EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title II, § 2902(b), Mar. 23, 2010, 124 Stat. 333, provided that: ''The amendments made by this section [amending this section] shall apply to items or services furnished on or after January 1, 2010.''

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title IV, § 432(a)] of Pub. L. 106–554 applicable to services furnished on or after July 1, 2001, see section 1(a)(6) [title IV, § 432(c)] of Pub. L. 106–554, set out as a note under section 1395u of this title.

Amendment by Pub. L. 106–417 effective Oct. 1, 2000, see section 3(c) of Pub. L. 106–417, set out as a note under section 1645 of Title 25, Indians.

MEDICARE PAYMENTS NOT CONSIDERED IN DETERMINING APPROPRIATIONS FOR INDIAN HEALTH CARE

Pub. L. 94–437, title IV, § 401(c), Sept. 30, 1976, 90 Stat. 1409, provided that any payments received for services provided to beneficiaries under this section were not to be considered in determining appropriations for health care and services to Indians, prior to the general amendment of section 401 of Pub. L. 94–437 by Pub. L. 102–573, title IV, § 401(a), Oct. 29, 1992, 106 Stat. 4565. Similar provisions are contained in section 401(a) of Pub. L. 94–437, which is classified to section 1641(a) of Title 25, Indians.

PREFERENCE IN SERVICES FOR INDIANS WITH MEDICARE COVERAGE NOT AUTHORIZED

Pub. L. 94–437, title IV, § 401(d), Sept. 30, 1976, 90 Stat. 1409, which provided that nothing in this section authorized the Secretary to provide services to an Indian beneficiary with coverage under this subchapter, in preference to an Indian beneficiary without such coverage, prior to the general amendment of section 401 of Pub. L. 94–437 by Pub. L. 102–573, title IV, § 401(a), Oct. 29, 1992, 106 Stat. 4565. Similar provisions are contained in section 401(b) of Pub. L. 94–437, which is classified to section 1641(b) of Title 25, Indians.

§ 1395rr. End stage renal disease program

(a) Type, duration, and scope of benefits

The benefits provided by parts A and B of this subchapter shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 426–1 of this title, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this subchapter, the type, duration, and scope of the benefit provided by parts A and B with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 426–1 of this title shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b) Payments with respect to services; dialysis; regulations; physicians' services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine

(1) Payments under this subchapter with respect to services, in addition to services for which payment would otherwise be made under this subchapter, furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in paragraph (3)(A) of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1395x(s)(2)(P)[1] of this title if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations.

(2)(A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end stage renal disease for which payments may be made under part B of this subchapter, such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this subchapter, the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in accordance with section 1395x(v) of this title or section 1395ww of this title (if applicable). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagraph (B) and the deductible amount imposed by section 1395*l*(b) of this title.

(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1395x(v) of this title) and consistent with any regulations promulgated under paragraph (7), the amounts of payments to be made for part B services furnished by such providers and facilities to such individuals.

[1] See References in Text note below.

(C) Such regulations, in the case of services furnished by proprietary providers and facilities (other than hospital outpatient departments) may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1395x(v)(1)(B) of this title.

(D) For purposes of section 1395*oo* of this title, a renal dialysis facility shall be treated as a provider of services.

(3) With respect to payments for physicians' services furnished to individuals determined to have end stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services—

(A) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services or, for services furnished on or after January 1, 1992, on the basis described in section 1395w–4 of this title) except that payment may not be made under this subparagraph for routine services furnished during a maintenance dialysis episode, or

(B) on a comprehensive monthly fee or other basis (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis) for an aggregate of services provided over a period of time (as defined in regulations).

(4)(A) Pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payments to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility, on the basis of a target reimbursement rate (as defined in paragraph (6)) or on the basis of a method established under paragraph (7).

(B) The Secretary shall make payments to a supplier of home dialysis supplies and equipment furnished to a patient whose self-care home dialysis is not under the direct supervision of an approved provider of services or renal dialysis facility only in accordance with a written agreement under which—

(i) the patient certifies that the supplier is the sole provider of such supplies and equipment to the patient,

(ii) the supplier agrees to receive payment for the cost of such supplies and equipment only on an assignment-related basis, and

(iii) the supplier certifies that it has entered into a written agreement with an approved provider of services or renal dialysis facility under which such provider or facility agrees to furnish to such patient all self-care home dialysis support services and all other necessary dialysis services and supplies, including institutional dialysis services and supplies and emergency services.

(5) An agreement under paragraph (4) shall require, in accordance with regulations prescribed by the Secretary, that the provider or facility will—

(A) assume full responsibility for directly obtaining or arranging for the provision of—

(i) such medically necessary dialysis equipment as is prescribed by the attending physician;

(ii) dialysis equipment maintenance and repair services;

(iii) the purchase and delivery of all necessary medical supplies; and

(iv) where necessary, the services of trained home dialysis aides;

(B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A);

(C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment, supplies, and services furnished to the facility's home dialysis patient population; and

(D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section.

(6) The Secretary shall establish, for each calendar year, commencing with January 1, 1979, a target reimbursement rate for home dialysis which shall be adjusted for regional variations in the cost of providing home dialysis. In establishing such a rate, the Secretary shall include—

(A) the Secretary's estimate of the cost of providing medically necessary home dialysis supplies and equipment;

(B) an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and

(C) an allowance, in an amount determined by the Secretary, to cover administrative costs and to provide an incentive for the efficient delivery of home dialysis;

but in no event (except as may be provided in regulations under paragraph (7)) shall such target rate exceed 75 percent of the national average payment, adjusted for regional variations, for maintenance dialysis services furnished in approved providers and facilities during the preceding fiscal year. Any such target rate so established shall be utilized, without renegotiation of the rate, throughout the calendar year for which it is established. During the last quarter of each calendar year, the Secretary shall establish a home dialysis target reimbursement rate for the next calendar year based on the most recent data available to the Secretary at the time. In establishing any rate under this paragraph, the Secretary may utilize a competitive-bid procedure, a prenegotiated rate procedure, or any other procedure (including methods established under paragraph (7)) which the Secretary determines is appropriate and feasible in order to carry out this paragraph in an effective and efficient manner.

(7) Subject to paragraph (12), the Secretary shall provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home. Such method (or methods) shall provide for the prospective determination of a rate (or rates) for each mode

of care based on a single composite weighted formula (which takes into account the mix of patients who receive dialysis services at a facility or at home and the relative costs of providing such services in such settings) for hospital-based facilities and such a single composite weighted formula for other renal dialysis facilities, or based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services and will provide greater incentives for increased use of home dialysis than through the single composite weighted formulas. The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities. Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary shall provide for such exceptions to such methods as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed. The Secretary may provide that such method will serve in lieu of any target reimbursement rate that would otherwise be established under paragraph (6). The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2). The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—

(A) the geographic size of the network area;

(B) the number of providers of end stage renal disease services in the network area;

(C) the number of individuals who are entitled to end stage renal disease services in the network area; and

(D) the proportion of the aggregate administrative funds collected in the network area.

The Secretary shall increase the amount of each composite rate payment for dialysis services furnished during 2000 by 1.2 percent above such composite rate payment amounts for such services furnished on December 31, 1999, for such services furnished on or after January 1, 2001, and before January 1, 2005, by 2.4 percent above such composite rate payment amounts for such services furnished on December 31, 2000, and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004.

(8) For purposes of this subchapter, the term ''home dialysis supplies and equipment'' means medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.

(9) For purposes of this subchapter, the term ''self-care home dialysis support services'', to the extent permitted in regulation, means—

(A) periodic monitoring of the patient's home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan prepared and periodically reviewed by a professional team (as defined in regulations) including the individual's physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

(10) For purposes of this subchapter, the term ''self-care dialysis unit'' means a renal dialysis facility or a distinct part of such facility or of a provider of services, which has been approved by the Secretary to make self-dialysis services, as defined by the Secretary in regulations, available to individuals who have been trained for self-dialysis. A self-care dialysis unit must, at a minimum, furnish the services, equipment and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for such appropriate lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis), and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

(11)(A) Hepatitis B vaccine and its administration, when provided to a patient determined to have end stage renal disease, shall not be included as dialysis services for purposes of payment under any prospective payment amount or comprehensive fee established under this section. Payment for such vaccine and its administration shall be made separately in accordance with section 1395*l* of this title.

(B) Erythropoietin, when provided to a patient determined to have end stage renal disease, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee established under this section, and subject to paragraphs (12) and (13) payment for such item shall be made separately—

(i) in the case of erythropoietin provided by a physician, in accordance with section 1395*l* of this title; and

(ii) in the case of erythropoietin provided by a provider of services, renal dialysis facility,

or other supplier of home dialysis supplies and equipment—

(I) for erythropoietin provided during 1994, in an amount equal to $10 per thousand units (rounded to the nearest 100 units), and

(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item.

(12)(A) Subject to paragraph (14), in lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics. Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(B) The system described in subparagraph (A) shall include—

(i) the services comprising the composite rate established under paragraph (7); and

(ii) the difference between payment amounts under this subchapter for separately billed drugs and biologicals (including erythropoietin) and acquisition costs of such drugs and biologicals, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—

(I) beginning with 2005, for such drugs and biologicals for which a billing code exists prior to January 1, 2004; and

(II) beginning with 2007, for such drugs and biologicals for which a billing code does not exist prior to January 1, 2004,

adjusted to 2005, or 2007, respectively, as determined to be appropriate by the Secretary.

(C)(i) In applying subparagraph (B)(ii) for 2005, such payment amounts under this subchapter shall be determined using the methodology specified in paragraph (13)(A)(i).

