Pub. L. 114–255 applicable to items and services furnished on or after Jan. 1, 2021. See 2016 Amendment note below.

REFERENCES IN TEXT

Section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (a)(14)(H)(i), is section 302(c)(1)(B) of Pub. L. 108–173, which is set out as a note under this section.

Section 4531(a) of the Balanced Budget Act of 1997, referred to in subsec. (*l*)(3)(A), is section 4531(a) of Pub. L. 105–33, which amended sections 1395u and 1395x of this title.

Section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015, referred to in subsec. (*l*)(16)(A), is section 515(a) of Pub. L. 114–10, title V, Apr. 16, 2015, 129 Stat. 174, which relates to the initial expansion of prior authorization model for repetitive scheduled nonemergent ambulance transports and is not classified to the Code.

CODIFICATION

Amendment of subsec. (a)(4) by Pub. L. 101–508, § 4152(c)(4)(B)(i), did not become effective pursuant to Pub. L. 101–508, § 4152(c)(4)(B)(ii), because of action of Secretary in developing specific criteria for the treatment of wheelchairs as customized items for purposes of subsec. (a)(4). See Effective Date of 1990 Amendment note below.

PRIOR PROVISIONS

A prior section 1395m, act Aug. 14, 1935, ch. 531, title XVIII, § 1834, as added July 30, 1965, Pub. L. 89–97, title I, § 102(a), 79 Stat. 303, prescribed limitations on payments for home health services, prior to repeal by Pub. L. 96–499, title IX, § 930(i), Dec. 5, 1980, 94 Stat. 2631, effective with respect to services furnished on or after July 1, 1981.

AMENDMENTS

2018—Subsec. (a)(2)(A)(iv). Pub. L. 115–123, § 50411, struck out ''and before October 1, 2018,'' after ''October 1, 2015,''.

Subsec. (h)(5). Pub. L. 115–123, § 50402, added par. (5).

Subsec. (*l*)(12)(A). Pub. L. 115–123, § 50203(a)(2), substituted ''2023'' for ''2018''.

Subsec. (*l*)(13)(A). Pub. L. 115–123, § 50203(a)(1), substituted ''2023'' for ''2018'' wherever appearing.

Subsec. (*l*)(15). Pub. L. 115–123, § 53108, substituted ''during the period beginning on October 1, 2013, and ending on September 30, 2018, and by 23 percent for such services furnished on or after October 1, 2018'' for ''on or after October 1, 2013''.

Subsec. (*l*)(17). Pub. L. 115–123, § 50203(b), added par. (17).

Subsec. (m)(2)(B). Pub. L. 115–123, § 50302(b)(2), redesignated existing provisions as cl. (i), inserted heading, substituted ''Subject to clause (ii), with respect to'' for ''With respect to'', redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i), substituted ''subclause (I) or this subclause'' for ''clause (i) or this clause'' in subcl. (II), and added cl. (ii).

Subsec. (m)(2)(B)(i). Pub. L. 115–271, § 2001(a)(1)(A), substituted ''clause (ii) and paragraph (6)(C)'' for ''clause (ii)'' in introductory provisions.

Subsec. (m)(2)(B)(ii). Pub. L. 115–271, § 2001(a)(1)(B), struck out ''for home dialysis therapy'' after ''site'' in heading.

Subsec. (m)(4)(C)(i). Pub. L. 115–271, § 2001(a)(2)(A), substituted ''paragraphs (5), (6), and (7)'' for ''paragraph (6)'' in introductory provisions.

Pub. L. 115–123, § 50325(1), substituted ''Except as provided in paragraph (6), the term'' for ''The term'' in introductory provisions.

Subsec. (m)(4)(C)(ii)(IX). Pub. L. 115–123, § 50302(b)(1)(A), added subcl. (IX).

Subsec. (m)(4)(C)(ii)(X). Pub. L. 115–271, § 2001(a)(2)(B), inserted ''or telehealth services described in paragraph (7)'' before period at end.

Pub. L. 115–123, § 50302(b)(1)(A), added subcl. (X).

Subsec. (m)(5). Pub. L. 115–123, § 50302(b)(1)(B), added par. (5).

Subsec. (m)(6). Pub. L. 115–123, § 50325(2), added par. (6).

Subsec. (m)(7). Pub. L. 115–271, § 2001(a)(3), added par. (7).

Subsec. (*o*)(3). Pub. L. 115–271, § 6083(a), added par. (3).

Subsec. (u)(7). Pub. L. 115–123, § 50401(a), added par. (7).

Subsec. (v). Pub. L. 115–123, § 53107, added subsec. (v).

Subsec. (w). Pub. L. 115–271, § 2005(c)(2), added subsec. (w).

2016—Subsec. (a)(1)(G). Pub. L. 114–255, § 16008(a), inserted at end ''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—'' and added cls. (i) and (ii).

Subsec. (h)(1)(H)(ii). Pub. L. 114–255, § 16008(b)(1), substituted ''subject to subsection (a)(1)(G), the Secretary'' for ''the Secretary''.

Subsec. (t). Pub. L. 114–255, § 4011, added subsec. (t).

Subsec. (u). Pub. L. 114–255, § 5012(b), added subsec. (u).

2015—Subsec. (a)(2)(A)(iv). Pub. L. 114–40 added cl. (iv).

Subsec. (a)(11)(B)(ii). Pub. L. 114–10, § 504(a), struck out ''the physician documenting that'' after ''written pursuant to'' and substituted ''documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter'' for ''has had a face-to-face encounter''.

Subsec. (*l*)(12)(A). Pub. L. 114–10, § 203(b), substituted ''January 1, 2018'' for ''April 1, 2015''.

Subsec. (*l*)(13)(A). Pub. L. 114–10, § 203(a), substituted ''January 1, 2018'' for ''April 1, 2015'' wherever appearing.

Subsec. (*l*)(16). Pub. L. 114–10, § 515(b), added par. (16).

Subsec. (r). Pub. L. 114–27 added subsec. (r).

Subsec. (s). Pub. L. 114–113 added subsec. (s).

2014—Subsec. (a)(1)(I). Pub. L. 113–295 added subpar. (I).

Subsec. (*l*)(12)(A). Pub. L. 113–93, § 104(b), substituted ''April 1, 2015'' for ''April 1, 2014''.

Subsec. (*l*)(13)(A). Pub. L. 113–93, § 104(a), substituted ''April 1, 2015'' for ''April 1, 2014'' wherever appearing.

Subsec. (p). Pub. L. 113–93, § 218(a)(1), added subsec. (p).

Subsec. (q). Pub. L. 113–93, § 218(b)(1), added subsec. (q).

2013—Subsec. (a)(1)(F). Pub. L. 112–240, § 636(a)(1), substituted ''subparagraphs (G) and (H)'' for ''subparagraph (G)'' in introductory provisions.

Subsec. (a)(1)(H). Pub. L. 112–240, § 636(a)(2), added subpar. (H).

Subsec. (a)(22). Pub. L. 112–240, § 636(b), added par. (22).

Subsec. (k)(7). Pub. L. 112–240, § 633(b), added par. (7).

Subsec. (*l*)(12)(A). Pub. L. 113–67, § 1104(b), substituted ''April 1, 2014'' for ''January 1, 2014''.

Pub. L. 112–240, § 604(c), substituted ''January 1, 2014'' for ''January 1, 2013''.

Subsec. (*l*)(13)(A). Pub. L. 113–67, § 1104(a), substituted ''April 1, 2014'' for ''January 1, 2014'' wherever appearing.

Pub. L. 112–240, § 604(a), substituted ''January 1, 2014'' for ''January 1, 2013'' wherever appearing.

Subsec. (*l*)(15). Pub. L. 112–240, § 637, added par. (15).

2012—Subsec. (*l*)(12)(A). Pub. L. 112–96, §3007(c), substituted ''January 1, 2013'' for ''March 1, 2012''.

Subsec. (*l*)(13)(A). Pub. L. 112–96, §3007(a), substituted ''January 1, 2013'' for ''March 1, 2012'' wherever appearing.

2011—Subsec. (*l*)(12)(A). Pub. L. 112–78, §306(c), substituted ''March 1, 2012'' for ''January 1, 2012''.

Subsec. (*l*)(13)(A). Pub. L. 112–78, §306(a), substituted ''March 1, 2012'' for ''January 1, 2012'' wherever appearing.

2010—Subsec. (a)(1)(F)(ii). Pub. L. 111–148, §6410(b)(2)(A), inserted ''(and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall)'' after ''may''.

Subsec. (a)(1)(F)(iii). Pub. L. 111–148, §6410(b)(1), (2)(B), (3), added cl. (iii).

Subsec. (a)(7)(A)(i)(II). Pub. L. 111–148, §3136(a)(1)(A), inserted ''subclause (III) and'' after ''Subject to''.

Subsec. (a)(7)(A)(i)(III). Pub. L. 111–148, §3136(a)(1)(B), added subcl. (III).

Subsec. (a)(7)(A)(iii). Pub. L. 111–148, §3136(a)(2)(B), inserted ''complex, rehabilitative'' after ''case of a''.

Pub. L. 111–148, §3136(a)(2)(A), inserted ''complex, rehabilitative'' after ''option for'' in heading.

Subsec. (a)(7)(C)(ii)(II). Pub. L. 111–148, §3136(b), struck out ''(A)(ii) or'' after ''subparagraph''.

Subsec. (a)(11)(B). Pub. L. 111–148, §6407(b)(1), designated existing provisions as cl. (i) and inserted heading.

Pub. L. 111–148, §6405(a), substituted ''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'' for ''physician''.

Subsec. (a)(11)(B)(ii). Pub. L. 111–148, §6407(b)(2), added cl. (ii).

Subsec. (a)(14). Pub. L. 111–148, §3401(m)(3), inserted concluding provisions.

Subsec. (a)(14)(K). Pub. L. 111–148, §3401(m)(1), struck out ''2011, 2012, and 2013,'' after ''2010,'' and inserted ''and'' at the end.

Subsec. (a)(14)(L), (M). Pub. L. 111–148, §3401(m)(2), added subpar. (L) and struck out former subpars. (L) and (M) which read as follows:

''(L) for 2014—

''(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, plus 2.0 percentage points; 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 2013; and

''(M) for a subsequent year, 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.''

Subsec. (a)(16)(B). Pub. L. 111–148, §6402(g)(1), inserted ''that the Secretary determines is commensurate with the volume of the billing of the supplier'' after ''$50,000''.

Subsec. (a)(20)(F)(i). Pub. L. 111–148, §3109(a)(1)(B), which directed amendment by inserting '', except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011'' before semicolon ''at the end'', was executed by making the insertion before ''; and'' to reflect the probable intent of Congress.

Pub. L. 111–148, §3109(a)(1)(A), inserted ''and subparagraph (G)'' after ''clause (ii)''.

Subsec. (a)(20)(G). Pub. L. 111–148, §3109(a)(2), added subpar. (G).

Subsec. (g)(2)(A). Pub. L. 111–148, §3128(a), inserted ''101 percent of'' after ''subparagraph (B),''.

Subsec. (g)(2)(B). Pub. L. 111–148, §5501(b)(2), substituted ''Subsections (x) and (y) of section 1395*l*'' for ''Section 1395*l*(x)''.

Pub. L. 111–148, §5501(a)(2), inserted at end ''Section 1395*l*(x) of this title shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.''

Subsec. (h)(4)(A). Pub. L. 111–148, §3401(n)(1)(D), inserted concluding provisions.

Subsec. (h)(4)(A)(x). Pub. L. 111–148, §3401(n)(1)(B)(i), substituted ''for each of 2007 through 2010'' for ''a subsequent year''.

Subsec. (h)(4)(A)(xi). Pub. L. 111–148, §3401(n)(1)(A), (B)(ii), (C), added cl. (xi).

Subsec. (*l*)(3). Pub. L. 111–148, §3401(j)(4), inserted concluding provisions.

Subsec. (*l*)(3)(B). Pub. L. 111–148, §3401(j)(2)(A), inserted '', subject to subparagraph (C) and the succeeding sentence of this paragraph,'' after ''increased''.

Subsec. (*l*)(3)(C). Pub. L. 111–148, §3401(j)(1), (2)(B), (3), added subpar. (C).

Subsec. (*l*)(8). Pub. L. 111–148, §3128(a), inserted ''101 percent of'' after ''pay'' in introductory provisions.

Subsec. (*l*)(12)(A). Pub. L. 111–309, §106(c), substituted ''2012'' for ''2011''.

Pub. L. 111–148, §10311(c), substituted ''2011'' for ''2010, and on or after April 1, 2010, and before January 1, 2011''.

Pub. L. 111–148, §3105(c), substituted ''2010, and on or after April 1, 2010, and before January 1, 2011'' for ''2010''.

Subsec. (*l*)(13)(A). Pub. L. 111–309, §106(a)(1), substituted ''2012,'' for ''2011'' in introductory provisions.

Pub. L. 111–148, §10311(a)(1), in introductory provisions, substituted ''2007, and for'' for ''2007, for'' and ''2011'' for ''2010, and for such services furnished on or after April 1, 2010, and before January 1, 2011''.

Pub. L. 111–148, §3105(a)(1), in introductory provisions, substituted ''2007, for'' for ''2007, and for'' and ''2010, and for such services furnished on or after April 1, 2010, and before January 1, 2011,'' for ''2010''.

Subsec. (*l*)(13)(A)(i), (ii). Pub. L. 111–309, §106(a)(2), substituted ''January 1, 2012'' for ''January 1, 2011''.

Pub. L. 111–148, §10311(a)(2)(B), substituted ''January 1, 2011'' for ''January 1, 2010''.

Pub. L. 111–148, §10311(a)(2)(A), struck out '', and on or after April 1, 2010, and before January 1, 2011'' after ''January 1, 2010''.

Pub. L. 111–148, §3105(a)(2), inserted '', and on or after April 1, 2010, and before January 1, 2011'' after ''January 1, 2010''.

Subsec. (n). Pub. L. 111–148, §5502(b), which directed the addition of subsec. (n) relating to development and implementation of prospective payment system, was repealed by Pub. L. 111–148, §10501(i)(1).

Pub. L. 111–148, §4105(a), added subsec. (n) relating to authority to modify or eliminate coverage of certain preventive services.

Subsec. (*o*). Pub. L. 111–148, §10501(i)(3)(A), added subsec. (*o*).

2009—Subsec. (a)(20)(F)(i). Pub. L. 111–72 inserted '', except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010'' before semicolon.

2008—Subsec. (a)(1)(E)(ii). Pub. L. 110–275, §154(d)(2), substituted ''1395x(r)'' for ''1395x(r)(1)''.

Subsec. (a)(1)(F). Pub. L. 110–275, §154(a)(3), (4)(A)(i), in introductory provisions, substituted ''January 1, 2011'' for ''January 1, 2009'' and inserted ''subject to subparagraph (G),'' before ''that are included''.

Subsec. (a)(1)(G). Pub. L. 110–275, §154(a)(4)(A)(ii), added subpar. (G).