(ii) For 2006, the Secretary shall provide for an adjustment to the payments under clause (i) to reflect the difference between the payment amounts using the methodology under paragraph (13)(A)(i) and the payment amount determined using the methodology applied by the Secretary under paragraph (13)(A)(iii) of such paragraph, as estimated by the Secretary.

(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period.

(E)(i) Such system shall be designed to result in the same aggregate amount of expenditures for such services, as estimated by the Secretary, as would have been made for 2005 if this paragraph did not apply.

(ii) The adjustment made under subparagraph (B)(ii)(II) shall be done in a manner to result in the same aggregate amount of expenditures after such adjustment as would otherwise have been made for such services for 2006 or 2007, respectively, as estimated by the Secretary, if this paragraph did not apply.

(F) Beginning with 2006, the Secretary shall annually increase the basic case-mix adjusted payment amounts established under this paragraph, by an amount determined by—

(i) applying the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable to the component of the basic case-mix adjusted system described in subparagraph (B)(ii); and

(ii) converting the amount determined in clause (i) to an increase applicable to the basic case-mix adjusted payment amounts established under subparagraph (B).

Except as provided in subparagraph (G), nothing in this paragraph or paragraph (14) shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B) or under the system under paragraph (14).

(G) The Secretary shall increase the amount of the composite rate component of the basic case-mix adjusted system under subparagraph (B) for dialysis services—

(i) furnished on or after January 1, 2006, and before April 1, 2007, by 1.6 percent above the amount of such composite rate component for such services furnished on December 31, 2005;

(ii) furnished on or after April 1, 2007, and before January 1, 2009, by 1.6 percent above the amount of such composite rate component for such services furnished on March 31, 2007;

(iii) furnished on or after January 1, 2009, and before January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2008; and

(iv) furnished on or after January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2009.

(H) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of the case-mix system, relative weights, payment amounts, the geographic adjustment factor, or

the update for the system established under this paragraph, or the determination of the difference between medicare payment amounts and acquisition costs for separately billed drugs and biologicals (including erythropoietin) under this paragraph and paragraph (13).

(13)(A) Subject to paragraph (14), the payment amounts under this subchapter for separately billed drugs and biologicals furnished in a year, beginning with 2004, are as follows:

(i) For such drugs and biologicals (other than erythropoietin) furnished in 2004, the amount determined under section 1395u(*o*)(1)(A)(v) of this title for the drug or biological.

(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006 and subsequent years, such acquisition cost or the amount determined under section 1395w–3a of this title for the drug or biological, as the Secretary may specify.

(B) Drugs and biologicals (including erythropoietin) which were separately billed under this subsection on the day before December 8, 2003, shall continue to be separately billed on and after such date, subject to paragraph (14).

(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

(ii) In implementing the system under this paragraph the Secretary shall ensure that the estimated total amount of payments under this subchapter for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this subchapter with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (I), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

(B) For purposes of this paragraph, the term ''renal dialysis services'' includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(C) The system under this paragraph may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies.

(D) Such system—

(i) shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors;

(ii) shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management;

(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent; and

(iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—

(I) for pediatric providers of services and renal dialysis facilities;

(II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and

(III) for providers of services or renal dialysis facilities located in rural areas.

The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

(E)(i) The Secretary shall provide for a four-year phase-in (in equal increments) of the payment amount under the payment system under this paragraph, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014.

(ii) A provider of services or renal dialysis facility may make a one-time election to be excluded from the phase-in under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph. Such an election shall be made prior to January 1, 2011, in a form and manner specified by the Secretary, and is final and may not be rescinded.

(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including pay-

ments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

(F)(i)(I) Subject to subclauses (II) and (III) and clause (ii), beginning in 2012, the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. In order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018.

(II) Subject to subclause (III), for 2012 and each subsequent year, after determining the increase factor described in subclause (I), the Secretary shall reduce such increase factor 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 such increase factor being less than 0.0 for a year, and may result in payment rates under the payment system under this paragraph for a year being less than such payment rates for the preceding year.

(III) Notwithstanding subclauses (I) and (II), in order to accomplish the purposes of subparagraph (I) with respect to 2015, the increase factor described in subclause (I) for 2015 shall be 0.0 percent pursuant to the regulation issued by the Secretary on December 2, 2013, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule'' (78 Fed. Reg. 72156).

(ii) For years during which a phase-in of the payment system pursuant to subparagraph (E) is applicable, the following rules shall apply to the portion of the payment under the system that is based on the payment of the composite rate that would otherwise apply if the system under this paragraph had not been enacted:

(I) The update under clause (i) shall not apply.

(II) Subject to clause (i)(II), the Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I).

(G) There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise of the determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

(H) Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under part B if they are—

(i) furnished to an individual for the treatment of end stage renal disease; and

(ii) included in subparagraph (B) for purposes of payment under this paragraph.

(I) For services furnished on or after January 1, 2014, and before January 1, 2015, the Secretary shall, by comparing per patient utilization data from 2007 with such data from 2012, make reductions to the single payment that would otherwise apply under this paragraph for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of drugs and biologicals described in clauses (ii), (iii), and (iv) of subparagraph (B) (other than oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary in the Federal Register on August 12, 2010 (75 Fed. Reg. 49030)). In making reductions under the preceding sentence, the Secretary shall take into account the most recently available data on average sales prices and changes in prices for drugs and biological[2] reflected in the ESRD market basket percentage increase factor under subparagraph (F).

(c) Renal disease network areas; coordinating councils, executive committees, and medical review boards; national end stage renal disease medical information system; functions of network organizations

(1)(A)(i) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)—

(I) establish at least 17 end stage renal disease network areas, and

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish (aa) a network council of renal dialysis and transplant facilities located in the area and (bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and social workers engaged in treatment relating to end stage renal disease.

The Secretary shall publish in the Federal Register a description of the geographic area that he determines, after consultation with appropriate professional and patient organizations, constitutes each network area and the criteria on the basis of which such determination is made.

(ii)(I) In order to determine whether the Secretary should enter into, continue, or terminate an agreement with a network administrative organization designated for an area established under clause (i), the Secretary shall develop and publish in the Federal Register standards, criteria, and procedures to evaluate an applicant organization's capabilities to perform (and, in the case of an organization with which such an agreement is in effect, actual performance of) the responsibilities described in paragraph (2). The Secretary shall evaluate each applicant

[2] So in original. Probably should be ''biologicals''.

based on quality and scope of services and may not accord more than 20 percent of the weight of the evaluation to the element of price.

(II) An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition.

(B) At least one patient representative shall serve as a member of each network council and each medical review board.

(C) The Secretary shall, in regulations, prescribe requirements with respect to membership in network organizations by individuals (and the relatives of such individuals) (i) who have an ownership or control interest in a facility or provider which furnishes services referred to in section 1395x(s)(2)(F) of this title, or (ii) who have received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services (including time and effort relative to the provision of professional medical services) or goods supplied to such facility or provider; and such requirements shall provide for the definition, disclosure, and, to the maximum extent consistent with effective administration, prevention of potential or actual financial or professional conflicts of interest with respect to decisions concerning the appropriateness, nature, or site of patient care.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for—

(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

(C) evaluating the procedure by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities;

(D) implementing a procedure for evaluating and resolving patient grievances;

(E) conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the network organization to assure proper medical care;

(F) collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) and to assure the maintenance of the registry established under paragraph (7);

(G) identifying facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care; and

(H) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs), identification of those facilities that have consistently failed to cooperate with network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

(3) Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to him, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, he may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until he determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals. If the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

(4) The Secretary shall, in determining whether to certify additional facilities or expansion of existing facilities within a network, take into account the network's goals and performance as reflected in the network's annual report.

(5) The Secretary, after consultation with appropriate professional and planning organizations, shall provide such guidelines with respect to the planning and delivery of renal disease services as are necessary to assist network organizations in their development of their respective networks' goals to promote the optimum use of self-dialysis and transplantation by suitable candidates for such modalities.

(6) It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation

should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

(7) The Secretary shall establish a national end stage renal disease registry the purpose of which shall be to assemble and analyze the data reported by network organizations, transplant centers, and other sources on all end stage renal disease patients in a manner that will permit—

(A) the preparation of the annual report to the Congress required under subsection (g);[1]

(B) an identification of the economic impact, cost-effectiveness, and medical efficacy of alternative modalities of treatment;

(C) an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of end stage renal disease;

(D) the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and

(E) such other analyses relating to the treatment and management of end stage renal disease as will assist the Congress in evaluating the end stage renal disease program under this section.

The Secretary shall provide for such coordination of data collection activities, and such consolidation of existing end stage renal disease data systems, as is necessary to achieve the purpose of such registry, shall determine the appropriate location of the registry, and shall provide for the appointment of a professional advisory group to assist the Secretary in the formulation of policies and procedures relevant to the management of such registry.

(8) The provisions of sections 1320c–6 and 1320c–9 of this title shall apply with respect to network administrative organizations (including such organizations as medical review boards) with which the Secretary has entered into agreements under this subsection.

(d) Donors of kidney for transplant surgery

Notwithstanding any provision to the contrary in section 426 of this title any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of this subchapter with respect to such donation. Reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions of this subchapter), in such manner as may be prescribed by the Secretary in regulations, for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation, including but not limited to the expenses for which payment could be made if he were an eligible individual for purposes of parts A and B of this subchapter without regard to this subsection. Payments for postoperation recovery expenses shall be limited to the actual period of recovery.