Subsec. (a)(5)(F). Pub. L. 110–275, §144(b)(1), substituted ''Rental cap'' for ''Ownership of equipment'' in heading, added cl. (ii), and struck out former cl. (ii) which related to transfer of title to equipment and payments for oxygen and maintenance and servicing.

Subsec. (a)(14)(J) to (M). Pub. L. 110–275, §154(a)(2)(A), added subpars. (J) to (L) and redesignated former subpar. (J) as (M).

Subsec. (a)(20)(B). Pub. L. 110–275, §125(b)(5), substituted ''section 1395bb(a)'' for ''section 1395bb(b)''.

Subsec. (a)(20)(E). Pub. L. 110–275, §154(b)(1)(A)(i), inserted ''including subparagraph (F),'' after ''under this paragraph,''.

Subsec. (a)(20)(F). Pub. L. 110–275, §154(b)(1)(A)(ii), added subpar. (F).

Subsec. (e). Pub. L. 110–275, §135(a)(1), added subsec. (e).

Subsec. (g)(4). Pub. L. 110–275, §148(a), substituted ''Treatment of'' for ''No beneficiary cost-sharing for'' in heading and inserted at end ''For purposes of the preceding sentence and section 1395x(mm)(3) of this title, clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.''

Subsec. (h)(1)(H). Pub. L. 110–275, §154(a)(3), (4)(B), in introductory provisions, substituted ''January 1, 2011'' for ''January 1, 2009'' and inserted ''subject to subsection (a)(1)(G),'' before ''that are included''.

Subsec. (*l*)(13)(A). Pub. L. 110–275, §146(a)(1), inserted ''and for such services furnished on or after July 1, 2008, and before January 1, 2010'' after ''2007,'' in introductory provisions, ''(or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010)'' after ''2 percent'' in cl. (i), and ''(or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2010)'' after ''1 percent'' in cl. (ii).

Subsec. (*l*)(13)(B). Pub. L. 110–275, §146(a)(2), substituted ''applicable period'' for ''2006'' in heading and inserted ''applicable'' before ''period'' in text.

Subsec. (*l*)(14)(B)(i). Pub. L. 110–275, §146(b)(2)(A), substituted ''certifies or reasonably determines'' for ''reasonably determines or certifies''.

Subsec. (m)(4)(C)(ii)(VI) to (VIII). Pub. L. 110–275, §149(a), added subcls. (VI) to (VIII).

2006—Subsec. (a)(5)(A). Pub. L. 109–171, §5101(b)(1)(A), substituted ''(E), and (F)'' for ''and (E)''.

Subsec. (a)(5)(F). Pub. L. 109–171, §5101(b)(1)(B), added subpar. (F).

Subsec. (a)(7)(A). Pub. L. 109–171, §5101(a)(1), amended heading and text of subpar. (A) generally, revising and restating as cls. (i) to (iv) provisions of former cls. (i) to (vi).

Subsec. (d)(2)(C)(ii). Pub. L. 109–171, §5113(b), struck out ''deductible and'' before ''coinsurance'' in heading and struck out ''deductible or'' before ''copayment'' and before ''coinsurance'' in subcl. (I).

Subsec. (d)(3)(C)(ii). Pub. L. 109–171, §5113(b), struck out ''deductible and'' before ''coinsurance'' in heading and struck out ''deductible or'' before ''coinsurance'' in two places in subcl. (I).

2003—Subsec. (a)(1)(B). Pub. L. 108–173, §302(d)(1)(A), substituted ''Subject to subparagraph (F)(i), the payment basis'' for ''The payment basis'' in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 108–173, §302(d)(1)(B), substituted ''Subject to subparagraph (F)(ii), this subsection'' for ''This subsection''.

Subsec. (a)(1)(E). Pub. L. 108–173, §302(a)(2), added subpar. (E).

Subsec. (a)(1)(F). Pub. L. 108–173, §302(d)(1)(C), added subpar. (F).

Subsec. (a)(10)(B). Pub. L. 108–173, §302(d)(1)(D), inserted ''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)'' after ''under this subsection''.

Subsec. (a)(14)(F). Pub. L. 108–173, §302(c)(1)(A)(ii), substituted ''2003'' for ''a subsequent year'' and ''2002;'' for ''the previous year.''

Subsec. (a)(14)(G) to (J). Pub. L. 108–173, §302(c)(1)(A)(i), (iii), added subpars (G) to (J).

Subsec. (a)(17), (19). Pub. L. 108–173, §302(a)(1)(A), redesignated par. (17), relating to certain upgraded items, as (19) and transferred it to the end of subsec. (a).

Subsec. (a)(20). Pub. L. 108–173, §302(a)(1)(B), added par. (20).

Subsec. (a)(21). Pub. L. 108–173, §302(c)(2), added par. (21).

Subsec. (b)(4)(D)(iv). Pub. L. 108–173, §736(b)(4), substituted ''clause (vi)'' for ''clauses (vi)''.

Subsec. (g)(1). Pub. L. 108–173, §405(a)(1), inserted ''equal to 101 percent of'' before ''the reasonable costs''.

Subsec. (g)(2). Pub. L. 108–173, §405(d)(1), inserted concluding provisions.

Subsec. (g)(5). Pub. L. 108–173, §405(b)(1), in heading, inserted ''certain'' before ''emergency'' and substituted ''providers'' for ''physicians'', and, in text, substituted ''physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services'' for ''emergency room physicians who are on-call (as defined by the Secretary)'' and ''services covered under this subchapter'' for ''physicians' services''.

Subsec. (h)(1)(B). Pub. L. 108–173, §302(d)(2)(A), substituted '', (E), and (H)(i)'' for ''and (E)'' in introductory provisions.

Subsec. (h)(1)(D). Pub. L. 108–173, §302(d)(2)(B), substituted ''Subject to subparagraph (H)(ii), this subsection'' for ''This subsection''.

Subsec. (h)(1)(H). Pub. L. 108–173, §302(d)(2)(C), added subpar. (H).

Subsec. (h)(4)(A)(viii). Pub. L. 108–173, §302(c)(3)(B), substituted ''2003'' for ''a subsequent year''.

Subsec. (h)(4)(A)(ix), (x). Pub. L. 108–173, §302(c)(3)(A), (C), added cls. (ix) and (x).

Subsec. (h)(4)(C). Pub. L. 108–173, §627(b)(1), inserted ''(and includes shoes described in section 1395x(s)(12) of this title)'' after ''in section 1395x(s)(9) of this title''.

Subsec. (*l*)(2)(E). Pub. L. 108–173, §414(a)(1), inserted ''consistent with paragraph (11)'' after ''in an efficient and fair manner''.

Subsec. (*l*)(8), (9). Pub. L. 108–173, §414(a)(2), redesignated par. (8), relating to transitional assistance for rural providers, as (9).

Subsec. (*l*)(10). Pub. L. 108–173, §414(a)(3), added par. (10).

Subsec. (*l*)(11). Pub. L. 108–173, §414(b), added par. (11).

Subsec. (*l*)(12). Pub. L. 108–173, §414(c)(1), added par. (12).

Subsec. (*l*)(13). Pub. L. 108–173, §414(d), added par. (13).

Subsec. (*l*)(14). Pub. L. 108–173, §415(a), added par. (14).

Subsec. (m)(4)(C)(ii)(III). Pub. L. 108–173, §736(b)(5), substituted ''1395x(aa)(2)'' for ''1395x(aa)(s)''.

2000—Subsec. (a)(14)(C). Pub. L. 106–554, §1(a)(6) [title IV, §425(a)(2)], substituted ''through 2000'' for ''through 2002'' and struck out ''and'' at end.

Subsec. (a)(14)(D) to (F). Pub. L. 106–554, §1(a)(6) [title IV, §425(a)(1), (3)], added subpars. (D) and (E) and redesignated former subpar. (D) as (F).

Subsec. (c). Pub. L. 106–554, §1(a)(6) [title I, §104(b)], amended heading and text generally, substituting present provisions for provisions which had set forth similar standards for screening mammography but had provided for payment limited to 80 percent of the least of the actual charge, a statutory fee schedule, if applicable, or the indexed dollar limit described, and which had set forth provisions relating to reduction of indexed dollar limit, application of limit in a hospital outpatient setting, and limitation of charges of nonparticipating physicians.

Subsec. (d)(2)(E)(ii). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(1)], inserted before period at end ''or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy''.

Subsec. (d)(3). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(A)], struck out ''for individuals at high risk for colorectal cancer'' after ''colonoscopy'' in heading.

Subsec. (d)(3)(A). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(B)], struck out ''for individuals at high risk for colorectal cancer (as defined in section 1395x(pp)(2) of this title)'' after ''screening colonoscopy''.

Subsec. (d)(3)(E). Pub. L. 106–554, §1(a)(6) [title I, §103(b)(2)(C)], inserted before period at end ''or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy''.

Subsec. (g)(2)(B). Pub. L. 106–554, §1(a)(6) [title II, §202(a)], inserted ''115 percent of'' before ''such amounts''.

Subsec. (g)(4). Pub. L. 106–554, §1(a)(6) [title II, §201(a)], added par. (4).

Subsec. (g)(5). Pub. L. 106–554, §1(a)(6) [title II, §204(a)], added par. (5).

Subsec. (h)(1)(F). Pub. L. 106–554, §1(a)(6) [title IV, §427(a)], added subpar. (F).

Subsec. (h)(1)(G). Pub. L. 106–554, §1(a)(6) [title IV, §428(a)], added subpar. (G).

Subsec. (h)(4)(A)(v). Pub. L. 106–554, §1(a)(6) [title IV, §426(a)(2)], substituted ''through 2000'' for ''through 2002'' and struck out ''and'' at end.

Subsec. (h)(4)(A)(vi) to (viii). Pub. L. 106–554, §1(a)(6) [title IV, §426(a)(1), (3)], added cls. (vi) and (vii) and redesignated former cl. (vi) as (viii).

Subsec. (*l*)(2)(E). Pub. L. 106–554, §1(a)(6) [title IV, §423(b)(1)], inserted before period at end '', except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported''.

Subsec. (*l*)(3)(A), (B). Pub. L. 106–554, §1(a)(6) [title IV, §423(a)(1)], substituted ''reduced in the case of 2002'' for ''reduced in the case of 2001 and 2002''.

Subsec. (*l*)(8). Pub. L. 106–554, §1(a)(6) [title II, §221(a)], added par. (8) relating to transitional assistance for rural providers.

Pub. L. 106–554, §1(a)(6) [title II, §205(a)], added par. (8) relating to services furnished by critical access hospitals.

Subsec. (m). Pub. L. 106–554, §1(a)(6) [title II, §223(b)], added subsec. (m).

1999—Subsec. (a)(13). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(2)(A)], substituted ''1395x(m)(5) of this title, but not including implantable items for which payment may be made under section 1395*l*(t) of this title'' for ''1395x(m)(5) of this title)''.

Subsec. (g). Pub. L. 106–113, §1000(a)(6) [title IV, §403(d)(1)], amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: ''The amount of payment under this part for outpatient critical access hospital services is the reasonable costs of the critical access hospital in providing such services.''

Subsec. (h)(4)(A)(i). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(3)(A)], substituted semicolon for comma at end.

Subsec. (h)(4)(A)(v). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(3)(B)], substituted ''; and'' for '', and'' at end.

Subsec. (h)(4)(B). Pub. L. 106–113, §1000(a)(6) [title II, §201(e)(2)(B)], inserted ''and does not include an implantable item for which payment may be made under section 1395*l*(t) of this title'' before the semicolon.

1997—Subsec. (a)(2)(B)(iv). Pub. L. 105–33, §4105(b)(2), inserted before period at end ''(reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes)''.

Subsec. (a)(9)(B)(iv). Pub. L. 105–33, §4552(a)(2)(A), substituted ''1995, 1996, and 1997'' for ''each subsequent year''.

Subsec. (a)(9)(B)(v), (vi). Pub. L. 105–33, §4552(a)(1), (2)(B), (3), added cls. (v) and (vi).

Subsec. (a)(9)(D). Pub. L. 105–33, §4552(b), which directed amendment of section 1848(a)(9) (42 U.S.C. 1395m(a)(9)) by adding subpar. (D) at end, was executed by adding subpar. (D) at end of subsec. (a)(9) of this section, to reflect the probable intent of Congress.

Subsec. (a)(10)(B). Pub. L. 105–33, §4316(b), substituted ''The Secretary'' for ''For covered items furnished on or after January 1, 1991, the Secretary'' and struck out ''(other than subparagraph (D))'' before ''of section 1395u(b) of this title'' and ''as such provisions would otherwise apply to physicians' services and physicians and a reasonable charge under section 1395u(b) of this title but for the application of section 1395w–4(i)(3) of this title. In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable'' before period at end.

Subsec. (a)(14)(B). Pub. L. 105–33, §4551(a)(1)(B)(i), substituted ''1993, 1994, 1995, 1996, and 1997'' for ''a subsequent year''.

Subsec. (a)(14)(C), (D). Pub. L. 105–33, §4551(a)(1)(A), (B)(ii), (C), added subpars. (C) and (D).

Subsec. (a)(16). Pub. L. 105–33, §4312(c), inserted at end ''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.''

Pub. L. 105–33, §4312(a), added par. (16).

Subsec. (a)(17). Pub. L. 105–33, §4551(c)(1), added par. (17) relating to certain upgraded items.

Subsec. (c)(1)(C). Pub. L. 105–33, §4101(c), in introductory provisions, struck out '', subject to the deductible established under section 1395*l*(b) of this title,'' before ''be equal to 80''.

Subsec. (c)(2)(A)(iii). Pub. L. 105–33, §4101(a)(1), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: ''In the case of a woman over 39 years of age, but under 50 years of age, who—

''(I) is at a high risk of developing breast cancer (as determined pursuant to factors identified by the Secretary), payment may not be made under this part for a screening mammography performed within the 11 months following the month in which a previous screening mammography was performed, or

''(II) is not at a high risk of developing breast cancer, payment may not be made under this part for a screening mammography performed within the 23 months following the month in which a previous screening mammography was performed.''

Subsec. (c)(2)(A)(iv), (v). Pub. L. 105–33, §4101(a)(2), struck out cls. (iv) and (v), which read as follows:

''(iv) In the case of a woman over 49 years of age, but under 65 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

''(v) In the case of a woman over 64 years of age, payment may not be made for screening mammography performed within 23 months following the month in which a previous screening mammography was performed.''

Subsec. (d). Pub. L. 105–33, §4104(b)(1), added subsec. (d).

Subsec. (g). Pub. L. 105–33, §4201(c)(5), amended heading and text of subsec. (g) generally. Prior to amendment, text related to payment for outpatient rural primary care hospital services as determined, in par. (1), by either the cost-based facility fee plus professional charges method or the all-inclusive rate method and, in par. (2), by the prospective payment system.

Subsec. (h)(4)(A)(iv). Pub. L. 105–33, §4551(a)(2)(B), substituted ''1996 and 1997'' for ''a subsequent year''.