(e) Reimbursement of providers, facilities, and nonprofit entities for costs of artificial kidney and automated dialysis peritoneal machines for home dialysis

(1) Notwithstanding any other provision of this subchapter, the Secretary may, pursuant to agreements with approved providers of services, renal dialysis facilities, and nonprofit entities which the Secretary finds can furnish equipment economically and efficiently, reimburse such providers, facilities, and nonprofit entities (without regard to the deductible and coinsurance provisions of this subchapter) for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines (including supportive equipment) which are to be used exclusively by entitled individuals dialyzing at home.

(2) An agreement under this subsection shall require that the provider, facility, or other entity will—

(A) make the equipment available for use only by entitled individuals dialyzing at home;

(B) recondition the equipment, as needed, for reuse by such individuals throughout the useful life of the equipment, including modification of the equipment consistent with advances in research and technology;

(C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and

(D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment.

(3) For purposes of this section, the term ''supportive equipment'' includes blood pumps, heparin pumps, bubble detectors, other alarm systems, and such other items as the Secretary may determine are medically necessary.

(f) Experiments, studies, and pilot projects

(1) The Secretary shall initiate and carry out, at selected locations in the United States, pilot projects under which financial assistance in the purchase of new or used durable medical equipment for renal dialysis is provided to individuals suffering from end stage renal disease at the time home dialysis is begun, with provision for a trial period to assure successful adaptation to home dialysis before the actual purchase of such equipment.

(2) The Secretary shall conduct experiments to evaluate methods for reducing the costs of the end stage renal disease program. Such experiments shall include (without being limited to) reimbursement for nurses and dialysis technicians to assist with home dialysis, and reimbursement to family members assisting with home dialysis.

(3) The Secretary shall conduct experiments to evaluate methods of dietary control for reducing the costs of the end stage renal disease program, including (without being limited to) the use of protein-controlled products to delay the necessity for, or reduce the frequency of, dialysis in the treatment of end stage renal disease.

(4) The Secretary shall conduct a comprehensive study of methods for increasing public par-

ticipation in kidney donation and other organ donation programs.

(5) The Secretary shall conduct a full and complete study of the reimbursement of physicians for services furnished to patients with end stage renal disease under this subchapter, giving particular attention to the range of payments to physicians for such services, the average amounts of such payments, and the number of hours devoted to furnishing such services to patients at home, in renal disease facilities, in hospitals, and elsewhere.

(6) The Secretary shall conduct a study of the number of patients with end stage renal disease who are not eligible for benefits with respect to such disease under this subchapter (by reason of this section or otherwise), and of the economic impact of such noneligibility of such individuals. Such study shall include consideration of mechanisms whereby governmental and other health plans might be instituted or modified to permit the purchase of actuarially sound coverage for the costs of end stage renal disease.

(7)(A) The Secretary shall establish protocols on standards and conditions for the reuse of dialyzer filters for those facilities and providers which voluntarily elect to reuse such filters.

(B) With respect to dialysis services furnished on or after January 1, 1988 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines), no dialysis facility may reuse dialysis supplies (other than dialyzer filters) unless the Secretary has established a protocol with respect to the reuse of such supplies and the facility follows the protocol so established.

(C) The Secretary shall incorporate protocols established under this paragraph, and the requirement of subparagraph (B), into the requirements for facilities prescribed under subsection (b)(1)(A) and failure to follow such a protocol or requirement subjects such a facility to denial of participation in the program established under this section and to denial of payment for dialysis treatment not furnished in compliance with such a protocol or in violation of such requirement.

(8) The Secretary shall submit to the Congress no later than October 1, 1979, a full report on the experiments conducted under paragraphs (1), (2), (3), and (7), and the studies under paragraphs (4), (5), (6), and (7). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of such experiments and studies.

(g) Conditional approval of dialysis facilities; restriction-of-payments notice to public and facility; notice and hearing; judicial review

(1) In any case where the Secretary—

(A) finds that a renal dialysis facility is not in substantial compliance with requirements for such facilities prescribed under subsection (b)(1)(A),

(B) finds that the facility's deficiencies do not immediately jeopardize the health and safety of patients, and

(C) has given the facility a reasonable opportunity to correct its deficiencies,

the Secretary may, in lieu of terminating approval of the facility, determine that payment under this subchapter shall be made to the facility only for services furnished to individuals who were patients of the facility before the effective date of the notice.

(2) The Secretary's decision to restrict payments under this subsection shall be made effective only after such notice to the public and to the facility as may be prescribed in regulations, and shall remain in effect until (A) the Secretary finds that the facility is in substantial compliance with the requirements under subsection (b)(1)(A), or (B) the Secretary terminates the agreement under this subchapter with the facility.

(3) A facility dissatisfied with a determination by the Secretary under paragraph (1) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(*l*) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(h) Quality incentives in the end-stage renal disease program

(1) Quality incentives

(A) In general

With respect to renal dialysis services (as defined in subsection (b)(14)(B)) furnished on or after January 1, 2012, in the case of a provider of services or a renal dialysis facility that does not meet the requirement described in subparagraph (B) with respect to the year, payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(B) Requirement

The requirement described in this subparagraph is that the provider or facility meets (or exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

(C) No effect in subsequent years

The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

(2) Measures

(A) In general

The measures specified under this paragraph with respect to the year involved shall include—

(i) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;

(ii) to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify;

(iii) for 2016 and subsequent years, measures described in subparagraph (E)(i); and

(iv) such other measures as the Secretary specifies, including, to the extent feasible, measures on—

(I) iron management;

(II) bone mineral metabolism; and

(III) vascular access, including for maximizing the placement of arterial venous fistula.

(B) Use of endorsed measures

(i) In general

Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iv) must have been endorsed by the entity with a contract under section 1395aaa(a) of this title.

(ii) Exception

In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1395aaa(a) of this title, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) Updating measures

The Secretary shall establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties.

(D) Consideration

In specifying measures under subparagraph (A), the Secretary shall consider the availability of measures that address the unique treatment needs of children and young adults with kidney failure.

(E) Measures specific to the conditions treated with oral-only drugs

(i) In general

The measures described in this subparagraph are measures specified by the Secretary that are specific to the conditions treated with oral-only drugs. To the extent feasible, such measures shall be outcomes-based measures.

(ii) Consultation

In specifying the measures under clause (i), the Secretary shall consult with interested stakeholders.

(iii) Use of endorsed measures

(I) In general

Subject to subclause (I), any measures specified under clause (i) must have been endorsed by the entity with a contract under section 1395aaa(a) of this title.

(II) Exception

If the entity with a contract under section 1395aaa(a) of this title has not endorsed a measure for a specified area or topic related to measures described in clause (i) that the Secretary determines appropriate, the Secretary may specify a measure that is endorsed or adopted by a consensus organization recognized by the Secretary that has expertise in clinical guidelines for kidney disease.

(3) Performance scores

(A) Total performance score

(i) In general

Subject to clause (ii), the Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D) (in this subsection referred to as the ''total performance score'').

(ii) Application

For providers of services and renal dialysis facilities that do not meet (or exceed) the total performance score established by the Secretary, the Secretary shall ensure that the application of the methodology developed under clause (i) results in an appropriate distribution of reductions in payment under paragraph (1) among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reduction in payment under paragraph (1)(A).

(iii) Weighting of measures

In calculating the total performance score, the Secretary shall weight the scores with respect to individual measures calculated under subparagraph (B) to reflect priorities for quality improvement, such as weighting scores to ensure that providers of services and renal dialysis facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

(B) Performance score with respect to individual measures

The Secretary shall also calculate separate performance scores for each measure, including for dialysis adequacy and anemia management.

(4) Performance standards

(A) Establishment

Subject to subparagraph (E), the Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period with respect to a year (as established under subparagraph (D)).

(B) Achievement and improvement

The performance standards established under subparagraph (A) shall include levels of achievement and improvement, as determined appropriate by the Secretary.

(C) Timing

The Secretary shall establish the performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved.

(D) Performance period

The Secretary shall establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.

(E) Special rule

The Secretary shall initially use as the performance standard for the measures specified under paragraph (2)(A)(i) for a provider of services or a renal dialysis facility the lesser of—

(i) the performance of such provider or facility for such measures in the year selected by the Secretary under the second sentence of subsection (b)(14)(A)(ii); or

(ii) a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

(5) Limitation 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 following:

(A) The determination of the amount of the payment reduction under paragraph (1).

(B) The establishment of the performance standards and the performance period under paragraph (4).

(C) The specification of measures under paragraph (2).

(D) The methodology developed under paragraph (3) that is used to calculate total performance scores and performance scores for individual measures.

(6) Public reporting

(A) In general

The Secretary shall establish procedures for making information regarding performance under this subsection available to the public, including—

(i) the total performance score achieved by the provider of services or renal dialysis facility under paragraph (3) and appropriate comparisons of providers of services and renal dialysis facilities to the national average with respect to such scores; and

(ii) the performance score achieved by the provider or facility with respect to individual measures.

(B) Opportunity to review

The procedures established under subparagraph (A) shall ensure that a provider of services and a renal dialysis facility has the opportunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

(C) Certificates

(i) In general

The Secretary shall provide certificates to providers of services and renal dialysis facilities who furnish renal dialysis services under this section to display in patient areas. The certificate shall indicate the total performance score achieved by the provider or facility under paragraph (3).

(ii) Display

Each facility or provider receiving a certificate under clause (i) shall prominently display the certificate at the provider or facility.

(D) Web-based list

The Secretary shall establish a list of providers of services and renal dialysis facilities who furnish renal dialysis services under this section that indicates the total performance score and the performance score for individual measures achieved by the provider and facility under paragraph (3). Such information shall be posted on the Internet website of the Centers for Medicare & Medicaid Services in an easily understandable format.

(Aug. 14, 1935, ch. 531, title XVIII, § 1881, as added Pub. L. 95–292, § 2, June 13, 1978, 92 Stat. 308; amended Pub. L. 96–499, title IX, § 957, Dec. 5, 1980, 94 Stat. 2648; Pub. L. 97–35, title XXI, § 2145(a), Aug. 13, 1981, 95 Stat. 799; Pub. L. 98–21, title VI, § 602(i), Apr. 20, 1983, 97 Stat. 165; Pub. L. 98–369, div. B, title III, §§ 2323(c), 2352(a), 2354(b)(41), July 18, 1984, 98 Stat. 1086, 1099, 1102; Pub. L. 98–617, § 3(b)(8), Nov. 8, 1984, 98 Stat. 3296; Pub. L. 99–509, title IX, § 9335(a)(2), (d)(1), (e)–(i)(1), (j)(1), (k)(1), Oct. 21, 1986, 100 Stat. 2029–2033; Pub. L. 100–93, § 12, Aug. 18, 1987, 101 Stat. 697; Pub. L. 100–203, title IV, §§ 4036(b), (c)(2), (d)(5), 4065(b), Dec. 22, 1987, 101 Stat. 1330–79, 1330–80, 1330–112; Pub. L. 101–239, title VI, §§ 6102(e)(8), 6203(b)(1), (2), 6219(a), (b), Dec. 19, 1989, 103 Stat. 2188, 2235, 2254; Pub. L. 101–508, title IV, § 4201(c)(1), (d)(2), formerly (d)(2), (3), Nov. 5, 1990, 104 Stat. 1388–103, 1388–104, renumbered Pub. L. 103–432, title I, § 160(d)(3), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 103–66, title XIII, § 13566(a), Aug. 10, 1993, 107 Stat. 607; Pub. L. 103–296, title I, § 108(c)(5), Aug. 15, 1994, 108 Stat. 1485; Pub. L. 106–113, div. B, § 1000(a)(6) [title II, § 222(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352; Pub. L. 106–554, § 1(a)(6) [title IV, § 422(a)(1)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516; Pub. L. 108–173, title VI, § 623(a), (b)(2), (d), Dec. 8, 2003, 117 Stat. 2312, 2313; Pub. L. 109–171, title V, § 5106, Feb. 8, 2006, 120 Stat. 42; Pub. L. 109–432, div. B, title I, § 103(a), Dec. 20, 2006, 120 Stat. 2981; Pub. L. 110–275, title I, § 153(a), (b)(1), (3)(A), (c), July 15, 2008, 122 Stat. 2553, 2556; Pub. L. 111–148, title III, § 3401(h), Mar. 23, 2010, 124 Stat. 485; Pub. L. 112–240, title VI, § 632(a), Jan. 2, 2013, 126 Stat. 2354; Pub. L. 113–93, title II, § 217(b), (d), Apr. 1, 2014, 128 Stat. 1061, 1062.)

REFERENCES IN TEXT

Section 1395x(s)(2)(P) of this title, referred to in subsec. (b)(1), was redesignated section 1395x(s)(2)(O) of this title by Pub. L. 103–432, title I, § 147(f)(6)(B)(iii)(II), Oct. 31, 1994, 108 Stat. 4432.

Section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (b)(7), is section 1(a)(6) [title IV, § 422(a)(2)] of Pub. L. 106–554, which is set out as a note under this section.

Section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (b)(12)(B)(ii), (13)(A)(ii), is section 623(c) of Pub. L. 108–173, which is set out as a note under this section.

Subsection (g), referred to in subsec. (c)(7)(A), was repealed, and subsec. (h) was redesignated (g), by Pub. L. 100–203, title IV, §§4036(d)(5)(C), (D), Dec. 22, 1987, 101 Stat. 1330–80.

AMENDMENTS

2014—Subsec. (b)(14)(F)(i)(I). Pub. L. 113–93, §217(b)(2)(A), substituted ''subclauses (II) and (III)'' for ''subclause (II)'' and inserted at end ''In order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018.''

Subsec. (b)(14)(F)(i)(II). Pub. L. 113–93, §217(b)(2)(B), substituted ''Subject to subclause (III), for 2012'' for ''For 2012''.

Subsec. (b)(14)(F)(i)(III). Pub. L. 113–93, §217(b)(2)(C), added subcl. (III).

Subsec. (b)(14)(I). Pub. L. 113–93, §217(b)(1), inserted ''and before January 1, 2015,'' after ''January 1, 2014,''.

Subsec. (h)(2)(A)(iii), (iv). Pub. L. 113–93, §217(d)(1), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (h)(2)(B)(i). Pub. L. 113–93, §217(d)(2), substituted ''(A)(iv)'' for ''(A)(iii)''.

Subsec. (h)(2)(E). Pub. L. 113–93, §217(d)(3), added subpar. (E).

2013—Subsec. (b)(14)(I). Pub. L. 112–240 added subpar. (I).

2010—Subsec. (b)(14)(F)(i). Pub. L. 111–148, §3401(h)(1), designated existing provisions as subcl. (I), substituted ''subclause (II) and clause (ii)'' for ''clause (ii)'' and struck out ''minus 1.0 percentage point'' before period at end, and added subcl. (II).

Subsec. (b)(14)(F)(ii)(II). Pub. L. 111–148, §3401(h)(2), substituted ''Subject to clause (i)(II), the'' for ''The'' and ''clause (i)(I)'' for ''clause (i) minus 1.0 percentage point''.

2008—Subsec. (b)(12)(A). Pub. L. 110–275, §153(a)(2), (b)(3)(A)(i), substituted ''Subject to paragraph (14), in lieu of payment'' for ''In lieu of payment'' and inserted at end ''Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.''

Subsec. (b)(12)(F). Pub. L. 110–275, §153(b)(3)(A)(ii), in concluding provisions, inserted ''or paragraph (14)'' after ''this paragraph'' and ''or under the system under paragraph (14)'' after ''subparagraph (B)''.

Subsec. (b)(12)(G). Pub. L. 110–275, §153(a)(1), inserted ''and before January 1, 2009,'' after ''April 1, 2007,'' in cl. (ii) and added cls. (iii) and (iv).

Subsec. (b)(13)(A). Pub. L. 110–275, §153(b)(3)(A)(iii)(I), substituted ''Subject to paragraph (14), the payment amounts'' for ''The payment amounts'' in introductory provisions.

Subsec. (b)(13)(B). Pub. L. 110–275, §153(b)(3)(A)(iii)(II), redesignated cl. (i) as subpar. (B), inserted '', subject to paragraph (14)'' before period at end, and struck out cl. (ii) which read as follows: ''Nothing in this paragraph, section 1395u(*o*) of this title, section 1395w–3a of this title, or section 1395w–3b of this title shall be construed as requiring or authorizing the bundling of payment for drugs and biologicals into the basic case-mix adjusted payment system under this paragraph.''

Subsec. (b)(14). Pub. L. 110–275, §153(b)(1), added par. (14).

Subsec. (h). Pub. L. 110–275, §153(c), added subsec. (h).

2006—Subsec. (b)(12)(F). Pub. L. 109–171, §5106(1), substituted ''Except as provided in subparagraph (G), nothing'' for ''Nothing'' in concluding provisions.

Subsec. (b)(12)(G). Pub. L. 109–432 amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: ''The Secretary shall increase the amount of the composite rate component of the basic case-mix adjusted system under subparagraph (B) for dialysis services furnished on or after January 1, 2006, by 1.6 percent above the amount of such composite rate component for such services furnished on December 31, 2005.''

Pub. L. 109–171, §5106(3), added subpar. (G). Former subpar. (G) redesignated (H).

Subsec. (b)(12)(H). Pub. L. 109–171, §5106(2), redesignated subpar. (G) as (H).

2003—Subsec. (b)(7). Pub. L. 108–173, §623(a), (b)(2), (d)(2), in first sentence substituted ''Subject to paragraph (12), the Secretary'' for ''The Secretary'', in fourth sentence substituted ''Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary'' for ''The Secretary'', and, in concluding provisions, struck out ''and'' before ''for such services furnished on or after January 1, 2001,'', inserted ''and before January 1, 2005,'' after ''January 1, 2001,'', and inserted '', and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004'' before period at end.

Subsec. (b)(11)(B). Pub. L. 108–173, §623(d)(3), inserted ''subject to paragraphs (12) and (13)'' before ''payment for such item'' in introductory provisions.

Subsec. (b)(12), (13). Pub. L. 108–173, §623(d)(1), added pars. (12) and (13).

2000—Subsec. (b)(7). Pub. L. 106–554 substituted ''for such services furnished on or after January 1, 2001, by 2.4 percent'' for ''for such services furnished on or after January 1, 2001, by 1.2 percent'' in concluding provisions.

1999—Subsec. (b)(7). Pub. L. 106–113 inserted concluding provisions.

1994—Subsec. (g)(3). Pub. L. 103–296 inserted before period at end '', except that, in so applying such sections and in applying section 405(*l*) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively''.

1993—Subsec. (b)(1)(C). Pub. L. 103–66, §13566(a)(1), substituted ''section 1395x(s)(2)(P)'' for ''section 1395x(s)(2)(Q)''.

Subsec. (b)(11)(B)(ii)(I). Pub. L. 103–66, §13566(a)(2), substituted ''1994'' for ''1991'' and ''$10'' for ''$11''.