Subsec. (h)(4)(A)(v), (vi). Pub. L. 105–33, §4551(a)(2)(A), (C), added cls. (v) and (vi).

Subsec. (k). Pub. L. 105–33, §4541(a)(2), added subsec. (k).

Subsec. (*l*). Pub. L. 105–33, §4531(b)(2), added subsec. (*l*).

1994—Subsec. (a)(3)(D). Pub. L. 103–432, §135(e)(5), struck out heading and text of subpar. (D). Text read as follows: ''If the reasonable useful lifetime of such an item, as established under paragraph (7)(C), has been reached during a continuous period of medical need, or the Secretary determines on the basis of investigation by the carrier that the item is lost or irreparably dam-

aged, payment for an item serving as a replacement for such item shall be made on a monthly basis for the rental of the replacement item in accordance with subparagraph (A).''

Subsec. (a)(5)(E). Pub. L. 103–432, §135(d)(1), substituted ''pressure of 56'' for ''pressure of 55''.

Subsec. (a)(7). Pub. L. 103–432, §135(e)(2), made technical amendment to directory language of Pub. L. 101–508, §4152(c)(2). See 1990 Amendment note below.

Subsec. (a)(7)(A)(iii)(II). Pub. L. 103–432, §135(e)(3), substituted ''clause (vi)'' for ''clause (v)''.

Subsec. (a)(7)(C)(i). Pub. L. 103–432, §135(e)(4), substituted ''this paragraph'' for ''this paragraph or paragraph (3)''.

Subsec. (a)(10)(B). Pub. L. 103–432, §134(a)(1), inserted at end ''In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable.''

Pub. L. 103–432, §126(g)(10)(B), substituted ''would otherwise apply to physicians' services'' for ''apply to physicians' services'' and inserted before period at end ''but for the application of section 1395w–4(i)(3) of this title''.

Subsec. (a)(14)(A). Pub. L. 103–432, §135(a)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''for 1991 and 1992, reduction of 1 percentage point; and''.

Subsec. (a)(15). Pub. L. 103–432, §135(b)(1), amended heading and text of par. (15) generally. Prior to amendment, text read as follows:

''(A) DEVELOPMENT OF LIST OF ITEMS BY SECRETARY.—The Secretary shall 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, and shall include in such list seat-lift mechanisms, transcutaneous electrical nerve stimulators, and motorized scooters.

''(B) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance whether payment for an item included on the list developed by the Secretary under subparagraph (A) may not be made because of the application of section 1395y(a)(1) of this title.''

Subsec. (a)(16). Pub. L. 103–432, §131(a)(2), struck out heading and text of par. (16). Text read as follows:

''(A) IN GENERAL.—A supplier of a covered item under this subsection may not distribute to physicians or to individuals entitled to benefits under this part for commercial purposes any completed or partially completed forms or other documents required by the Secretary to be submitted to show that a covered item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

''(B) PENALTY.—Any supplier of a covered item who knowingly and willfully distributes a form or other document in violation of subparagraph (A) is subject to a civil money penalty in an amount not to exceed $1,000 for each such form or document so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.''

Subsec. (a)(17), (18). Pub. L. 103–432, §132(a)(1), (2), added pars. (17) and (18).

Subsec. (b)(4)(D). Pub. L. 103–432, §126(b)(2)(A), in introductory provisions substituted ''shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:'' for ''shall be determined as follows:''.

Subsec. (b)(4)(D)(iv). Pub. L. 103–432, §126(b)(2)(B), substituted ''Adjusted conversion factor'' for ''Local adjustment'' in heading and ''The adjusted conversion factor for'' for ''Subject to clause (vii), the conversion factor to be applied to'' in text.

Subsec. (b)(4)(D)(vii). Pub. L. 103–432, §126(b)(2)(C), (D), struck out ''under this subparagraph'' after ''applied to a locality'' and inserted ''reduced under this subparagraph by'' before ''more than 9.5 percent''.

Subsec. (b)(4)(E). Pub. L. 103–432, §126(b)(5), inserted heading ''Rule for certain scanning services''.

Pub. L. 103–432, §126(b)(4), made technical amendment to directory language of Pub. L. 101–508, §4102(d). See 1990 Amendment note below.

Pub. L. 103–432, §126(b)(1), redesignated subpar. (E), relating to subsequent updating, as (F).

Subsec. (b)(4)(F), (G). Pub. L. 103–432, §126(b)(1), redesignated subpars. (E), relating to subsequent updating, and (F) as (F) and (G), respectively.

Subsec. (c)(1)(B). Pub. L. 103–432, §145(a)(1), substituted ''is conducted by a facility that has a certificate (or provisional certificate) issued under section 263b of this title'' for ''meets the quality standards established under paragraph (3)''.

Subsec. (c)(1)(C)(iii). Pub. L. 103–432, §145(a)(2), substituted ''paragraph (3)'' for ''paragraph (4)''.

Subsec. (c)(3) to (5). Pub. L. 103–432, §145(a)(3), (4), redesignated pars. (4) and (5) as (3) and (4), respectively, and struck out former par. (3) which directed Secretary to establish standards to assure the safety and accuracy of screening mammography performed under this part.

Subsec. (f). Pub. L. 103–432, §126(g)(1), substituted ''during 1991'' for ''during fiscal year 1991'' in heading.

Subsec. (g)(1). Pub. L. 103–432, §102(e)(1)(A), (2), substituted in introductory provisions ''during a year before the prospective payment system described in paragraph (2) is in effect'' for ''during a year before 1993'' and inserted at end ''The amount of payment shall be determined under either method without regard to the amount of the customary or other charge.''

Subsec. (g)(1)(B). Pub. L. 103–432, §156(a)(2)(C), struck out ''and for items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title, or a third opinion, if the second opinion was in disagreement with the first opinion'' after ''section 1395x(s)(10)(A) of this title''.

Subsec. (g)(2). Pub. L. 103–432, §102(e)(1)(B), substituted ''January 1, 1996'' for ''January 1, 1993''.

Subsec. (h)(3). Pub. L. 103–432, §135(b)(3), substituted ''Paragraphs (12), (15), and (17)'' for ''Paragraphs (12) and (17)''.

Pub. L. 103–432, §132(b), substituted ''Paragraphs (12) and (17)'' for ''Paragraph (12)''.

Subsec. (j). Pub. L. 103–432, §131(a)(1), added subsec. (j).

Subsec. (j)(4), (5). Pub. L. 103–432, §133(a)(1), added par. (4) and redesignated former par. (4) as (5).

1993—Subsec. (a)(1)(D). Pub. L. 103–66, §13545(a), substituted ''45 percent'' for ''15 percent'' after ''(as previously reduced) by''.

Subsec. (a)(2)(A)(iii). Pub. L. 103–66, §13543(b), added cl. (iii).

Subsec. (a)(2)(C). Pub. L. 103–66, §13542(a)(1), in cl. (i)(II), substituted ''for 1992, 1993, and 1994'' for ''for 1992'' and ''update for the year'' for ''update for 1992'', and in cl. (ii), struck out ''and'' at end of subcl. (I), added subcls. (II) and (III), and redesignated former subcl. (II) as (IV).

Subsec. (a)(3)(A). Pub. L. 103–66, §13543(a), substituted ''IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices'' for ''ventilators, aspirators, IPPB machines, and nebulizers''.

Subsec. (a)(3)(C). Pub. L. 103–66, §13542(a)(1), in cl. (i)(II), substituted ''for 1992, 1993, and 1994'' for ''for 1992'' and ''update for the year'' for ''update for 1992'', and in cl. (ii), struck out ''and'' at end of subcl. (I), added subcls. (II) and (III), and redesignated former subcl. (II) as (IV).

Subsec. (a)(8)(A)(ii)(III). Pub. L. 103–66, §13542(a)(2)(A), substituted ''1992, 1993, and 1994'' for ''1992''.

Subsec. (a)(8)(B)(ii) to (iv). Pub. L. 103–66, §13542(a)(2)(B), added cls. (ii) and (iii) and redesignated former cl. (ii) as (iv).

Subsec. (a)(9)(A)(ii)(II). Pub. L. 103–66, §13542(a)(3)(A), substituted ''1991, 1992, 1993, and 1994'' for ''1991 and 1992''.

Subsec. (a)(9)(B)(ii) to (iv). Pub. L. 103–66, §13542(a)(3)(B), added cls. (ii) and (iii) and redesignated former cl. (ii) as (iv).

Subsec. (h)(1)(B). Pub. L. 103–66, §13544(a)(2), substituted ''subparagraphs (C) and (E)'' for ''subparagraph (C)'' in introductory provisions.

Subsec. (h)(1)(E). Pub. L. 103–66, §13544(a)(1), added subpar. (E).

Subsec. (h)(4)(A). Pub. L. 103–66, §13546, struck out ''and'' at end of cl. (i), substituted ''1992 and 1993'' for ''a subsequent year'' in cl. (ii), and added cls. (iii) and (iv).

Subsec. (i). Pub. L. 103–66, §13544(b)(1), added subsec. (i).

1990—Subsec. (a). Pub. L. 101–508, §4153(a)(2)(D)(i), struck out '', prosthetic devices, orthotics, and prosthetics'' after ''medical equipment'' in heading.

Subsec. (a)(1)(D). Pub. L. 101–508, §4152(a)(1), inserted before period at end '', 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 15 percent''.

Subsec. (a)(2)(A). Pub. L. 101–508, §4153(a)(2)(D)(ii), substituted ''(13)'' for ''(13)(A)''.

Pub. L. 101–508, §4152(c)(4)(A), inserted ''or'' after ''$150,'' in cl. (i), struck out ''or'' after ''purchase,'' in cl. (ii), and struck out cl. (iii) which read as follows: ''which is a power-driven wheelchair (other than a customized wheelchair that is classified as a customized item under paragraph (4) pursuant to criteria specified by the Secretary),''.

Subsec. (a)(2)(B). Pub. L. 101–508, §4152(b)(1)(A), (B), struck out ''or'' after ''1987;'' in cl. (i), added cls. (ii) to (iv), and struck out former cl. (ii) which read as follows: ''in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by 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 that preceding year.''

Subsec. (a)(2)(C). Pub. L. 101–508, §4152(b)(1)(C), added subpar. (C).

Subsec. (a)(3)(B). Pub. L. 101–508, §4152(b)(1)(A), (B), struck out ''or'' after ''1987;'' in cl. (i), added cls. (ii) to (iv), and struck out former cl. (ii) which read as follows: ''in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by 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 that preceding year.''

Subsec. (a)(3)(C). Pub. L. 101–508, §4152(b)(1)(C), added subpar. (C).

Subsec. (a)(3)(D). Pub. L. 101–508, §4152(c)(3), added subpar. (D).

Subsec. (a)(4). Pub. L. 101–508, §4152(c)(4)(B)(i), directed amendment of par. (4) by inserting at end ''In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.'' The amendment did not become effective pursuant to Pub. L. 101–508, §4152(c)(4)(B)(ii). See Effective Date of 1990 Amendment note below.

Subsec. (a)(5)(A). Pub. L. 101–508, §4152(g)(1)(A), substituted ''(B), (C), and (E)'' for ''(B) and (C)''.

Subsec. (a)(5)(E). Pub. L. 101–508, §4152(g)(1)(B), added subpar. (E).

Subsec. (a)(7)(A)(i). Pub. L. 101–508, §4152(c)(2)(A), as amended by Pub. L. 103–432, §135(e)(2), substituted ''15 months, or, in the case of an item for which a purchase agreement has been entered into under clause (iii), a period of continuous use of longer than 13 months'' for ''15 months''.

Pub. L. 101–508, §4152(c)(1), substituted ''for each of the first 3 months of such period'' for ''for each such month'' and '', and for each of the remaining months of such period is 7.5 percent of such purchase price;'' for semicolon at end.

Subsec. (a)(7)(A)(ii), (iii). Pub. L. 101–508, §4152(c)(2)(D), as amended by Pub. L. 103–432, §135(e)(2), added cls. (ii) and (iii). Former cls. (ii) and (iii) redesignated (iv) and (v), respectively.

Subsec. (a)(7)(A)(iv). Pub. L. 101–508, §4152(c)(2)(B), as amended by Pub. L. 103–432, §135(e)(2), redesignated cl. (ii) as (iv), substituted ''in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii), during the first 6-month period of medical need that follows the period of medical need during which payment is made under clause (i),'' for ''during the succeeding 6-month period of medical need,'' and struck out ''and'' at end.

Subsec. (a)(7)(A)(v). Pub. L. 101–508, §4152(c)(2)(C), as amended by Pub. L. 103–432, §135(e)(2), redesignated cl. (iii) as (v), inserted at beginning ''in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii),'', and substituted ''; and'' for period at end.

Subsec. (a)(7)(A)(vi). Pub. L. 101–508, §4152(c)(2)(E), as amended by Pub. L. 103–432, §135(e)(2), added cl. (vi).

Subsec. (a)(7)(C). Pub. L. 101–508, §4152(c)(2)(F), as amended by Pub. L. 103–432, §135(e)(2), added subpar. (C).

Subsec. (a)(8)(A)(ii). Pub. L. 101–508, §4152(b)(2)(A), added subcl. (II), redesignated former subcl. (II) as (III), struck out ''1991 or'' before ''1992'', and substituted ''the covered item update for the year'' for ''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''.

Subsec. (a)(8)(B). Pub. L. 101–508, §4152(b)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

''(i) for 1991 and for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

''(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by 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.''

Subsec. (a)(8)(C). Pub. L. 101–508, §4152(b)(2)(C)(ii), struck out ''and subject to subparagraph (D)'' after ''and (7)'' in introductory provisions.

Subsec. (a)(8)(C)(ii). Pub. L. 101–508, §4152(b)(2)(C)(i), (iii), in subcl. (I) substituted ''67 percent'' for ''75 percent'' and in subcl. (II) substituted ''33 percent'' for ''25 percent'' and ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(C)(iii). Pub. L. 101–508, §4152(b)(2)(C)(i), (iv), in subcl. (I) substituted ''33 percent'' for ''50 percent'' and ''subparagraph (A)(ii)(III)'' for ''subparagraph (A)(ii)(II)'' and in subcl. (II) substituted ''67 percent'' for ''50 percent'' and ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(C)(iv). Pub. L. 101–508, §4152(b)(2)(C)(i), substituted ''national limited purchase price'' for ''regional purchase price''.

Subsec. (a)(8)(D). Pub. L. 101–508, §4152(b)(2)(D), struck out subpar. (D) which read as follows: ''The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

''(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

''(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.''

Subsec. (a)(9)(A)(ii)(II). Pub. L. 101–508, § 4152(b)(3)(A), substituted ''the covered item increase for the year'' for ''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''.

Subsec. (a)(9)(B). Pub. L. 101–508, § 4152(b)(3)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''With respect to the furnishing of an item in each region (as defined by the Secretary), the Secretary shall compute a regional monthly payment rate—

''(i) for 1991 and 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local monthly payment rates for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

''(ii) for each subsequent year, equal to the regional monthly payment rates computed under this subparagraph for the previous year increased by 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.''