1990—Subsec. (b)(1). Pub. L. 101–508, §4201(d)(2)(A), formerly §4201(d)(2), as renumbered by Pub. L. 103–432, §160(d)(3), added cl. (C).

Subsec. (b)(11). Pub. L. 101–508, §4201(d)(2)(B), formerly §4201(d)(3), as renumbered by Pub. L. 103–432, §160(d)(3), added subpar. (C).

Pub. L. 101–508, §4201(c)(1), designated existing provisions as subpar. (A) and added subpar. (B).

1989—Subsec. (b)(3)(A). Pub. L. 101–239, §6102(e)(8), inserted ''or, for services furnished on or after January 1, 1992, on the basis described in section 1395w–4 of this title'' after ''comparable services''.

Subsec. (b)(4). Pub. L. 101–239, §6203(b)(2), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (b)(7). Pub. L. 101–239, §6219(a), substituted ''organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2). The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—'' and subpars. (A) to (D) for ''network administrative organization (designated under subsection (c)(1)(A) for the network area in which the treatment is provided) for its necessary and proper administrative costs incurred in carrying out its responsibilities under subsection (c)(2).'' in last sentence.

Pub. L. 101–239, § 6203(b)(1), inserted after second sentence ''The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities.''

Subsec. (c)(8). Pub. L. 101–239, § 6219(b), added par. (8).

1987—Subsec. (b)(1). Pub. L. 100–203, § 4036(b), substituted ''transplantations'' for ''covered procedures and for self-dialysis training programs''.

Subsec. (b)(2)(C). Pub. L. 100–203, § 4065(b), substituted ''facilities (other than hospital outpatient departments)'' for ''facilities''.

Subsec. (c)(2)(F). Pub. L. 100–203, § 4036(d)(5)(A), struck out ''and subsection (g) of this section'' after ''required by subparagraph (H)''.

Subsec. (c)(6). Pub. L. 100–203, § 4036(d)(5)(B), struck out at end ''The Secretary shall periodically submit to the Congress such legislative recommendations as the Secretary finds warranted on the basis of such consultation and evidence to further the national objective of maximizing the use of home dialysis and transplantation consistent with good medical practice.''

Subsec. (f)(7)(B). Pub. L. 100–203, § 4036(c)(2), inserted ''(or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines)'' after ''January 1, 1988''.

Subsec. (g). Pub. L. 100–203, § 4036(d)(5)(C), (D), redesignated subsec. (h) as (g) and struck out former subsec. (g) which directed the Secretary to submit to Congress on July 1, 1979, and on July 1 of each year thereafter a report on end stage renal disease program.

Subsec. (h). Pub. L. 100–203, § 4036(d)(5)(D), redesignated subsec. (h) as (g).

Pub. L. 100–93 added subsec. (h).

1986—Subsec. (b)(7). Pub. L. 99–509, § 9335(j)(1), inserted at end ''The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the network administrative organization (designated under subsection (c)(1)(A) for the network area in which the treatment is provided) for its necessary and proper administrative costs incurred in carrying out its responsibilities under subsection (c)(2).''

Pub. L. 99–509, § 9335(a)(2), inserted ''and of pediatric facilities'' after ''isolated rural areas'' in third sentence, and inserted after third sentence ''Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed.''

Subsec. (c)(1)(A). Pub. L. 99–509, § 9335(d)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall establish, in accordance with such criteria as he finds appropriate, renal disease network areas, such network organizations (including a coordinating council, an executive committee of such council, and a medical review board, for each network area) as he finds necessary to accomplish such purpose, and a national end stage renal disease medical information system. The Secretary may by regulations provide for such coordination of network planning and quality assurance activities and such exchange of data and information among agencies with responsibilities for health planning and quality assurance activities under Federal law as is consistent with the economical and efficient administration of this section and with the responsibilities established for network organizations under this section.''

Subsec. (c)(1)(B). Pub. L. 99–509, § 9335(e), amended subpar. (B) generally, substituting ''network council and each medical review board'' for ''coordinating council and executive committee''.

Subsec. (c)(2)(A). Pub. L. 99–509, § 9335(f)(1), inserted ''and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs'' before the semicolon.

Subsec. (c)(2)(B). Pub. L. 99–509, § 9335(f)(2), inserted ''and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs'' before first semicolon.

Subsec. (c)(2)(D) to (F). Pub. L. 99–509, § 9335(f)(5), added subpars. (D) to (F). Former subpars. (D) and (E) redesignated (G) and (H), respectively.

Subsec. (c)(2)(G). Pub. L. 99–509, § 9335(f)(3), (5), redesignated former subpar. (D) as (G) and inserted ''and reporting to the Secretary on facilities and providers that are not providing appropriate medical care'' before the semicolon.

Subsec. (c)(2)(H). Pub. L. 99–509, § 9335(f)(4), (5), redesignated former subpar. (E) as (H) and inserted ''and encouraging participation in vocational rehabilitation programs'' after ''and transplantation''.

Subsec. (c)(3). Pub. L. 99–509, § 9335(g), inserted ''or to follow the recommendations of the medical review board'' after ''network plans and goals''.

Subsec. (c)(6). Pub. L. 99–509, § 9335(h), inserted ''and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment'' at end of first sentence.

Subsec. (c)(7). Pub. L. 99–509, § 9335(i)(1), added par. (7).

Subsec. (f)(7). Pub. L. 99–509, § 9335(k)(1), amended par. (7) generally. Prior to amendment, par. (7) read as follows: ''The Secretary shall conduct a study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients. In such cases in which the Secretary determines that such home cleaning and reuse of filters is a medically sound procedure, the Secretary shall conduct experiments to evaluate such home cleaning and reuse as a method of reducing the costs of the end stage renal disease program.''

1984—Subsecs. (a), (b)(1), (2)(A), (B), (3), (8). Pub. L. 98–369, § 2354(b)(41), substituted ''end stage'' for ''end-stage'' wherever appearing.

Subsec. (b)(11). Pub. L. 98–617 realigned margin of par. (11).

Pub. L. 98–369, § 2323(c), added par. (11).

Subsec. (c)(3). Pub. L. 98–369, § 2352(a), inserted provision that if the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

1983—Subsec. (b)(2)(A). Pub. L. 98–21 inserted ''or section 1395ww of this title (if applicable)'' after ''section 1395x(v) of this title''.

1981—Subsec. (b)(2)(B). Pub. L. 97–35, § 2145(a)(1), (2), substituted ''section 1395x(v) of this title) and consistent with any regulations promulgated under paragraph (7)'' for ''section 1395x(v) of this title)'' and struck out provisions that such regulations provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services, and include a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of services.

Subsec. (b)(3)(B). Pub. L. 97–35, § 2145(a)(3), substituted ''or other basis (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis)'' for ''or other basis''.

Subsec. (b)(4). Pub. L. 97–35, § 2145(a)(4), inserted reference to alternative basis of a method established under par. (7).

Subsec. (b)(6). Pub. L. 97–35, § 2145(a)(5), (6), substituted ''(except as may be provided in regulations

under paragraph (7)) shall such target rate exceed 75 percent'' and ''any other procedure (including methods established under paragraph (7)) which the Secretary'' for ''shall such target rate exceed 70 percent'' and ''any other procedure which the Secretary'', respectively.

Subsec. (b)(7) to (10). Pub. L. 97–35, §2145(a)(7), (8), added par. (7) and redesignated former pars. (7) to (9) as (8) to (10), respectively.

1980—Subsec. (e)(1). Pub. L. 96–499, §957(a)(1)–(3), substituted ''services, renal dialysis facilities, and nonprofit entities which the Secretary finds can furnish equipment economically and efficiently,'' for ''services and renal dialysis facilities'' and ''such providers, facilities, and nonprofit entities'' for ''such providers and facilities''.

Subsec. (e)(2). Pub. L. 96–499, §957(a)(4), substituted '', facility, or other entity will'' for ''or facility will''.

Subsec. (g). Pub. L. 96–499, §957(b), substituted ''July'' for ''April'' in two places.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103–296, set out as a note under section 401 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–66 applicable to erythropoietin furnished on or after Jan. 1, 1994, see section 13566(c) of Pub. L. 103–66, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–508, title IV, §4201(c)(2), Nov. 5, 1990, 104 Stat. 1388–104, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to erythropoietin furnished on or after January 1, 1991.''

Amendment by section 4201(d)(2) of Pub. L. 101–508 applicable to items and services furnished on or after July 1, 1991, see section 4201(d)(3)[(4)] of Pub. L. 101–508, set out as a note under section 1395x of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6203(b)(3), Dec. 19, 1989, 103 Stat. 2235, provided that: ''The amendments made by this subsection [amending this section] shall apply with respect to dialysis services, supplies, and equipment furnished on or after February 1, 1990.''

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by section 4065(b) of Pub. L. 100–203 effective Jan. 1, 1988, see section 4065(c) of Pub. L. 100–203, set out as a note under section 1395x of this title.

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–509, title IX, §9335(a)(3), Oct. 21, 1986, 100 Stat. 2029, provided that: ''The amendments made by paragraph (2) [amending this section] shall apply to applications filed on or after the date of the enactment of this Act [Oct. 21, 1986].''

Pub. L. 99–509, title IX, §9335(j)(2), Oct. 21, 1986, 100 Stat. 2032, as amended by Pub. L. 100–203, title IV, §4085(i)(21)(C), Dec. 22, 1987, 101 Stat. 1330–133, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to treatment furnished on or after January 1, 1987[,] except that, until network administrative organizations are established under section 1881(c)(1)(A) of the Social Security Act [42 U.S.C. 1395rr(c)(1)(A)] (as amended by subsection (d)(1) of this section), the distribution of payments described in the last sentence of section 1881(b)(7) of such Act shall be made based on the distribution of payments under section 1881 of such Act to network administrative organizations for fiscal year 1986.''