Subsec. (a)(9)(C)(ii). Pub. L. 101–508, § 4152(b)(3)(C)(i), (ii), in subcl. (I) substituted ''67 percent'' for ''75 percent'' and in subcl. (II) substituted ''33 percent'' for ''25 percent'' and ''national limited monthly payment rate'' for ''regional monthly payment rate''.

Subsec. (a)(9)(C)(iii). Pub. L. 101–508, § 4152(b)(3)(C)(i), (iii), in subcl. (I) substituted ''33 percent'' for ''50 percent'' and in subcl. (II) substituted ''67 percent'' for ''50 percent'', ''national limited monthly payment rate'' for ''regional monthly payment rate'', and ''subparagraph (B)(ii)'' for ''subparagraph (B)(i)''.

Subsec. (a)(9)(C)(iv). Pub. L. 101–508, § 4152(b)(3)(C)(i), substituted ''national limited monthly payment rate'' for ''regional monthly payment rate''.

Subsec. (a)(9)(D). Pub. L. 101–508, § 4152(b)(3)(D), struck out subpar. (D) which read as follows: ''The amount that is recognized under subparagraph (C) as the base monthly payment amount for an item furnished—

''(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year; and

''(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year.''

Subsec. (a)(12). Pub. L. 101–508, § 4152(b)(5), struck out ''defined for purposes of paragraphs (8)(B) and (9)(B)'' after ''one or more entire regions''.

Subsec. (a)(13). Pub. L. 101–508, § 4153(a)(2)(D)(iii), substituted ''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).'' for ''means—

''(A) durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title;

''(B) prosthetic devices (described in section 1395x(s)(8) of this title), but not including parenteral and enteral nutrition nutrients, supplies, and equipment; and

''(C) orthotics and prosthetics (described in section 1395x(s)(9) of this title);

but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title.''

Subsec. (a)(14). Pub. L. 101–508, § 4152(b)(4), added par. (14).

Subsec. (a)(15). Pub. L. 101–508, § 4152(e), added par. (15).

Subsec. (a)(16). Pub. L. 101–508, § 4152(f)(1), added par. (16).

Subsec. (b)(1)(B). Pub. L. 101–508, § 4163(b)(1), inserted ''and subject to subsection (c)(1)(A)'' after ''conversion factors''.

Pub. L. 101–508, § 4102(f), inserted ''locality,'' after ''statewide,''.

Subsec. (b)(4)(D). Pub. L. 101–508, § 4102(a)(2), added subpar. (D). Former subpar. (D) redesignated (E) relating to subsequent updating.

Subsec. (b)(4)(E). Pub. L. 101–508, § 4102(d), as amended by Pub. L. 103–432, § 126(b)(4), added subpar. (E) relating to rule for certain scanning services.

Pub. L. 101–508, § 4102(a)(1), redesignated subpar. (D), relating to subsequent updating, as (E). Former subpar. (E) redesignated (F).

Subsec. (b)(4)(F). Pub. L. 101–508, § 4102(a)(1), redesignated subpar. (E) as (F).

Subsec. (c). Pub. L. 101–508, § 4163(b)(2), added subsec. (c).

Subsec. (f). Pub. L. 101–508, § 4104(a), amended subsec. (f) generally, substituting provisions relating to reduction in payments for physician pathology services during 1991 for provisions directing Secretary to provide for application of a fee schedule with respect to such services.

Subsec. (h). Pub. L. 101–508, § 4153(a)(1), added subsec. (h).

1989—Subsec. (a)(1)(D). Pub. L. 101–239, § 6112(c), added subpar. (D).

Subsec. (a)(2)(A)(iii). Pub. L. 101–239, § 6112(d)(1), added cl. (iii).

Subsec. (a)(2)(B)(i), (3)(B)(i). Pub. L. 101–239, § 6112(a)(1), inserted ''and in 1990'' after ''1989''.

Subsec. (a)(7)(A)(i). Pub. L. 101–239, § 6112(a)(4)(A), substituted ''this clause'' for ''this subparagraph''.

Subsec. (a)(7)(B)(i). Pub. L. 101–239, § 6112(a)(4)(B), inserted ''in'' after ''rental of the item''.

Subsec. (a)(7)(B)(ii). Pub. L. 101–239, § 6112(a)(4)(C), substituted ''clause (i) shall apply in the same manner as it applies to items furnished during 1989'' for ''the payment amount recognized under subparagraph (A)(i) shall not be more than the maximum amount established under clause (i), and shall not be less than the minimum amount established under such clause, for 1989, each such amount increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 1989''.

Subsec. (a)(8)(A)(ii)(I). Pub. L. 101–239, § 6112(a)(2)(A), inserted ''and 1990'' after ''1989''.

Subsec. (a)(8)(A)(ii)(II). Pub. L. 101–239, § 6112(a)(2)(B), substituted ''1991 or 1992'' for ''1990, 1991, or 1992''.

Subsec. (a)(8)(D)(i). Pub. L. 101–239, § 6140(1), substituted ''1991, may not exceed 125 percent, and may not be lower than 85 percent'' for ''1991, may not exceed 130 percent, and may not be lower than 80 percent''.

Subsec. (a)(8)(D)(ii). Pub. L. 101–239, § 6140(2), substituted ''120 percent, and may not be lower than 90 percent'' for ''125 percent, and may not be lower than 85 percent''.

Subsec. (a)(9)(A)(ii)(I). Pub. L. 101–239, § 6112(a)(3)(A), inserted ''and 1990'' after ''1989''.

Subsec. (a)(9)(A)(ii)(II). Pub. L. 101–239, § 6112(a)(3)(B), substituted ''1991 and 1992'' for ''1990, 1991, and 1992''.

Subsec. (a)(9)(D)(i). Pub. L. 101–239, § 6140(1), substituted ''1991, may not exceed 125 percent, and may not be lower than 85 percent'' for ''1991, may not exceed 130 percent, and may not be lower than 80 percent''.

Subsec. (a)(9)(D)(ii). Pub. L. 101–239, § 6140(2), substituted ''120 percent, and may not be lower than 90 percent'' for ''125 percent, and may not be lower than 85 percent''.

Subsec. (a)(13). Pub. L. 101–239, § 6112(e)(2), inserted before period at end ''or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title''.

Subsec. (b)(1)(B). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 204(b)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (b)(4)(A). Pub. L. 101–234, § 301(b)(1), (c)(1), amended subpar. (A) identically, substituting ''coinsurance and deductibles under sections 1395*l*(a)(1)(J)'' for ''insurance and deductibles under section 1395n(a)(1)(I)''.

Subsec. (b)(4)(C) to (E). Pub. L. 101–239, § 6105(a), added subpar. (C) and redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsecs. (c) to (e). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, §§ 202(b)(4), 203(c)(1)(F), 204(b)(2), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below.

Subsec. (f). Pub. L. 101–239, § 6102(f)(1), added subsec. (f).

Subsec. (g). Pub. L. 101–239, § 6116(b)(2), added subsec. (g).

1988—Pub. L. 100–360, § 411(g)(1)(A), inserted ''items and'' in section catchline.

Subsec. (a)(1)(C). Pub. L. 100–360, § 411(g)(1)(B)(i), inserted ''or under part A to a home health agency'' before period at end.

Subsec. (a)(2)(A). Pub. L. 100–360, § 411(g)(1)(B)(iii), struck out ''rental'' before ''payments'' in concluding provisions.

Subsec. (a)(2)(B)(i). Pub. L. 100–360, § 411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowed''.

Subsec. (a)(3)(A). Pub. L. 100–360, § 411(g)(1)(B)(iv), struck out the extra space appearing in text of original act after ''ventilators''.

Subsec. (a)(3)(B)(i). Pub. L. 100–360, § 411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowable''.

Subsec. (a)(4). Pub. L. 100–360, § 411(g)(1) (B)(v)–(vii), inserted '', and for that reason cannot be grouped with similar items for purposes of payment under this subchapter,'' after ''individual patient'', inserted cl. (A) and (B) designations, and in cl. (B), substituted ''servicing'' for ''service'' in two places.

Subsec. (a)(7)(A)(ii). Pub. L. 100–360, § 411(g)(1) (B)(vii), inserted ''maintenance and'' before ''servicing''.

Subsec. (a)(7)(A)(iii). Pub. L. 100–360, § 411(g)(1) (B)(vii), (viii), substituted ''maintenance and servicing'' for ''service and maintenance'', and in subcl. (I) substituted ''fee or fees established by the Secretary'' for ''fee established by the carrier''.

Subsec. (a)(7)(B)(i). Pub. L. 100–360, § 411(a)(3)(A), (C)(ii), provided that subsec. (a)(7)(B)(i) of this section, as inserted by section 4062(b) of Pub. L. 100–203, is deemed to have a reference to ''1987'' immediately after ''December''.

Subsec. (a)(8)(A)(i)(I). Pub. L. 100–360, § 411(g)(1) (B)(iii), substituted ''reasonable'' for ''allowable''.

Subsec. (a)(8)(B). Pub. L. 100–360, § 411(g)(1)(B)(xi), as amended Pub. L. 100–485, § 608(d)(22)(A)(i), substituted ''(as defined by the Secretary)'' for ''(as defined in section 1395ww(d)(2)(D) of this title)'', and in cl. (i) struck out the comma after ''1991''.

Subsec. (a)(9)(A)(ii)(I). Pub. L. 100–360, § 411(g)(1) (B)(ix), substituted ''6-month'' for ''12-month''.

Subsec. (a)(9)(A)(ii)(II). Pub. L. 100–360, § 411(g)(1) (B)(x), substituted '', 1991, and 1992'' for ''and to 1991''.

Subsec. (a)(9)(B). Pub. L. 100–360, § 411(g)(1)(B)(xi), as amended by Pub. L. 100–485, § 608(d)(22)(A)(i), substituted ''(as defined by the Secretary)'' for ''(as defined in section 1395ww(d)(2)(D) of this title)'', and in cl. (i) struck out the comma after ''1991''.

Subsec. (a)(9)(C)(i). Pub. L. 100–360, § 411(g)(1) (B)(xii), substituted ''subparagraph (A)(ii)'' for ''subparagraph (A)(ii)(I)''.

Subsec. (a)(10)(B). Pub. L. 100–360, § 411(g)(1) (B)(xiii), inserted before period at end ''and payments under this subsection as such provisions apply to physicians' services and physicians and a reasonable charge under section 1395u(b) of this title''.

Subsec. (a)(11)(A). Pub. L. 100–360, § 411(g)(1) (B)(vii), (xiv), inserted ''maintenance and'' before ''servicing'' and substituted ''section 1395u(j)(2) of this title'' for ''subsection (j)(2) of this section''.

Subsec. (a)(12). Pub. L. 100–360, § 411(g)(1)(B)(xv), as amended by Pub. L. 100–485, § 608(d)(22)(A)(ii), substituted ''one or more entire regions defined for purposes of paragraphs (8)(B) and (9)(B)'' for ''each region (as defined in section 1395ww(d)(2)(D) of this title)''.

Subsec. (a)(14). Pub. L. 100–360, § 411(g)(1)(B)(xvi), struck out par. (14) which read as follows: ''In this subsection, any reference to the term 'carrier' includes a reference, with respect to durable medical equipment furnished by a home health agency as part of home health services, to a fiscal intermediary.''

Subsec. (b). Pub. L. 100–360, § 411(a)(3)(A), (B)(ii), (f)(8)(B)(ii), amended Pub. L. 100–203, § 4049(a)(2), see 1987 Amendment note below.

Subsec. (b)(1)(B). Pub. L. 100–360, § 204(b)(1), inserted ''and subject to subsection (e)(1)(A) of this section'' after ''conversion factors''.

Subsec. (b)(4)(C). Pub. L. 100–360, § 411(f)(8)(D)(ii), as added by Pub. L. 100–485, § 608(d)(21)(C), substituted ''For radiologist'' for ''Radiologist'' and ''1395u(i)(3) of this title'' for ''1395u(b)(4)(E)(ii) of this title''.

Subsec. (b)(4)(D), (5). Pub. L. 100–360, § 411(f)(8)(D)(i), inserted ''and suppliers'' after ''physicians'' in heading.

Subsec. (b)(5)(C). Pub. L. 100–360, § 411(f)(8)(D)(iii), (iv), formerly (ii), (iii), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''bills'' for ''imposes a charge'' and inserted ''in the same manner as such sanctions may apply to a physician'' before period at end.

Subsec. (b)(6). Pub. L. 100–360, § 411(f)(8)(D)(v), formerly (iv), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''and section 1395*l*(a)(1)(J) of this title'' for '', section 1395*l*(a)(1)(I) of this title, and section 1395u(h)(1)(B) of this title''.

Pub. L. 100–360, § 411(f)(8)(A), substituted ''radiology'' for ''radiologic''.

Subsec. (b)(6)(B). Pub. L. 100–360, § 411(f)(8)(D)(vi), formerly (v), as redesignated by Pub. L. 100–485, § 608(d)(21)(C), substituted ''the total amount of charges'' for ''billings''.

Pub. L. 100–360, § 411(f)(8)(A), substituted ''radiology'' for ''radiologic''.

Subsec. (c). Pub. L. 100–360, § 202(b)(4), added subsec. (c) relating to payment for covered outpatient drugs.

Subsec. (d). Pub. L. 100–360, § 203(c)(1)(F), added subsec. (d) relating to home intravenous drug therapy services.

Subsec. (e). Pub. L. 100–360, § 204(b)(2), added subsec. (e) relating to payments and standards for screening mammography.

1987—Subsec. (b). Pub. L. 100–203, § 4049(a)(2), as amended by Pub. L. 100–360, § 411(a)(3)(A), (B)(ii), (f)(8)(B)(ii), added subsec. (b).

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by section 5012(b) of Pub. L. 114–255 applicable to items and services furnished on or after Jan. 1, 2021, see section 5012(d) of Pub. L. 114–255, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–113 applicable to items furnished on or after Jan. 1, 2017, see section 504(d) of Pub. L. 114–113, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3128(b), Mar. 23, 2010, 124 Stat. 426, provided that: ''The amendments made by subsection (a) [amending this section] shall take effect

as if included in the enactment of section 405(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2266).''

Pub. L. 111–148, title III, §3136(c), Mar. 23, 2010, 124 Stat. 438, provided that:

''(1) IN GENERAL.—Subject to paragraph (2), the amendments made by subsection (a) [amending this section] shall take effect on January 1, 2011, and shall apply to power-driven wheelchairs furnished on or after such date.

''(2) APPLICATION TO COMPETITIVE BIDDING.—The amendments made by subsection (a) shall not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) prior to January 1, 2011, pursuant to the implementation of subsection (a)(1)(B)(i)(I) of such section 1847.''

Amendment by section 6405(a) of Pub. L. 111–148 applicable to written orders and certifications made on or after July 1, 2010, see section 6405(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 125(b)(5) of Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110–275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1395bb of this title.

Pub. L. 110–275, title I, §144(b)(2), July 15, 2008, 122 Stat. 2547, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 2009.''

Pub. L. 110–275, title I, §146(b)(2)(B), July 15, 2008, 122 Stat. 2548, provided that: ''The amendment made by subparagraph (A) [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [July 15, 2008].''

Pub. L. 110–275, title I, §148(b), July 15, 2008, 122 Stat. 2549, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2009.''

Pub. L. 110–275, title I, §149(c), July 15, 2008, 122 Stat. 2549, provided that: ''The amendments made by this section [amending this section and section 1395yy of this title] shall apply to services furnished on or after January 1, 2009.''

Pub. L. 110–275, title I, §154(e), July 15, 2008, 122 Stat. 2568, provided that: ''The amendments made by this section [amending this section, sections 1395u and 1395w–3 of this title, and provisions set out as notes under section 1395w–3 of this title] shall take effect as of June 30, 2008.''

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–171, title V, §5101(a)(2), Feb. 8, 2006, 120 Stat. 38, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to items furnished for which the first rental month occurs on or after January 1, 2006.''

Pub. L. 109–171, title V, §5101(b)(2), Feb. 8, 2006, 120 Stat. 39, provided that:

''(A) IN GENERAL.—The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 2006.

''(B) APPLICATION TO CERTAIN INDIVIDUALS.—In the case of an individual receiving oxygen equipment on December 31, 2005, for which payment is made under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)), the 36-month period described in paragraph (5)(F)(i) of such section, as added by paragraph (1), shall begin on January 1, 2006.''

Amendment by section 5113(b) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2007, see section 5113(c) of Pub. L. 109–171, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 405(a)(1) of Pub. L. 108–173 applicable to payments for services furnished during cost reporting periods beginning on or after Jan. 1, 2004, see section 405(a)(2) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Pub. L. 108–173, title IV, §405(b)(2), Dec. 8, 2003, 117 Stat. 2266, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply with respect to costs incurred for services furnished on or after January 1, 2005.''

Pub. L. 108–173, title IV, §405(d)(2), Dec. 8, 2003, 117 Stat. 2267, provided that:

''(A) IN GENERAL.—Except as provided in subparagraph (B), the amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 2004.

''(B) RULE OF APPLICATION.—In the case of a critical access hospital that made an election under section 1834(g)(2) of the Social Security Act (42 U.S.C. 1395m(g)(2)) before November 1, 2003, the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2001.''

Pub. L. 108–173, title IV, §415(c), Dec. 8, 2003, 117 Stat. 2282, provided that: ''The amendments made by this subsection [probably should be ''this section'', amending this section and section 1395x of this title] shall apply to services furnished on or after January 1, 2005.''

Amendment by section 627(b)(1) of Pub. L. 108–173 applicable to items furnished on or after Jan. 1, 2005, see section 627(c) of Pub. L. 108–173, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, §1(a)(6) [title I, §103(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–469, provided that: ''The amendments made by this section [amending this section and section 1395x of this title] shall apply to colorectal cancer screening services provided on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title I, §104(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–470, provided that: ''The amendments made by subsections (a) and (b) [amending this section and section 1395w–4 of this title] shall apply with respect to screening mammographies furnished on or after January 1, 2002.''

Amendment by section 1(a)(6) [title II, §201(a)] of Pub. L. 106–554 applicable to services furnished on or after Nov. 29, 1999, see section 1(a)(6) [title II, §201(c)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title II, §202(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: ''The amendment made by subsection (a) [amending this section] shall apply with respect to items and services furnished on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title II, §204(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–482, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 2001.''

Amendment by section 1(a)(6) [title II, §205(a)] of Pub. L. 106–554 applicable to services furnished on or after Dec. 21, 2000, see section 1(a)(6) [title II, §205(c)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title II, §221(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2001. In applying such amendment to services furnished on or after such date and before January 1, 2002, the amount of the rate increase provided under such amendment shall be equal to $1.25 per mile.''

Amendment by section 1(a)(6) [title II, §223(b)] of Pub. L. 106–554 effective for services furnished on or after Oct. 1, 2001, see section 1(a)(6) [title II, §223(e)] of Pub. L. 106–554, set out as a note under section 1395*l* of this title.

Pub. L. 106–554, §1(a)(6) [title IV, §423(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after July 1, 2001.''

Pub. L. 106–554, §1(a)(6) [title IV, §428(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to items replaced on or after April 1, 2001.''

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(6) [title II, §201(e)(2)] of Pub. L. 106–113 effective as if included in enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see §1000(a)(6) [title II, §201(m)] of Pub. L. 106–113, set out as a note under section 1395*l* of this title.

Amendment by section 1000(a)(6) [title III, §321(k)(3)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §403(d)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–371, as amended by Pub. L. 106–554, §1(a)(6) [title II, §201(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: ''Paragraphs (1) through (3) of section 1834(g) of the Social Security Act [42 U.S.C. 1395m(g)(1)–(3)] (as amended by paragraph (1)) apply for cost reporting periods beginning on or after October 1, 2000.''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4101(a), (c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4101(d) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4104(b)(1) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Pub. L. 105–33, title IV, §4105(d), Aug. 5, 1997, 111 Stat. 367, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 1395w–4 and 1395x of this title] shall apply to items and services furnished on or after July 1, 1998.

''(2) TESTING STRIPS.—The amendment made by subsection (b)(2) [amending this section] shall apply with respect to blood glucose testing strips furnished on or after January 1, 1998.''

Amendment by section 4201(c)(5) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Pub. L. 105–33, title IV, §4312(f)(1), Aug. 5, 1997, 111 Stat. 387, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to suppliers of durable medical equipment with respect to such equipment furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4312(f)(3), Aug. 5, 1997, 111 Stat. 388, provided that: ''The amendments made by subsections (c) through (e) [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and may be applied with respect to items and services furnished on or after January 1, 1998.''

Pub. L. 105–33, title IV, §4316(c), Aug. 5, 1997, 111 Stat. 392, provided that: ''The amendments made by this section [amending this section and section 1395u of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997].''

Amendment by section 4531(b)(2) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 2000, see section 4531(b)(3) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Amendment by section 4541(a)(2) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, including portions of cost reporting periods occurring on or after such date, except that subsec. (k) of this section inapplicable to services described in section 1395*l*(a)(8)(B) of this title that are furnished during 1998, see section 4541(e) of Pub. L. 105–33, set out as a note under section 1395*l* of this title.

Pub. L. 105–33, title IV, §4551(c)(2), Aug. 5, 1997, 111 Stat. 459, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to purchases or rentals after the effective date of any regulations issued pursuant to such amendment.''

Pub. L. 105–33, title IV, §4552(e), Aug. 5, 1997, 111 Stat. 459, provided that:

''(1) OXYGEN.—The amendments made by subsection (a) [amending this section] shall apply to items furnished on and after January 1, 1998.

''(2) OTHER PROVISIONS.—The amendments made by this section other than subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Aug. 5, 1997].''

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–432, title I, §126(i), Oct. 31, 1994, 108 Stat. 4416, provided that: ''Except as provided in subsection (h) [amending section 1395u of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as a note under section 1395w–4 of this title], the amendments made by this section and the provisions of this section [amending this section and sections 1395u, 1395w–1, and 1395w–4 of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as notes under this section and sections 1395u and 1395w–4 of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].''

Pub. L. 103–432, title I, §131(a)(2), Oct. 31, 1994, 108 Stat. 4419, provided that the amendment made by that section is effective 60 days after Oct. 31, 1994.

Pub. L. 103–432, title I, §132(c), Oct. 31, 1994, 108 Stat. 4421, provided that: ''The amendments made by subsections (a) and (b) [amending this section] shall apply to items furnished after the expiration of the 60-day period that begins on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §133(c), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendments made by this section [amending this section and sections 1395m and 1395pp of this title] shall apply to items or services furnished on or after January 1, 1995.''

Pub. L. 103–432, title I, §134(a)(2), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(a)(2), Oct. 31, 1994, 108 Stat. 4422, provided that: ''The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(b)(1), Oct. 31, 1994, 108 Stat. 4422, provided that the amendment made by that section is effective Oct. 31, 1994.

Pub. L. 103–432, title I, §135(b)(3), Oct. 31, 1994, 108 Stat. 4423, provided that the amendment made by that section is effective Oct. 31, 1994.

Pub. L. 103–432, title I, §135(d)(2), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994].''

Pub. L. 103–432, title I, §135(e)(8), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendments made by this subsection [amending this section and provisions set out as notes under this section and section 1395cc of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].''

Pub. L. 103–432, title I, §145(d), Oct. 31, 1994, 108 Stat. 4428, provided that: ''The amendments made by this section [amending this section and sections 1395x to 1395bb of this title] shall apply to mammography furnished by a facility on and after the first date that the certificate requirements of section 354(b) of the Public Health Service Act [section 263b(b) of this title] apply to such mammography conducted by such facility.''

Amendment by section 156(a)(2)(C) of Pub. L. 103–432 applicable to services provided on or after Oct. 31, 1994,

see section 156(a)(3) of Pub. L. 103–432, set out as a note under section 1320c–3 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, § 13542(b), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this section [amending this section] shall apply to items furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, § 13543(c), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this section [amending this section] shall apply to items furnished on or after January 1, 1994.''

Pub. L. 103–66, title XIII, § 13544(a)(3), Aug. 10, 1993, 107 Stat. 589, provided that: ''The amendments made by this subsection [amending this section] shall apply to items furnished on or after January 1, 1994.''

Amendment by section 13544(b)(1) of Pub. L. 103–66 applicable to items furnished on or after Jan. 1, 1994, see section 13544(b)(3) of Pub. L. 103–66, set out as a note under section 1395*l* of this title.

Pub. L. 103–66, title XIII, § 13545(b), Aug. 10, 1993, 107 Stat. 590, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to items furnished on or after January 1, 1994.''

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, § 4102(i), Nov. 5, 1990, 104 Stat. 1388–58, provided that:

''(1) Except as otherwise provided, the amendments made by this section [amending this section, section 1395w–4 of this title, and provisions set out as a note below] shall apply to services furnished on or after January 1, 1991.

''(2) The amendment made by subsection (f) [amending this section] shall be effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].''

Amendment by section 4104(a) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4104(d) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

Pub. L. 101–508, title IV, § 4152(a)(3), Nov. 5, 1990, 104 Stat. 1388–74, as amended by Pub. L. 103–432, title I, § 135(e)(1), Oct. 31, 1994, 108 Stat. 4424, provided that: ''The amendments made by this subsection [amending this section and section 1395x of this title] shall apply to items furnished on or after January 1, 1991.''

Pub. L. 101–508, title IV, § 4152(c)(4)(B)(ii), Nov. 5, 1990, 104 Stat. 1388–79, provided that: ''The amendment made by clause (i) [amending this section] shall apply to items furnished on or after January 1, 1992, unless the Secretary develops specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1834(a)(4) of the Social Security Act [subsec. (a)(4) of this section] (in which case the amendment made by such clause shall not become effective).'' [Criteria established by Secretary Nov. 1, 1991, see 56 F.R. 65995, Dec. 20, 1991, 42 CFR § 414.224.]

Pub. L. 101–508, title IV, § 4152(f)(2), Nov. 5, 1990, 104 Stat. 1388–80, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to forms and documents distributed on or after January 1, 1991.''

Pub. L. 101–508, title IV, § 4152(g)(2), Nov. 5, 1990, 104 Stat. 1388–80, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to patients who first receive home oxygen therapy services on or after January 1, 1991.''

Pub. L. 101–508, title IV, § 4152(i), Nov. 5, 1990, 104 Stat. 1388–81, provided that: ''Except as otherwise provided, the amendments made by this section [amending this section, section 1395x of this title, and provisions set out as a note under section 1395f of this title] shall apply to items furnished on or after January 1, 1991.''

Amendment by section 4153(a)(1), (2)(D) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(a)(3) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4163(b) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6102(f)(1) of Pub. L. 101–239 applicable to services furnished on or after Jan. 1, 1991, see section 6102(f)(3) of Pub. L. 101–239, set out as a note under section 1395*l* of this title.

Pub. L. 101–239, title VI, § 6112(e)(4), Dec. 19, 1989, 103 Stat. 2216, provided that: ''The amendments made by this subsection [amending this section and sections 1395x and 1395cc of this title] shall apply with respect to items furnished on or after January 1, 1990.''

Amendment by section 201(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

Pub. L. 101–234, title III, § 301(b)(1), (c)(1), Dec. 13, 1989, 103 Stat. 1985, provided that the amendments made by that section are effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 202(b)(4) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100–360, set out as a note under section 1395u of this title.

Amendment by section 203(c)(1)(F) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Pub. L. 100–360, title II, § 204(e), July 1, 1988, 102 Stat. 729, which provided that the amendments made by section 204 of Pub. L. 100–360 [amending this section and sections 1395*l*, 1395x to 1395z, 1395aa, 1395bb, 1396a, and 1396n of this title] applied to screening mammography performed on or after January 1, 1990, and that subsec. (e)(5) of this section only applied until such time as the Secretary of Health and Human Services implemented the physician fee schedules based on relative value scale developed under section 1395w–1(e) of this title, was repealed by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(a)(3)(A), (B)(ii), (C)(ii), (f)(8)(A), (B)(ii), (D), (g)(1)(A) and (B) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–203, title IV, § 4049(b)(2), Dec. 22, 1987, 101 Stat. 1330–92, as amended by Pub. L. 101–239, title VI, § 6102(e)(6)(B), Dec. 19, 1989, 103 Stat. 2188; Pub. L. 101–508, title IV, § 4118(h)(2), Nov. 5, 1990, 104 Stat. 1388–70, provided that: ''The amendments made by this section [amending this section and section 1395*l* of this title] shall apply to services performed on or after April 1, 1989.''

[Pub. L. 101–508, title IV, § 4118(h), Nov. 5, 1990, 104 Stat. 1388–70, provided that the amendment by that section to section 4049(b)(2) of Pub. L. 100–203, set out above, is effective as if included in enactment of Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.]

EFFECTIVE DATE

Subsection (a) of this section applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, set out as an Effective

Date of 1987 Amendment note under section 1395f of this title.

REGULATIONS

Pub. L. 106–554, §1(a)(6) [title IV, §427(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–521, provided that: ''Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall promulgate revised regulations to carry out the amendment made by subsection (a) [amending this section] using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.''

CONSTRUCTION OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3109(c), Mar. 23, 2010, 124 Stat. 420, provided that: ''Nothing in the provisions of or amendments made by this section [amending this section and enacting provisions set out as a note under this section] shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).''

Pub. L. 111–148, title IV, §4105(b), Mar. 23, 2010, 124 Stat. 559, provided that: ''Nothing in the amendment made by paragraph (1) [probably means subsec. (a), amending this section] shall be construed to affect the coverage of diagnostic or treatment services under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].''

CONSTRUCTION OF 2009 AMENDMENT

Pub. L. 111–72, §1(b), Oct. 13, 2009, 123 Stat. 2059, provided that: ''Nothing in subsection (a) [amending this section] shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).''