[Pub. L. 100–203, title IV, §4085(i)(21), Dec. 22, 1987, 101 Stat. 1330–133, provided that the amendment of section 9335(j)(2) of Pub. L. 99–509, set out above, by section 4085(i)(21)(C) of Pub. L. 100–203 is effective as if included in the enactment of Pub. L. 99–509.]

Pub. L. 99–509, title IX, §9335(*l*), Oct. 21, 1986, 100 Stat. 2033, provided that: ''The amendments made by subsections (e), (f), and (g) [amending this section] shall apply to network administrative organizations designated for network areas established under the amendment made by subsection (d)(1) [amending this section].''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98–369, see section 3(c) of Pub. L. 98–617, set out as a note under section 1395f of this title.

Amendment by section 2323(c) of Pub. L. 98–369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(d) of Pub. L. 98–369, set out as a note under section 1395*l* of this title.

Pub. L. 98–369, div. B, title III, §2352(b), July 18, 1984, 98 Stat. 1099, provided that: ''The amendment made by this section [amending this section] shall apply to determinations made by the Secretary on or after the date of the enactment of this Act [July 18, 1984].''

Amendment by section 2354(b)(41) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by Pub. L. 98–21 applicable to items and services furnished by or under arrangement with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, see section 604(a)(1) of Pub. L. 98–21, set out as a note under section 1395ww of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXI, §2145(b), Aug. 13, 1981, 95 Stat. 800, provided that: ''The amendments made by subsection (a) [amending this section] apply to services furnished on or after October 1, 1981, and the Secretary of Health and Human Services shall first promulgate regulations to carry out section 1881(b)(7) of the Social Security Act [42 U.S.C. 1395rr(b)(7)] not later than October 1, 1981.''

EFFECTIVE DATE

Section effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility's or provider's first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as an Effective Date of 1978 Amendment note under section 426 of this title.

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–275, title I, §153(b)(4), July 15, 2008, 122 Stat. 2556, provided that: ''Nothing in this subsection [amending this section and sections 1395x and 1395y of this title and repealing provisions set out as a note under this section] or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to

make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act [July 15, 2008].''

DRUG DESIGNATIONS

Pub. L. 113–93, title II, § 217(c), Apr. 1, 2014, 128 Stat. 1062, provided that: ''As part of the promulgation of annual rule for the Medicare end stage renal disease prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) for calendar year 2016, the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall establish a process for—

''(1) determining when a product is no longer an oral-only drug; and

''(2) including new injectable and intravenous products into the bundled payment under such system.''

AUDITS OF COST REPORTS OF ESRD PROVIDERS AS RECOMMENDED BY MEDPAC

Pub. L. 113–93, title II, § 217(e), Apr. 1, 2014, 128 Stat. 1063, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct audits of Medicare cost reports beginning during 2012 for a representative sample of providers of services and renal dialysis facilities furnishing renal dialysis services.

''(2) FUNDING.—For purposes of carrying out paragraph (1), the Secretary of Health and Human Services 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) to the Centers for Medicare & Medicaid Services Program Management Account of $18,000,000 for fiscal year 2014. Amounts transferred under this paragraph for a fiscal year shall be available until expended.''

DELAY OF IMPLEMENTATION OF ORAL-ONLY ESRD-RELATED DRUGS IN THE ESRD PROSPECTIVE PAYMENT SYSTEM; MONITORING

Pub. L. 112–240, title VI, § 632(b), Jan. 2, 2013, 126 Stat. 2354, as amended by Pub. L. 113–93, title II, § 217(a), Apr. 1, 2014, 128 Stat. 1061; Pub. L. 113–295, div. B, title II, § 204, Dec. 19, 2014, 128 Stat. 4065, provided that:

''(1) DELAY.—The Secretary of Health and Human Services may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2025. Notwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.

''(2) MONITORING.—With respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system under subsection (b)(14) of section 1881 of the Social Security Act (42 U.S.C. 1395rr(b)(14)), the Secretary of Health and Human Services shall monitor the bone and mineral metabolism of individuals with end stage renal disease.''

ANALYSIS OF CASE MIX PAYMENT ADJUSTMENTS

Pub. L. 112–240, title VI, § 632(c), Jan. 2, 2013, 126 Stat. 2354, provided that: ''By not later than January 1, 2016, the Secretary of Health and Human Services shall—

''(1) conduct an analysis of the case mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(D)(i)); and

''(2) make appropriate revisions to such case mix payment adjustments.''

INSPECTOR GENERAL STUDIES ON ESRD DRUGS

Pub. L. 108–173, title VI, § 623(c), Dec. 8, 2003, 117 Stat. 2312, provided that:

''(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct two studies with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the medicare program which are separately billed by end stage renal disease facilities.

''(2) STUDIES ON ESRD DRUGS.—

''(A) EXISTING DRUGS.—The first study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code exists prior to January 1, 2004.

''(B) NEW DRUGS.—The second study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code does not exist prior to January 1, 2004.

''(3) MATTERS STUDIED.—Under each study conducted under paragraph (1), the Inspector General shall—

''(A) determine the difference between the amount of payment made to end stage renal disease facilities under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for such drugs and biologicals and the acquisition costs of such facilities for such drugs and biologicals and which are separately billed by end stage renal disease facilities, and

''(B) estimate the rates of growth of expenditures for such drugs and biologicals billed by such facilities.

''(4) REPORTS.—

''(A) EXISTING ESRD DRUGS.—Not later than April 1, 2004, the Inspector General shall report to the Secretary [of Health and Human Services] on the study described in paragraph (2)(A).

''(B) NEW ESRD DRUGS.—Not later than April 1, 2006, the Inspector General shall report to the Secretary on the study described in paragraph (2)(B).''

DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED PAYMENT SYSTEM FOR ESRD SERVICES

Pub. L. 108–173, title VI, § 623(e), Dec. 8, 2003, 117 Stat. 2315, which provided for establishment of a demonstration project, to be conducted for the 3-year period beginning on Jan. 1, 2006, of the use of a fully case-mix adjusted payment system for end stage renal disease services that bundled into payment rates amounts for drugs and biologicals (including erythropoietin) furnished to end stage renal disease patients under the medicare program which were separately billed by end stage renal disease facilities as of Dec. 8, 2003, and clinical laboratory tests related to such drugs and biologicals, and which authorized appropriations for the demonstration project, was repealed by Pub. L. 110–275, title I, § 153(b)(3)(C), July 15, 2008, 122 Stat. 2556.

REPORT ON A BUNDLED PROSPECTIVE PAYMENT SYSTEM FOR END STAGE RENAL DISEASE SERVICES

Pub. L. 108–173, title VI, § 623(f), Dec. 8, 2003, 117 Stat. 2316, provided that:

''(1) REPORT.—

''(A) IN GENERAL.—Not later than October 1, 2005, the Secretary [of Health and Human Services] shall submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).

''(B) RECOMMENDATIONS.—The Secretary shall include in such report recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.

''(2) ELEMENTS AND FEATURES OF A BUNDLED PROSPECTIVE PAYMENT SYSTEM.—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:

''(A) BUNDLE OF ITEMS AND SERVICES.—A description of the bundle of items and services to be included under the prospective payment system.

''(B) CASE MIX.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.

''(C) WAGE INDEX.—A description of an adjustment to account for geographic differences in wages.

''(D) RURAL AREAS.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

''(E) OTHER ADJUSTMENTS.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

''(F) UPDATE FRAMEWORK.—A methodology for appropriate updates under the prospective payment system.

''(G) ADDITIONAL RECOMMENDATIONS.—Such other matters as the Secretary determines to be appropriate.''

PROHIBITION ON EXCEPTIONS

Pub. L. 106–554, §1(a)(6) [title IV, §422(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, as amended by Pub. L. 108–173, title VI, §623(b)(1), Dec. 8, 2003 117 Stat. 2312, provided that:

''(A) IN GENERAL.—Subject to subparagraphs (B), (C), and (D), the Secretary of Health and Human Services may not provide for an exception under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)) on or after December 31, 2000.

''(B) DEADLINE FOR NEW APPLICATIONS.—Subject to subparagraph (D), in the case of a facility that during 2000 did not file for an exception rate under such section, the facility may submit an application for an exception rate by not later than July 1, 2001.

''(C) PROTECTION OF APPROVED EXCEPTION RATES.—Any exception rate under such section in effect on December 31, 2000 (or, in the case of an application under subparagraph (B), as approved under such application) shall continue in effect so long as such rate is greater than the composite rate as updated by the amendment made by paragraph (1) [amending this section].

''(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.''

DEVELOPMENT OF ESRD MARKET BASKET

Pub. L. 106–554, §1(a)(6) [title IV, §422(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that:

''(1) DEVELOPMENT.—The Secretary of Health and Human Services shall collect data and develop an ESRD market basket whereby the Secretary can estimate, before the beginning of a year, the percentage by which the costs for the year of the mix of labor and nonlabor goods and services included in the ESRD composite rate under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)) will exceed the costs of such mix of goods and services for the preceding year. In developing such index, the Secretary may take into account measures of changes in—

''(A) technology used in furnishing dialysis services;

''(B) the manner or method of furnishing dialysis services; and

''(C) the amounts by which the payments under such section for all services billed by a facility for a year exceed the aggregate allowable audited costs of such services for such facility for such year.