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–275, title I, §154(b)(1)(B), July 15, 2008, 122 Stat. 2565, provided that: ''Section 1834(a)(20)(F)(ii) of the Social Security Act [42 U.S.C. 1395m(a)(20)(F)(ii)], as added by subparagraph (A), shall not be construed as preventing the Secretary of Health and Human Services from implementing the first round of competition under section 1847 of such Act [42 U.S.C. 1395w–3] on a timely basis.''

TRANSFER OF FUNCTIONS

Physician Payment Review Commission (PPRC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 4022(c)(2), (3) of Pub. L. 105–33, set out as a note under section 1395b–6 of this title. Section 4022(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by PPRC, and that, for that purpose, any reference in law to PPRC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

IMPLEMENTATION OF 2018 AMENDMENT

Pub. L. 115–271, title II, §2001(b), Oct. 24, 2018, 132 Stat. 3925, provided that: ''The Secretary of Health and Human Services (in this section [amending this section] referred to as the 'Secretary') may implement the amendments made by this section by interim final rule.''

IMPLEMENTATION OF 2015 AMENDMENT

Pub. L. 114–10, title V, §504(b), Apr. 16, 2015, 129 Stat. 166, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.''

IMPLEMENTATION OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3109(b), Mar. 23, 2010, 124 Stat. 419, provided that: ''Notwithstanding any other provision of law, the Secretary may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.''

DEMONSTRATION PROJECT TO ASSESS THE APPROPRIATE USE OF IMAGING SERVICES

Pub. L. 110–275, title I, §135(b), July 15, 2008, 122 Stat. 2535, provided that:

''(1) CONDUCT OF DEMONSTRATION PROJECT.—

''(A) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a demonstration project using the models described in paragraph (2)(E) to collect data regarding physician compliance with appropriateness criteria selected under paragraph (2)(D) in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries.

''(B) ADVANCED DIAGNOSTIC IMAGING SERVICES.—In this subsection, the term 'advanced diagnostic imaging services' has the meaning given such term in section 1834(e)(1)(B) of the Social Security Act [42 U.S.C. 1395m(e)(1)(B)], as added by subsection (a).

''(C) AUTHORITY TO FOCUS DEMONSTRATION PROJECT.—The Secretary may focus the demonstration project with respect to certain advanced diagnostic imaging services, such as services that account for a large amount of expenditures under the Medicare program, services that have recently experienced a high rate of growth, or services for which appropriateness criteria exists.

''(2) IMPLEMENTATION AND DESIGN OF DEMONSTRATION PROJECT.—

''(A) IMPLEMENTATION AND DURATION.—

''(i) IMPLEMENTATION.—The Secretary shall implement the demonstration project under this subsection not later than January 1, 2010.

''(ii) DURATION.—The Secretary shall conduct the demonstration project under this subsection for a 2-year period.

''(B) APPLICATION AND SELECTION OF PARTICIPATING PHYSICIANS.—

''(i) APPLICATION.—Each physician that desires to participate in the demonstration project under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

''(ii) SELECTION.—The Secretary shall select physicians to participate in the demonstration project under this subsection from among physicians submitting applications under clause (i). The Secretary shall ensure that the physicians selected—

''(I) represent a wide range of geographic areas, demographic characteristics (such as urban, rural, and suburban), and practice settings (such as private and academic practices); and

''(II) have the capability to submit data to the Secretary (or an entity under a subcontract with the Secretary) in an electronic format in accordance with standards established by the Secretary.

''(C) ADMINISTRATIVE COSTS AND INCENTIVES.—The Secretary shall—

''(i) reimburse physicians for reasonable administrative costs incurred in participating in the demonstration project under this subsection; and

''(ii) provide reasonable incentives to physicians to encourage participation in the demonstration project under this subsection.

''(D) USE OF APPROPRIATENESS CRITERIA.—

''(i) IN GENERAL.—The Secretary, in consultation with medical specialty societies and other stakeholders, shall select criteria with respect to the clinical appropriateness of advanced diagnostic imaging services for use in the demonstration project under this subsection.

''(ii) CRITERIA SELECTED.—Any criteria selected under clause (i) shall—

''(I) be developed or endorsed by a medical specialty society; and

''(II) be developed in adherence to appropriateness principles developed by a consensus organization, such as the AQA alliance.

''(E) MODELS FOR COLLECTING DATA REGARDING PHYSICIAN COMPLIANCE WITH SELECTED CRITERIA.—Subject to subparagraph (H), in carrying out the demonstration project under this subsection, the Secretary shall use each of the following models for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D):

''(i) A model described in subparagraph (F).

''(ii) A model described in subparagraph (G).

''(iii) Any other model that the Secretary determines to be useful in evaluating the use of appropriateness criteria for advanced diagnostic imaging services.

''(F) POINT OF SERVICE MODEL DESCRIBED.—A model described in this subparagraph is a model that—

''(i) uses an electronic or paper intake form that—

''(I) contains a certification by the physician furnishing the imaging service that the data on the intake form was confirmed with the Medicare beneficiary before the service was furnished;

''(II) contains standardized data elements for diagnosis, service ordered, service furnished, and such other information determined by the Secretary, in consultation with medical specialty societies and other stakeholders, to be germane to evaluating the effectiveness of the use of appropriateness criteria selected under subparagraph (D); and

''(III) is accessible to physicians participating in the demonstration project under this subsection in a format that allows for the electronic submission of such form; and

''(ii) provides for feedback reports in accordance with paragraph (3)(B).

''(G) POINT OF ORDER MODEL DESCRIBED.—A model described in this subparagraph is a model that—

''(i) uses a computerized order-entry system that requires the transmittal of relevant supporting information at the time of referral for advanced diagnostic imaging services and provides automated decision-support feedback to the referring physician regarding the appropriateness of furnishing such imaging services; and

''(ii) provides for feedback reports in accordance with paragraph (3)(B).

''(H) LIMITATION.—In no case may the Secretary use prior authorization—

''(i) as a model for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D) under the demonstration project under this subsection; or

''(ii) under any model used for collecting such data under the demonstration project.

''(I) REQUIRED CONTRACTS AND PERFORMANCE STANDARDS FOR CERTAIN ENTITIES.—

''(i) IN GENERAL.—The Secretary shall enter into contracts with entities to carry out the model described in subparagraph (G).

''(ii) PERFORMANCE STANDARDS.—The Secretary shall establish and enforce performance standards for such entities under the contracts entered into under clause (i), including performance standards with respect to—

''(I) the satisfaction of Medicare beneficiaries who are furnished advanced diagnostic imaging services by a physician participating in the demonstration project;

''(II) the satisfaction of physicians participating in the demonstration project;

''(III) if applicable, timelines for the provision of feedback reports under paragraph (3)(B); and

''(IV) any other areas determined appropriate by the Secretary.

''(3) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC IMAGING SERVICES AND FEEDBACK REPORTS.—

''(A) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC IMAGING SERVICES.—The Secretary shall consult with medical specialty societies and other stakeholders to develop mechanisms for comparing the utilization of advanced diagnostic imaging services by physicians participating in the demonstration project under this subsection against—

''(i) the appropriateness criteria selected under paragraph (2)(D); and

''(ii) to the extent feasible, the utilization of such services by physicians not participating in the demonstration project.

''(B) FEEDBACK REPORTS.—The Secretary shall, in consultation with medical specialty societies and other stakeholders, develop mechanisms to provide feedback reports to physicians participating in the demonstration project under this subsection. Such feedback reports shall include—

''(i) a profile of the rate of compliance by the physician with appropriateness criteria selected under paragraph (2)(D), including a comparison of—

''(I) the rate of compliance by the physician with such criteria; and

''(II) the rate of compliance by the physician's peers (as defined by the Secretary) with such criteria; and

''(ii) to the extent feasible, a comparison of—

''(I) the rate of utilization of advanced diagnostic imaging services by the physician; and

''(II) the rate of utilization of such services by the physician's peers (as defined by the Secretary) who are not participating in the demonstration project.

''(4) CONDUCT OF DEMONSTRATION PROJECT AND WAIVER.—

''(A) CONDUCT OF DEMONSTRATION PROJECT.—Chapter 35 of title 44, United States Code, shall not apply to the conduct of the demonstration project under this subsection.

''(B) WAIVER.—The Secretary may waive such provisions of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary to carry out the demonstration project under this subsection.

''(5) EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall evaluate the demonstration project under this subsection to—

''(i) assess the timeliness and efficacy of the demonstration project;

''(ii) assess the performance of entities under a contract entered into under paragraph (2)(I)(i);

''(iii) analyze data—

''(I) on the rates of appropriate, uncertain, and inappropriate advanced diagnostic imaging services furnished by physicians participating in the demonstration project;

''(II) on patterns and trends in the appropriateness and inappropriateness of such services furnished by such physicians;

''(III) on patterns and trends in national and regional variations of care with respect to the furnishing of such services; and

''(IV) on the correlation between the appropriateness of the services furnished and image results; and

''(iv) address—

''(I) the thresholds used under the demonstration project to identify acceptable and outlier levels of performance with respect to the appropriateness of advanced diagnostic imaging services furnished;

''(II) whether prospective use of appropriateness criteria could have an effect on the volume of such services furnished;

''(III) whether expansion of the use of appropriateness criteria with respect to such services to a broader population of Medicare beneficiaries would be advisable;

''(IV) whether, under such an expansion, physicians who demonstrate consistent compliance

with such appropriateness criteria should be exempted from certain requirements;

''(V) the use of incident-specific versus practice-specific outlier information in formulating future recommendations with respect to the use of appropriateness criteria for such services under the Medicare program; and

''(VI) the potential for using methods (including financial incentives), in addition to those used under the models under the demonstration project, to ensure compliance with such criteria.

''(B) REPORT.—Not later than 1 year after the completion of the demonstration project under this subsection, the Secretary shall submit to Congress a report containing the results of the evaluation of the demonstration project conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

''(6) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of $10,000,000, for carrying out the demonstration project under this subsection (including costs associated with administering the demonstration project, reimbursing physicians for administrative costs and providing incentives to encourage participation under paragraph (2)(C), entering into contracts under paragraph (2)(I), and evaluating the demonstration project under paragraph (5)).''

AIR AMBULANCE PAYMENT IMPROVEMENTS

Pub. L. 110–275, title I, §146(b)(1), July 15, 2008, 122 Stat. 2548, as amended by Pub. L. 111–148, title III, §3105(b), title X, §10311(b), Mar. 23, 2010, 124 Stat. 417, 943; Pub. L. 111–309, title I, §106(b), Dec. 15, 2010, 124 Stat. 3287; Pub. L. 112–78, title III, §306(b), Dec. 23, 2011, 125 Stat. 1285; Pub. L. 112–96, title III, §3007(b), Feb. 22, 2012, 126 Stat. 190; Pub. L. 112–240, title VI, §604(b), Jan. 2, 2013, 126 Stat. 2348, provided that: ''Notwithstanding any other provision of law, for purposes of making payments under section 1834(*l*) of the Social Security Act (42 U.S.C. 1395m(*l*)) for air ambulance services furnished during the period beginning on July 1, 2008, and ending on June 30, 2013, any area that was designated as a rural area for purposes of making payments under such section for air ambulance services furnished on December 31, 2006, shall be treated as a rural area for purposes of making payments under such section for air ambulance services furnished during such period.''

EVALUATION OF CERTAIN CODE

Pub. L. 110–275, title I, §154(c)(3), July 15, 2008, 122 Stat. 2566, provided that: ''The Secretary of Health and Human Services shall evaluate the existing Health Care Common Procedure Coding System (HCPCS) codes for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such codes. In carrying out such evaluation, the Secretary shall use an existing process, administered by the Durable Medical Equipment Medicare Administrative Contractors, for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.''

GAO REPORT ON CLASS III MEDICAL DEVICES

Pub. L. 108–173, title III, §302(c)(1)(B), Dec. 8, 2003, 117 Stat. 2231, provided that: ''Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary [of Health and Human Services], a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C) [360c(a)(1)(C)]) furnished to medicare beneficiaries during 2007 and 2008.''

USE OF DATA

Pub. L. 108–173, title IV, §414(c)(2), Dec. 8, 2003, 117 Stat. 2280, provided that: ''In order to promptly implement section 1834(*l*)(12) of the Social Security Act [42 U.S.C. 1395m(*l*)(12)], as added by paragraph (1), the Secretary [of Health and Human Services] may use data furnished by the Comptroller General of the United States.''

IMPLEMENTATION OF 2003 AMENDMENT

Pub. L. 108–173, title IV, §414(e), Dec. 8, 2003, 117 Stat. 2280, provided that: ''The Secretary [of Health and Human Services] may implement the amendments made by this section [amending this section, section 1395x of this title, and provisions set out as a note under this section], and revise the conversion factor applicable under section 1834(*l*) of the Social Security Act (42 U.S.C. 1395m(*l*)) for purposes of implementing such amendments, on an interim final basis, or by program instruction.''

GAO REPORT ON COSTS AND ACCESS

Pub. L. 108–173, title IV, §414(f), Dec. 8, 2003, 117 Stat. 2280, which required the Comptroller General of the United States to submit to Congress initial and final reports on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule under section 1395m(*l*) of this title, was repealed by Pub. L. 111–68, div. A, title I, §1501(e)(1), Oct. 1, 2009, 123 Stat. 2041.

REPORT ON DEMONSTRATION PROJECT PERMITTING SKILLED NURSING FACILITIES TO BE ORIGINATING TELEHEALTH SITES; AUTHORITY TO IMPLEMENT

Pub. L. 108–173, title IV, §418, Dec. 8, 2003, 117 Stat. 2283, provided that:

''(a) EVALUATION.—The Secretary [of Health and Human Services], acting through the Administrator of the Health Resources and Services Administration in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a))[)] are treated as originating sites for telehealth services.

''(b) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall include recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, as is otherwise required by the Secretary.

''(c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar as the Secretary concludes in the report required under subsection (b) that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and that the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, the Secretary may deem a skilled nursing facility to be an originating site under paragraph (4)(C)(ii) of such section beginning on January 1, 2006.''

PAYMENT FOR NEW TECHNOLOGIES

Pub. L. 106–554, §1(a)(6) [title I, §104(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–470, as amended by Pub. L. 108–173,

title IX, § 900(e)(6)(H), Dec. 8, 2003, 117 Stat. 2374, provided that:

''(1) TESTS FURNISHED IN 2001.—

''(A) SCREENING.—For a screening mammography (as defined in section 1861(jj) of the Social Security Act (42 U.S.C. 1395x(jj))) furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology, payment for such screening mammography shall be made as follows:

''(i) In the case of a technology which directly takes a digital image (without involving film), in an amount equal to 150 percent of the amount of payment under section 1848 of such Act (42 U.S.C. 1395w–4) for a bilateral diagnostic mammography (under HCPCS code 76091) for such year.

''(ii) In the case of a technology which allows conversion of a standard film mammogram into a digital image and subsequently analyzes such resulting image with software to identify possible problem areas, in an amount equal to the limit that would otherwise be applied under section 1834(c)(3) of such Act (42 U.S.C. 1395m(c)(3)) for 2001, increased by $15.

''(B) BILATERAL DIAGNOSTIC MAMMOGRAPHY.—For a bilateral diagnostic mammography furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology described in subparagraph (A), payment for such mammography shall be the amount of payment provided for under such subparagraph.

''(C) ALLOCATION OF AMOUNTS.—The Secretary shall provide for an appropriate allocation of the amounts under subparagraphs (A) and (B) between the professional and technical components.

''(D) IMPLEMENTATION OF PROVISION.—The Secretary of Health and Human Services may implement the provisions of this paragraph by program memorandum or otherwise.

''(2) CONSIDERATION OF NEW HCPCS CODE FOR NEW TECHNOLOGIES AFTER 2001.—The Secretary shall determine, for such mammographies performed after 2001, whether the assignment of a new HCPCS code is appropriate for mammography that uses a new technology. If the Secretary determines that a new code is appropriate for such mammography, the Secretary shall provide for such new code for such tests furnished after 2001.

''(3) NEW TECHNOLOGY DESCRIBED.—For purposes of this subsection, a new technology with respect to a mammography is an advance in technology with respect to the test or equipment that results in the following:

''(A) A significant increase or decrease in the resources used in the test or in the manufacture of the equipment.

''(B) A significant improvement in the performance of the test or equipment.

''(C) A significant advance in medical technology that is expected to significantly improve the treatment of medicare beneficiaries.

''(4) HCPCS CODE DEFINED.—The term 'HCPCS code' means a code under the Health Care Common Procedure Coding System (HCPCS).''

MEDPAC STUDY AND REPORT ON MEDICARE COVERAGE OF CARDIAC AND PULMONARY REHABILITATION THERAPY SERVICES

Pub. L. 106–554, § 1(a)(6) [title I, § 127], Dec. 21, 2000, 114 Stat. 2763, 2763A–479, provided that:

''(a) STUDY.—

''(1) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study on coverage of cardiac and pulmonary rehabilitation therapy services under the medicare program under title XVIII of the Social Security Act [this subchapter].

''(2) FOCUS.—In conducting the study under paragraph (1), the Commission shall focus on the appropriate—

''(A) qualifying diagnoses required for coverage of cardiac and pulmonary rehabilitation therapy services;

''(B) level of physician direct involvement and supervision in furnishing such services; and

''(C) level of reimbursement for such services.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a) together with such recommendations for legislation and administrative action as the Commission determines appropriate.''

GAO STUDIES ON COSTS OF AMBULANCE SERVICES FURNISHED IN RURAL AREAS

Pub. L. 106–554, § 1(a)(6) [title II, § 221(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–486, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study on each of the matters described in paragraph (2).

''(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are the following:

''(A) The cost of efficiently providing ambulance services for trips originating in rural areas, with special emphasis on collection of cost data from rural providers.

''(B) The means by which rural areas with low population densities can be identified for the purpose of designating areas in which the cost of providing ambulance services would be expected to be higher than similar services provided in more heavily populated areas because of low usage. Such study shall also include an analysis of the additional costs of providing ambulance services in areas designated under the previous sentence.

''(3) REPORT.—Not later than June 30, 2002, the Comptroller General shall submit to Congress a report on the results of the studies conducted under paragraph (1) and shall include recommendations on steps that should be taken to assure access to ambulance services in rural areas.''

ADJUSTMENT IN RURAL RATES

Pub. L. 106–554, § 1(a)(6) [title II, § 221(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, as amended by Pub. L. 108–173, title IV, § 414(f)(1), formerly § 414(g)(1), Dec. 8, 2003, 117 Stat. 2281, as renumbered by Pub. L. 111–68, div. A, title I, § 1501(e)(2), Oct. 1, 2009, 123 Stat. 2041, provided that: ''In providing for adjustments under subparagraph (D) of section 1834(*l*)(2) of the Social Security Act (42 U.S.C. 1395m(*l*)(2)) for years beginning with 2004, the Secretary of Health and Human Services shall take into consideration the recommendations contained in the report under subsection (b)(3) [set out above] and shall adjust the fee schedule payment rates under such section for ambulance services provided in low density rural areas based on the increased cost (if any) of providing such services in such areas.''

STUDY AND REPORT ON ADDITIONAL COVERAGE FOR TELEHEALTH SERVICES

Pub. L. 106–554, § 1(a)(6) [title II, § 223(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–489, provided that:

''(1) STUDY.—The Secretary of Health and Human Services shall conduct a study to identify—

''(A) settings and sites for the provision of telehealth services that are in addition to those permitted under section 1834(m) of the Social Security Act [42 U.S.C. 1395m(m)], as added by subsection (b);

''(B) practitioners that may be reimbursed under such section for furnishing telehealth services that are in addition to the practitioners that may be reimbursed for such services under such section; and

''(C) geographic areas in which telehealth services may be reimbursed that are in addition to the geographic areas where such services may be reimbursed under such section.

''(2) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation that the Secretary determines are appropriate.''

SPECIAL RULES FOR PAYMENTS FOR 2001

Pub. L. 106–554, § 1(a)(6) [title IV, § 423(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: ''Notwith-

standing the amendment made by paragraph (1) [amending this section], for purposes of making payments for ambulance services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], for services furnished during 2001, the 'percentage increase in the consumer price index' specified in section 1834(*l*)(3)(B) of such Act (42 U.S.C. 1395m(*l*)(3)(B))—

''(A) for services furnished on or after January 1, 2001, and before July 1, 2001, shall be the percentage increase for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

''(B) for services furnished on or after July 1, 2001, and before January 1, 2002, shall be equal to 4.7 percent.''

Pub. L. 106–554, §1(a)(6) [title IV, §425(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–519, provided that: ''Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for durable medical equipment under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)), other than for oxygen and oxygen equipment specified in paragraph (9) of such section, the payment basis recognized for 2001 under such section—

''(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000] (including the application of section 228(a)(1) of BBRA [Pub. L. 106–113, §1000(a)(6) [title II, §228(a)(1)], set out as a note below]); and

''(2) for items furnished on or after July 1, 2001, and before January 1, 2002, shall be the payment basis that is determined under such section 1834(a) if such section 228(a)(1) did not apply and taking into account the amendment made by subsection (a), increased by a transitional percentage allowance equal to 3.28 percent (to account for the timing of implementation of the CPI update).''

Pub. L. 106–554, §1(a)(6) [title IV, §426(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–520, provided that: ''Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for prosthetic devices and orthotics and prosthetics (as defined in subparagraphs (B) and (C) of paragraph (4) of section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) under such section, the payment basis recognized for 2001 under paragraph (2) of such section—

''(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for 2001 as determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

''(2) for items furnished on or after July 1, 2001, and before January 1, 2002, shall be the payment basis that is determined under such section taking into account the amendments made by subsection (a), increased by a transitional percentage allowance equal to 2.6 percent (to account for the timing of implementation of the CPI update).''

Preemption of Rule

Pub. L. 106–554, §1(a)(6) [title IV, §428(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: ''The provisions of section 1834(h)(1)(G) [42 U.S.C. 1395m(h)(1)(G)] as added by subsection (a) shall supersede any rule that as of the date of the enactment of this Act [Dec. 21, 2000] may have applied a 5-year replacement rule with regard to prosthetic devices.''

GAO Study and Report on Costs of Emergency and Medical Transportation Services

Pub. L. 106–554, §1(a)(6) [title IV, §436], Dec. 21, 2000, 114 Stat. 2763, 2763A–527, provided that:

''(a) Study.—The Comptroller General of the United States shall conduct a study on the costs of providing emergency and medical transportation services across the range of acuity levels of conditions for which such transportation services are provided.

''(b) Report.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Comptroller General shall submit to Congress a report on the study conducted under subsection (a), together with recommendations for any changes in methodology or payment level necessary to fairly compensate suppliers of emergency and medical transportation services and to ensure the access of beneficiaries under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].''

Treatment of Temporary Payment Increases After Calendar Year 2001

Pub. L. 106–554, §1(a)(6) [title V, §547(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–553, provided that: ''The payment increase provided under the following sections shall not apply after calendar year 2001 and shall not be taken into account in calculating the payment amounts applicable for items and services furnished after such year:

''(1) Section 401(c)(2) [set out as a note under section 1395*l* of this title] (relating to covered OPD services).

''(2) Section 422(e)(2) [set out as a note under section 1395rr of this title] (relating to renal dialysis services paid for on a composite rate basis).

''(3) Section 423(a)(2)(B) [set out above] (relating to ambulance services).

''(4) Section 425(b)(2) [set out above] (relating to durable medical equipment).

''(5) Section 426(b)(2) [set out above] (relating to prosthetic devices and orthotics and prosthetics).''

Study of Delivery of Intravenous Immune Globulin (IVIG) Outside Hospitals and Physicians' Offices

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(n)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, required the Secretary of Health and Human Services to conduct a study of the extent to which intravenous immune globulin could be delivered and reimbursed under the medicare program outside of a hospital or physician's office and to submit a report on such study to Congress within 18 months after Nov. 29, 1999.

Temporary Increase in Payment Rates for Durable Medical Equipment and Oxygen

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §228], Nov. 29, 1999, 113 Stat. 1536, 1501A–356, provided that:

''(a) In General.—For purposes of payments under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) for covered items (as defined in paragraph (13) of that section) furnished during 2001 and 2002, the Secretary of Health and Human Services shall increase the payment amount in effect (but for this section) for such items for—

''(1) 2001 by 0.3 percent, and

''(2) 2002 by 0.6 percent.

''(b) Limiting Application to Specified Years.—The payment amount increase—

''(1) under subsection (a)(1) shall not apply after 2001 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year; and

''(2) under subsection (a)(2) shall not apply after 2002 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year.''

Demonstration of Coverage of Ambulance Services Under Medicare Through Contracts With Units of Local Government

Pub. L. 105–33, title IV, §4532, Aug. 5, 1997, 111 Stat. 453, as amended by Pub. L. 106–113, div. B, §1000(a)(6) [title II, §225], Nov. 29, 1999, 113 Stat. 1536, 1501A–353, provided that:

''(a) Demonstration Project Contracts with Local Governments.—The Secretary of Health and Human Services shall establish up to 3 demonstration projects

under which, at the request of a unit of local government, the Secretary enters into a contract with the unit of local government under which—

''(1) the unit of local government furnishes (or arranges for the furnishing of) ambulance services for which payment may be made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for individuals residing in the unit of local government who are enrolled under such part, except that the unit of local government may not enter into the contract unless the contract covers at least 80 percent of the individuals residing in the unit of local government who are enrolled under such part but not in a Medicare+Choice plan;

''(2) any individual or entity furnishing ambulance services under the contract meets the requirements otherwise applicable to individuals and entities furnishing such services under such part; and

''(3) for each month during which the contract is in effect, the Secretary makes a capitated payment to the unit of local government in accordance with subsection (b).

The projects may extend over a period of not to exceed 3 years each. Not later than July 1, 2000, the Secretary shall publish a request for proposals for such projects.

''(b) AMOUNT OF PAYMENT.—

''(1) IN GENERAL.—The amount of the monthly payment made for months occurring during a calendar year to a unit of local government under a demonstration project contract under subsection (a) shall be equal to the product of—

''(A) the Secretary's estimate of the number of individuals covered under the contract for the month; and

''(B) 1/12 of the capitated payment rate for the year established under paragraph (2).

''(2) CAPITATED PAYMENT RATE DEFINED.—In this subsection, the term 'capitated payment rate' means, with respect to a demonstration project—

''(A) in its first year, a rate established for the project by the Secretary, using the most current available data, in a manner that ensures that aggregate payments under the project will not exceed the aggregate payment that would have been made for ambulance services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in the local area of government's jurisdiction; and

''(B) in a subsequent year, the capitated payment rate established for the previous year increased by an appropriate inflation adjustment factor.

''(c) OTHER TERMS OF CONTRACT.—The Secretary and the unit of local government may include in a contract under this section such other terms as the parties consider appropriate, including—

''(1) covering individuals residing in additional units of local government (under arrangements entered into between such units and the unit of local government involved);

''(2) permitting the unit of local government to transport individuals to non-hospital providers if such providers are able to furnish quality services at a lower cost than hospital providers; or

''(3) implementing such other innovations as the unit of local government may propose to improve the quality of ambulance services and control the costs of such services.

''(d) CONTRACT PAYMENTS IN LIEU OF OTHER BENEFITS.—Payments under a contract to a unit of local government under this section shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the services covered under the contract which are furnished to individuals who reside in the unit of local government.

''(e) REPORT ON EFFECTS OF CAPITATED CONTRACTS.—

''(1) STUDY.—The Secretary shall evaluate the demonstration projects conducted under this section. Such evaluation shall include an analysis of the quality and cost-effectiveness of ambulance services furnished under the projects.

''(2) REPORT.—Not later than January 1, 2000, the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary considers appropriate, including recommendations regarding modifications to the methodology used to determine the amount of payments made under such contracts and extending or expanding such projects.''

[References to Medicare+Choice deemed to refer to Medicare Advantage, see section 201(b) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.]

[Pub. L. 106–113, div. B, §1000(a)(6) [title II, §225], Nov. 29, 1999, 113 Stat. 1536, 1501A–353, provided that the amendment made by that section to section 4532 of Pub. L. 105–33, set out above, is effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33.]

PAYMENT FREEZE FOR PARENTERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND EQUIPMENT

Pub. L. 105–33, title IV, §4551(b), Aug. 5, 1997, 111 Stat. 458, provided that: ''In determining the amount of payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] with respect to parenteral and enteral nutrients, supplies, and equipment during each of the years 1998 through 2002, the charges determined to be reasonable with respect to such nutrients, supplies, and equipment may not exceed the charges determined to be reasonable with respect to such nutrients, supplies, and equipment during 1995.''

SERVICE STANDARDS FOR PROVIDERS OF OXYGEN AND OXYGEN EQUIPMENT

Pub. L. 105–33, title IV, §4552(c), Aug. 5, 1997, 111 Stat. 459, provided that: ''The Secretary shall as soon as practicable establish service standards for persons seeking payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for the providing of oxygen and oxygen equipment to beneficiaries within their homes.''

ACCESS TO HOME OXYGEN EQUIPMENT

Pub. L. 105–33, title IV, §4552(d), Aug. 5, 1997, 111 Stat. 459, provided that:

''(1) STUDY.—The Comptroller General of the United States shall study issues relating to access to home oxygen equipment and shall, within 18 months after the date of the enactment of this Act [Aug. 5, 1997], report to the Committees on Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate the results of the study, including recommendations (if any) for legislation.

''(2) PEER REVIEW EVALUATION.—The Secretary of Health and Human Services shall arrange for peer review [now ''quality improvement''] organizations established under section 1154 of the Social Security Act [42 U.S.C. 1320c–3] to evaluate access to, and quality of, home oxygen equipment.''