''(2) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the index developed under paragraph (1) no later than July 1, 2002, and shall include in the report recommendations on the appropriateness of an annual or periodic update mechanism for renal dialysis services under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] based on such index.''

INCLUSION OF ADDITIONAL SERVICES IN COMPOSITE RATE

Pub. L. 106–554, §1(a)(6) [title IV, §422(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that:

''(1) DEVELOPMENT.—The Secretary of Health and Human Services shall develop a system which includes, to the maximum extent feasible, in the composite rate used for payment under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)), payment for clinical diagnostic laboratory tests and drugs (including drugs paid under section 1881(b)(11)(B) of such Act (42 U.S.C. 1395rr(b)(11)(B)) that are routinely used in furnishing dialysis services to medicare beneficiaries but which are currently separately billable by renal dialysis facilities.

''(2) REPORT.—The Secretary shall include, as part of the report submitted under subsection (b)(2) [set out above], a report on the system developed under paragraph (1) and recommendations on the appropriateness of incorporating the system into medicare payment for renal dialysis services.''

GAO STUDY ON ACCESS TO SERVICES

Pub. L. 106–554, §1(a)(6) [title IV, §422(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that:

''(1) STUDY.—The Comptroller General of the United States shall study access of medicare beneficiaries to renal dialysis services. Such study shall include whether there is a sufficient supply of facilities to furnish needed renal dialysis services, whether medicare payment levels are appropriate, taking into account audited costs of facilities for all services furnished, to ensure continued access to such services, and improvements in access (and quality of care) that may result in the increased use of long nightly and short daily hemodialysis modalities.

''(2) REPORT.—Not later than January 1, 2003, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).''

SPECIAL RULE FOR PAYMENT FOR 2001

Pub. L. 106–554, §1(a)(6) [title IV, §422(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that: ''Notwithstanding the amendment made by subsection (a)(1) [amending this section], for purposes of making payments under section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) for dialysis services furnished during 2001, the composite rate payment under paragraph (7) of such section—

''(1) for services furnished on or after January 1, 2001, and before April 1, 2001, shall be the composite rate payment 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 services furnished on or after April 1, 2001, and before January 1, 2002, shall be the composite rate payment (as determined taking into account the amendment made by subsection (a)(1)) increased by a transitional percentage allowance equal to 0.39 percent (to account for the timing of implementation of the CPI update).''

STUDY ON PAYMENT LEVEL FOR HOME HEMODIALYSIS

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §222(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, provided that: ''The Medicare Payment Advisory Commission shall conduct a study on the appropriateness of the differential in payment under the medicare program for hemodialysis services furnished in a facility and such services furnished in a home. Not later than 18 months

after the date of the enactment of this Act [Nov. 29, 1999], the Commission shall submit to Congress a report on such study and shall include recommendations regarding changes in medicare payment policy in response to the study.''

RENAL DIALYSIS-RELATED SERVICES

Pub. L. 105–33, title IV, § 4558, Aug. 5, 1997, 111 Stat. 463, provided that:

''(a) AUDITING OF COST REPORTS.—Beginning with cost reports for 1996, the Secretary shall audit cost reports of each renal dialysis provider at least once every 3 years.

''(b) IMPLEMENTATION OF QUALITY STANDARDS.—The Secretary of Health and Human Services shall develop, by not later than January 1, 1999, and implement, by not later than January 1, 2000, a method to measure and report quality of renal dialysis services provided under the medicare program under title XVIII of the Social Security Act [this subchapter].''

PROPAC STUDY ON ESRD COMPOSITE RATES

Pub. L. 101–508, title IV, § 4201(b), Nov. 5, 1990, 104 Stat. 1388–102, provided that:

''(1) IN GENERAL.—

''(A) STUDY.—The Prospective Payment Assessment Commission (in this subsection referred to as the 'Commission') shall conduct a study to determine the costs and services and profits associated with various modalities of dialysis treatments provided to end stage renal disease patients provided under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

''(B) RECOMMENDATIONS.—Based on information collected for the study described in subparagraph (A), the Commission shall make recommendations to Congress regarding the method or methods and the levels at which the payments made for the facility component of dialysis services by providers of service and renal dialysis facilities under title XVIII of the Social Security Act should be established for dialysis services furnished during fiscal year 1993 and the methodology to be used to update such payments for subsequent fiscal years. In making recommendations concerning the appropriate methodology the Commission shall consider—

''(i) hemodialysis and other modalities of treatment,

''(ii) the appropriate services to be included in such payments,

''(iii) the adjustment factors to be incorporated including facility characteristics, such as hospital versus free-standing facilities, urban versus rural, size and mix of services,

''(iv) adjustments for labor and nonlabor costs,

''(v) comparative profit margins for all types of renal dialysis providers of service and renal dialysis facilities,

''(vi) adjustments for patient complexity, such as age, diagnosis, case mix, and pediatric services, and

''(vii) efficient costs related to high quality of care and positive outcomes for all treatment modalities.

''(2) REPORT.—Not later than June 1, 1992, the Commission shall submit a report to the Committee on Finance of the Senate, and the Committees on Ways and Means and Energy and Commerce of the House of Representatives on the study conducted under paragraph (1)(A) and shall include in the report the recommendations described in paragraph (1)(B), taking into account the factors described in paragraph (1)(B).

''(3) ANNUAL REPORT.—The Commission, not later than March 1 before the beginning of each fiscal year (beginning with fiscal year 1993) shall report its recommendations to the Committee on Finance of the Senate and the Committees on Ways and Means and Energy and Commerce of the House of Representatives on an appropriate change factor which should be used for updating payments for services rendered in that fiscal year. The Commission in making such report to Congress shall consider conclusions and recommendations available from the Institute of Medicine.''

[Prospective Payment Assessment Commission (ProPAC) 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 ProPAC, and that, for that purpose, any reference in law to ProPAC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.]

STAFF-ASSISTED HOME DIALYSIS DEMONSTRATION PROJECT

Pub. L. 101–508, title IV, § 4202, Nov. 5, 1990, 104 Stat. 1388–104, as amended by Pub. L. 103–432, title I, § 160(b), Oct. 31, 1994, 108 Stat. 4443, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 9 months after the date of the enactment of this Act [Nov. 5, 1990], the Secretary of Health and Human Services shall establish and carry out a 3-year demonstration project to determine whether the services of a home dialysis staff assistant providing services to a patient during hemodialysis treatment at the patient's home may be covered under the medicare program in a cost-effective manner that ensures patient safety.

''(2) NUMBER OF PARTICIPANTS.—The total number of eligible patients receiving services under the demonstration project established under paragraph (1) may not exceed 800.

''(b) PAYMENTS TO PARTICIPATING PROVIDERS AND FACILITIES.—

''(1) SERVICES FOR WHICH PAYMENT MAY BE MADE.—

''(A) IN GENERAL.—Under the demonstration project established under subsection (a), the Secretary shall make payments for 3 years under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] to providers of services (other than a skilled nursing facility) or renal dialysis facilities for services of a qualified home hemodialysis staff assistant (as described in subsection (d)) provided to an individual described in subsection (c) during hemodialysis treatment at the individual's home in an amount determined under paragraph (2).

''(B) SERVICES DESCRIBED.—For purposes of subparagraph (A), the term 'services of a home hemodialysis staff assistant' means—

''(i) technical assistance with the operation of a hemodialysis machine in the patient's home and with such patient's care during in-home hemodialysis; and

''(ii) administration of medications within the patient's home to maintain the patency of the extra corporeal circuit.

''(2) AMOUNT OF PAYMENT.—

''(A) IN GENERAL.—Payment to a provider of services or renal dialysis facility participating in the demonstration project established under subsection (a) for the services described in paragraph (1) shall be prospectively determined by the Secretary, made on a per treatment basis, and shall be in an amount determined under subparagraph (B).

''(B) DETERMINATION OF PAYMENT AMOUNT.—(i) The amount of payment made under subparagraph (A) shall be the product of—

''(I) the rate determined under clause (ii) with respect to a provider of services or a renal dialysis facility; and

''(II) the factor by which the labor portion of the composite rate determined under section 1881(b)(7) of the Social Security Act [42 U.S.C. 1395rr(b)(7)] is adjusted for differences in area wage levels.

''(ii) The rate determined under this clause, with respect to a provider of services or renal dialysis facility, shall be equal to the difference between—

''(I) two-thirds of the labor portion of the composite rate applicable under section 1881(b)(7) of such Act to the provider or facility, and

''(II) the product of the national median hourly wage for a home hemodialysis staff assistant and the national median time expended in the provision of home hemodialysis staff assistant services (taking into account time expended in travel and predialysis patient care).

''(iii) For purposes of clause (ii)(II)—

''(I) the national median hourly wage for a home hemodialysis staff assistant and the national median average time expended for home hemodialysis staff assistant services shall be determined annually on the basis of the most recent data available, and

''(II) the national median hourly wage for a home hemodialysis staff assistant shall be the sum of 65 percent of the national median hourly wage for a licensed practical nurse and 35 percent of the national median hourly wage for a registered nurse.

''(C) PAYMENT AS ADD-ON TO COMPOSITE RATE.—The amount of payment determined under this paragraph shall be in addition to the amount of payment otherwise made to the provider of services or renal dialysis facility under section 1881(b) of such Act.