USE OF COVERED ITEMS BY DISABLED BENEFICIARIES

Pub. L. 103–432, title I, §131(b), Oct. 31, 1994, 108 Stat. 4419, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with representatives of suppliers of durable medical equipment under part B of the medicare program [42 U.S.C. 1395j et seq.] and individuals entitled to benefits under such program on the basis of disability, shall conduct a study of the effects of the methodology for determining payments for items of such equipment under such part on the ability of such individuals to obtain items of such equipment, including customized items.

''(2) REPORT.—Not later than one year after the date of the enactment of this Act [Oct. 31, 1994], the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary consid-

ers appropriate to assure that disabled medicare beneficiaries have access to items of durable medical equipment.''

CRITERIA FOR TREATMENT OF ITEMS AS PROSTHETIC DEVICES OR ORTHOTICS AND PROSTHETICS

Pub. L. 103–432, title I, §131(c), Oct. 31, 1994, 108 Stat. 4419, provided that not later than one year after Oct. 31, 1994, Secretary of Health and Human Services was to submit to Congress a report describing prosthetic devices or orthotics and prosthetics covered under this part that do not require individualized or custom fitting and adjustment to be used by a patient, including recommendations for appropriate methodology for determining amount of payment for such items.

ADJUSTMENT REQUIRED FOR CERTAIN ITEMS

Pub. L. 103–432, title I, §134(b), Oct. 31, 1994, 108 Stat. 4422, provided that:

''(1) IN GENERAL.—In accordance with section 1834(a)(10)(B) of the Social Security Act [42 U.S.C. 1395m(a)(10)(B)] (as amended by subsection (a)), the Secretary of Health and Human Services shall determine whether the payment amounts for the items described in paragraph (2) are not inherently reasonable, and shall adjust such amounts in accordance with such section if the amounts are not inherently reasonable.

''(2) ITEMS DESCRIBED.—The items referred to in paragraph (1) are decubitus care equipment, transcutaneous electrical nerve stimulators, and any other items considered appropriate by the Secretary.''

LIMITATION ON PREVAILING CHARGE FOR PHYSICIANS' RADIOLOGY SERVICES FURNISHED DURING 1991; EXCEPTIONS

Pub. L. 101–508, title IV, §4102(c), Nov. 5, 1990, 104 Stat. 1388–57, as amended by Pub. L. 103–432, title I, §126(b)(3), Oct. 31, 1994, 108 Stat. 4415, provided that:

''(1) IN GENERAL.—In applying part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.], the prevailing charge for physicians' services, furnished during 1991, which are radiology services may not exceed the fee schedule amount established under section 1834(b) of such Act [42 U.S.C. 1395m(b)] with respect to such services.

''(2) EXCEPTION.—Paragraph (1) shall not apply to nuclear medicine services.''

LIMITATION ON CARRIER ADJUSTMENTS FOR RADIOLOGIST SERVICES FURNISHED DURING 1991

Pub. L. 101–508, title IV, §4102(e), Nov. 5, 1990, 104 Stat. 1388–57, provided that: ''For radiologist services furnished during 1991 for which payment is made under section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)]—

''(1) a carrier may not make any adjustment, under section 1842(b)(3)(B) of such Act [42 U.S.C. 1395u(b)(3)(B)], in the payment amount for the service under section 1834(b) on the basis that the payment amount is higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier,

''(2) no payment adjustment may be made under section 1842(b)(8) of such Act, and

''(3) section 1842(b)(9) of such Act shall not apply.''

STUDY OF PAYMENTS FOR PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS

Pub. L. 101–508, title IV, §4153(c), Nov. 9, 1990, 104 Stat. 1388–84, as amended by Pub. L. 103–432, title I, §135(e)(6), Oct. 31, 1994, 108 Stat. 4424, directed Comptroller General to conduct a study of feasibility and desirability of establishing a separate fee schedule for use in determining the amount of payments for covered items under subsec. (h) of this section with respect to suppliers of prosthetic devices, orthotics, and prosthetics who provide professional services that would take into account the costs to such providers of providing such services and, not later than 1 year after Nov. 5, 1990, submit a report on the study to Committees on Energy and Commerce and Ways and Means of House of Representatives and Committee on Finance of Senate, including any recommendations regarding payments for prosthetic devices, orthotics, and prosthetics under the medicare program.

SPECIAL RULE FOR NUCLEAR MEDICINE PHYSICIANS

Pub. L. 101–239, title VI, §6105(b), Dec. 19, 1989, 103 Stat. 2210, as amended by Pub. L. 101–508, title IV, §4102(g)(1), Nov. 5, 1990, 104 Stat. 1388–57, provided that: ''In applying section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)] with respect to nuclear medicine services furnished by a physician for whom nuclear medicine services account for at least 80 percent of the total amount of charges made under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] beginning April 1, 1990, and ending December 31, 1991, there shall be substituted for the fee schedule otherwise applicable a fee schedule based ⅓ on the fee schedule computed under such section (without regard to this subsection) and ⅔ on 101 percent of the 1988 prevailing charge for such services.''

SPECIAL RULE FOR INTERVENTIONAL RADIOLOGISTS; ''SPLIT BILLING''

Pub. L. 101–239, title VI, §6105(c), Dec. 19, 1989, 103 Stat. 2210, as amended by Pub. L. 101–508, title IV, §4102(h), Nov. 5, 1990, 104 Stat. 1388–58, provided that: ''In applying section 1834(b) of the Social Security Act [42 U.S.C. 1395m(b)] to radiologist services furnished in 1990 or 1991, the exception for 'split billing' set forth at section 5262J of the Medicare Carriers Manual shall apply to services furnished in 1990 or 1991 in the same manner and to the same extent as the exception applied to services furnished in 1989.''

RENTAL PAYMENTS FOR ENTERAL AND PARENTERAL PUMPS

Pub. L. 101–239, title VI, §6112(b), Dec. 19, 1989, 103 Stat. 2215, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amount of any monthly rental payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for an enteral or parenteral pump furnished on or after April 1, 1990, shall be determined in accordance with the methodology under which monthly rental payments for such pumps were determined during 1989.

''(2) CAP ON RENTAL PAYMENTS, SERVICING, AND REPAIRS.—In the case of an enteral or parenteral pump described in paragraph (1) that is furnished on a rental basis during a period of medical need—

''(A) monthly rental payments shall not be made under part B of title XVIII of the Social Security Act for more than 15 months during such period, and

''(B) after monthly rental payments have been made for 15 months during such period, payment under such part shall be made for maintenance and servicing of the pump in such amounts as the Secretary of Health and Human Services determines to be reasonable and necessary to ensure the proper operation of the pump.''

TREATMENT OF POWER-DRIVEN WHEELCHAIRS AS CUSTOMIZED ITEMS

Pub. L. 101–239, title VI, §6112(d)(2), Dec. 19, 1989, 103 Stat. 2215, provided that: ''The Secretary of Health and Human Services shall by regulation specify criteria to be used by carriers in making determinations on a case-by-case basis as whether to classify power-driven wheelchairs as a customized item (as described in section 1834(a)(4) of the Social Security Act [42 U.S.C. 1395m(a)(4)]) for purposes of reimbursement under title XVIII of such Act [42 U.S.C. 1395 et seq.].''

STUDY OF PAYMENT FOR PORTABLE X-RAY SERVICES

Pub. L. 101–239, title VI, §6134, Dec. 19, 1989, 103 Stat. 2222, directed Secretary of Health and Human Services

to conduct a study of costs of furnishing, and payments for, portable x-ray services under part B and, not later than 1 year after Dec. 19, 1989, report to Congress on results of such study including a recommendation respecting whether payment for such services should be made in the same manner as for radiologists' services or on the basis of a separate fee schedule.

GAO STUDY OF STANDARDS FOR USE OF AND PAYMENT FOR ITEMS OF DURABLE MEDICAL EQUIPMENT

Pub. L. 101–239, title VI, § 6139, Dec. 19, 1989, 103 Stat. 2224, directed Comptroller General to conduct a study of appropriate uses of items of durable medical equipment and of appropriate criteria for making determinations of medical necessity under this subchapter for such items, with particular emphasis on items (including seat-lift chairs) that may be subject to abusive billing practices, such study to include an analysis of appropriate use of forms in making medical necessity determinations for items of durable medical equipment under such title, and procedures for identifying items of durable medical equipment that should no longer be covered under this subchapter, and to be conducted with a panel convened by the Comptroller General consisting of specialists in the disciplines of orthopedic medicine, rehabilitation, arthritis, and geriatric medicine, representatives of consumer organizations, and representatives of carriers under the medicare program, with the Comptroller General to submit not later than Apr. 1, 1991, a report to Committees on Ways and Means and Energy and Commerce of House of Representatives and Committee on Finance of Senate on the study including recommendations.

REPORTS ON MEDICARE BENEFICIARY DRUG EXPENSES

Pub. L. 100–360, title II, § 202(i), July 1, 1988, 102 Stat. 718, directed Secretary of Health and Human Services, by not later than Apr. 1, 1989, to report to Congress on expenses incurred by medicare beneficiaries for outpatient prescription drugs, and to provide Director of Congressional Budget Office with such data from that Survey as Director might request to make required estimates, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

ADDITIONAL STUDIES BY SECRETARY OR COMPTROLLER GENERAL

Pub. L. 100–360, title II, § 202(k), July 1, 1988, 102 Stat. 719, directed Secretary of Health and Human Services to conduct a study, and make a report to Congress by Jan. 1, 1990, on possibility of including drugs which have not yet been approved under section 355 or 357 of Title 21, Food and Drugs, and biological products which have not been licensed under section 262 of this title but which are commonly used in the treatment of cancer or in immunosuppressive therapy and other experimental drugs and biological products as covered outpatient drugs under medicare program, to conduct a study, and report to Congress by Jan. 1, 1990, evaluating potential to use mail service pharmacies to reduce costs to medicare program and to medicare beneficiaries, to conduct a study, and report to Congress by Jan. 1, 1993, on methods to improve utilization review of covered outpatient drugs, and to conduct a longitudinal study, and report to Congress by Jan. 1, 1993, on use of outpatient prescription drugs by medicare beneficiaries with respect to medical necessity, potential for adverse drug interactions, cost (including whether lower cost drugs could have been used), and patient stockpiling or wastage, and which further directed Comptroller General to conduct studies, and report to Congress by not later than May 1, 1991, on comparing average wholesale prices with actual pharmacy acquisition costs by type of pharmacy, on determining the overhead costs of retail pharmacies, and on discounts given by pharmacies to other third-party insurers, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

DEVELOPMENT OF STANDARD MEDICARE CLAIMS FORMS

Pub. L. 100–360, title II, § 202(*l*), July 1, 1988, 102 Stat. 720, directed Secretary of Health and Human Services to develop, in consultation with representatives of pharmacies and other interested individuals, a standard claims form (and a standard electronic claims format) to be used in requests for payment for covered outpatient drugs under medicare program and other third-party payors, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

STUDIES AND REPORTS ON SCREENING MAMMOGRAPHY

Pub. L. 100–360, title II, § 204(f), July 1, 1988, 102 Stat. 729, directed Physician Payment Review Commission to study and report, by July 1, 1989, to Committees on Ways and Means and Energy and Commerce of the House of Representatives and Committee on Finance of the Senate concerning the cost of providing screening mammography in a variety of settings and at different volume levels, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

DEADLINE FOR ESTABLISHMENT OF FEE SCHEDULES FOR RADIOLOGIST SERVICES; REPORT TO CONGRESS

Pub. L. 100–203, title IV, § 4049(b)(1), Dec. 22, 1987, 101 Stat. 1330–92, as amended by Pub. L. 100–360, title IV, § 411(f)(8)(E), July 1, 1988, 102 Stat. 780; Pub. L. 101–508, title IV, § 4118(g)(3), Nov. 5, 1990, 104 Stat. 1388–70, directed Secretary of Health and Human Services to propose the relative value scale and fee schedules for radiologist services (under subsec. (b) of this section) by not later than Aug. 1, 1988.

STUDY AND EVALUATION

Pub. L. 100–203, title IV, § 4062(c), Dec. 22, 1987, 101 Stat. 1330–107, as amended by Pub. L. 100–360, title IV, § 411(g)(1)(C), July 1, 1988, 102 Stat. 782, provided that:

''(1) The Secretary of Health and Human Services shall monitor the impact of the amendments made by this section [enacting this section, amending sections 1395f, 1395k, 1395*l*, and 1395cc of this title, and repealing section 1395zz of this title] on the availability of covered items and shall evaluate the appropriateness of the volume adjustment for oxygen and oxygen equipment under section 1834(a)(5)(C) of the Social Security Act [42 U.S.C. 1395m(a)(5)(C)] (as amended by subsection (b) of this section). The Secretary shall report to Congress, by not later than January 1, 1991, on such impact and on the evaluation and shall include in such report recommendations for changes in payment methodology for covered items under section 1834(a) of such Act.

''(2) Before January 1, 1991, the Secretary may not conduct any demonstration project respecting alternative methods of payment for covered items under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

''(3) In this subsection, the term 'covered item' has the meaning given such term in section 1834(a)(13) of the Social Security Act [42 U.S.C. 1395m(a)(13)] (as amended by subsection (b) of this section).

''(4) The Secretary shall, upon written request and payment of a reasonable copying fee which the Secretary may establish, provide the data and information used in determining the payment amounts for covered items under section 1834(a) of the Social Security Act [42 U.S.C. 1395m(a)], but only in a form which does not permit identification of individual suppliers.

''(5) The Comptroller General shall conduct a study on the appropriateness of the level of payments allowed for covered items under the medicare program, and shall report to Congress on the results of such study (including recommendations on the transition to regional or national rates) by not later than January 1, 1991. Entities furnishing such items which fail to provide the Comptroller General with reasonable access to necessary records to carry out the study under this paragraph are subject to exclusion from the medicare program under section 1128(a) of the Social Security Act [42 U.S.C. 1320a–7(a)].''

§ 1395m–1. Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

(A) General reporting requirements

Subject to subparagraph (B), beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary (referred to in this subsection as the ''reporting period''), applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(B) Revised reporting period

In the case of reporting with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the Secretary shall revise the reporting period under subparagraph (A) such that—

(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2020;

(ii) reporting is required during the period beginning January 1, 2021, and ending March 31, 2021; and

(iii) reporting is required every three years after the period described in clause (ii).

(2) Definition of applicable laboratory

In this section, the term ''applicable laboratory'' means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w–4 of this title. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

In this section, subject to subparagraph (B), the term ''applicable information'' means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

(A) In general

Subject to subparagraph (B), in this section, the term ''data collection period'' means a period of time, such as a previous 12 month period, specified by the Secretary.

(B) Exception

In the case of the reporting period described in paragraph (1)(B)(ii) with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the term ''data collection period'' means the period beginning January 1, 2019, and ending June 30, 2019.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1395w–3a(c)(3) of this title.

(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term ''private payor'' means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined in section 300gg–91 of this title).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).

(9) Civil money penalty

(A) In general

If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

(B) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as they apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title.

(10) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by a laboratory under