''(c) INDIVIDUALS ELIGIBLE TO RECEIVE SERVICES UNDER PROJECT.—

''(1) IN GENERAL.—An individual may receive services from a provider of services or renal dialysis facility participating in the demonstration project if—

''(A) the individual is not a resident of a nursing facility;

''(B) the individual is an end stage renal disease patient entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.];

''(C) the individual's physician certifies that the individual is confined to a bed or wheelchair and cannot transfer themselves [sic] from a bed to a chair;

''(D) the individual has a serious medical condition (as specified by the Secretary) which would be exacerbated by travel to and from a dialysis facility;

''(E) the individual is eligible for ambulance transportation to receive routine maintenance dialysis treatments, and, based on the individual's medical condition, there is reasonable expectation that such transportation will be used by the individual for a period of at least 6 consecutive months, such that the cost of ambulance transportation can reasonably be expected to meet or exceed the cost of home hemodialysis staff assistance as provided under subsection (b)(2); and

''(F) no family member or other individual is available to provide such assistance to the individual.

''(2) COVERAGE OF INDIVIDUALS CURRENTLY RECEIVING SERVICES.—Any individual who, on the date of the enactment of this Act [Nov. 5, 1990], is receiving staff assistance under the experimental authority provided under section 1881(f)(2) of the Social Security Act [42 U.S.C. 1395rr(f)(2)] shall be deemed to be an eligible individual for purposes of this subsection.

''(3) CONTINUATION OF COVERAGE UPON TERMINATION OF PROJECT.—Notwithstanding any provision of title XVIII of the Social Security Act, any individual receiving services under the demonstration project established under subsection (a) as of the date of the termination of the project shall continue to be eligible for home hemodialysis staff assistance after such date under such title on the same terms and conditions as applied under the demonstration project.

''(d) QUALIFICATIONS FOR HOME HEMODIALYSIS STAFF ASSISTANTS.—For purposes of subsection (b), a home dialysis aide is qualified if the aide—

''(1) meets minimum qualifications as specified by the Secretary; and

''(2) meets any applicable qualifications as specified under the law of the State in which the home hemodialysis staff assistant is providing services.

''(e) REPORTS.—

''(1) INTERIM STATUS REPORT.—Not later than December 1, 1992, the Secretary shall submit to Congress a preliminary report on the status of the demonstration project established under subsection (a).

''(2) FINAL REPORT.—Not later than December 31, 1995, the Secretary shall submit to Congress a final report evaluating the project, and shall include in such report recommendations regarding appropriate eligibility criteria and cost-control mechanisms for medicare coverage of the services of a home dialysis aide providing medical assistance to a patient during hemodialysis treatment at the patient's home.

''(f) AUTHORIZATION OF APPROPRIATIONS.—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 not more than the following amounts to carry out the demonstration project established under subsection (a) (without regard to amounts appropriated in advance in appropriation Acts):

''(1) For fiscal year 1991, $4,000,000.

''(2) For fiscal year 1992, $4,000,000.

''(3) For fiscal year 1993, $3,000,000.

''(4) For fiscal year 1994, $2,000,000.

''(5) For fiscal year 1995, $1,000,000.''

STUDIES OF END-STAGE RENAL DISEASE PROGRAM

Pub. L. 100–203, title IV, §4036(d)(1)–(4), Dec. 22, 1987, 101 Stat. 1330–79, provided that:

''(1) The Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall arrange for a study of the end-stage renal disease program within the medicare program.

''(2) Among other items, the study shall address—

''(A) access to treatment by both individuals eligible for medicare benefits and those not eligible for such benefits;

''(B) the quality of care provided to end-stage renal disease beneficiaries, as measured by clinical indicators, functional status of patients, and patient satisfaction;

''(C) the effect of reimbursement on quality of treatment;

''(D) major epidemiological and demographic changes in the end-stage renal disease population that may affect access to treatment, the quality of care, or the resource requirements of the program; and

''(E) the adequacy of existing data systems to monitor these matters on a continuing basis.

''(3) The Secretary shall submit to Congress, not later than 3 years after the date of the enactment of this Act [Dec. 22, 1987], a report on the study.

''(4) The Secretary shall request the National Academy of Sciences, acting through the Institute of Medicine, to submit an application to conduct the study described in this section. If the Academy submits an acceptable application, the Secretary shall enter into an appropriate arrangement with the Academy for the conduct of the study. If the Academy does not submit an acceptable application to conduct the study, the Secretary may request one or more appropriate nonprofit private entities to submit an application to conduct the study and may enter into an appropriate arrangement for the conduct of the study by the entity which submits the best acceptable application.''

RATES FOR DIALYSIS SERVICES

Pub. L. 99–509, title IX, §9335(a)(1), Oct. 21, 1986, 100 Stat. 2029, as amended by Pub. L. 101–239, title VI, §6203(a)(1), Dec. 19, 1989, 103 Stat. 2235; Pub. L. 101–508, title IV, §4201(a), Nov. 5, 1990, 104 Stat. 1388–102; Pub. L. 106–113, div. B, §1000(a)(6) [title II, §222(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, provided that: ''Effective with respect to dialysis services provided on or after October

1, 1986, and before December 31, 1990, the Secretary of Health and Human Services shall establish the base rate for routine dialysis treatment in a free-standing facility and in a hospital-based facility under section 1881(b)(7) of the Social Security Act [42 U.S.C. 1395rr(b)(7)] at a level equal to the respective rate in effect as of May 13, 1986, reduced by $2.00. With respect to services furnished on or after January 1, 1991, and before January 1, 2000, such base rate shall be equal to the respective rate in effect as of September 30, 1990 (determined without regard to any reductions imposed pursuant to section 6201 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, set out as a note under section 904 of Title 2, The Congress]), increased by $1.00. No change may be made in the base rate in effect as of September 30, 1990, unless the Secretary makes such change in accordance with notice and comment requirements set forth in section 1871(b)(1) of such Act [42 U.S.C. 1395rr(b)(1)].''

[Pub. L. 101–239, title VI, § 6203(a)(2), Dec. 19, 1989, 103 Stat. 2235, provided that: ''The amendment made by paragraph (1) [amending section 9335(a)(1) of Pub. L. 99–509, set out above] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509].'']

STUDY AND REPORT ON MEDICARE PAYMENT RATE REDUCTIONS FOR PATIENTS WITH END STAGE RENAL DISEASE

Pub. L. 99–509, title IX, § 9335(b), Oct. 21, 1986, 100 Stat. 2029, directed Secretary of Health and Human Services to provide for a study to evaluate the effects of reductions in the rates of payment for facility and physicians' services under the medicare program for patients with end stage renal disease on their access to care or on the quality of care, and a report to Congress on results of the study by not later than Jan. 1, 1988, with Secretary to enter into an appropriate arrangement with the National Academy of Sciences or other appropriate nonprofit private entity for the conduct of the study.

DEADLINE FOR ESTABLISHING NEW END STAGE RENAL DISEASE NETWORK AREAS; TRANSITION

Pub. L. 99–509, title IX, § 9335(d)(2), (3), Oct. 21, 1986, 100 Stat. 2031, as amended by Pub. L. 100–203, title IV, § 4009(j)(6)(E), Dec. 22, 1987, 101 Stat. 1330–59, provided that:

''(2) DEADLINE FOR ESTABLISHING NEW AREAS.—The Secretary of Health and Human Services shall establish end stage renal disease network areas, pursuant to the amendment made by paragraph (1) [amending this section], not later than May 1, 1987. The Secretary shall designate network administrative organizations for such areas by not later than July 1, 1987.

''(3) TRANSITION.—If, under the amendment made by paragraph (1), the Secretary designates a network administrative organization for an area which was not previously designated for that area, the Secretary shall offer to continue to fund the previously designated organization for that area for a period of 30 days after the first date the newly designated organization assumes the duties of a network administrative organization for that area.''

REPORT ON ESTABLISHMENT OF NATIONAL END STAGE RENAL DISEASE REGISTRY

Pub. L. 99–509, title IX, § 9335(i)(2), Oct. 21, 1986, 100 Stat. 2032, provided that: ''The Secretary of Health and Human Services shall submit to the Congress, no later than April 1, 1987, a full report on the progress made in establishing the national end stage renal disease registry under the amendment made by paragraph (1) [amending this section] and shall establish such registry by not later than January 1, 1988.''

DEADLINE FOR ESTABLISHMENT OF PROTOCOLS ON REUSE OF DIALYZER FILTERS

Pub. L. 99–509, title IX, § 9335(k)(2), Oct. 21, 1986, 100 Stat. 2033, as amended by Pub. L. 100–203, title IV, § 4036(c)(1)(A), Dec. 22, 1987, 101 Stat. 1330–79, provided that: ''The Secretary of Health and Human Services shall establish the protocols described in section 1881(f)(7)(A) of the Social Security Act [42 U.S.C. 1395rr(f)(7)(A)] by not later than October 1, 1987 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines).''

[Pub. L. 100–203, title IV, § 4036(c)(1)(B), Dec. 22, 1987, 101 Stat. 1330–79, provided that: ''The amendment made by subparagraph (A) [amending section 9335(k)(2) of Pub. L. 99–509, set out above] shall be effective as if included in the enactment of section 9335(k)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509].'']

LIMITATION ON MERGER OF END STAGE RENAL DISEASE NETWORKS

Pub. L. 99–272, title IX, § 9214, Apr. 7, 1986, 100 Stat. 180, provided that: ''The Secretary of Health and Human Services shall maintain renal disease network organizations as authorized under section 1881(c) of the Social Security Act [42 U.S.C. 1395rr(c)], and may not merge the network organizations into other organizations or entities. The Secretary may consolidate such network organizations, but only if such consolidation does not result in fewer than 14 such organizations being permitted to exist.''

§ 1395rr–1. Medicare coverage for individuals exposed to environmental health hazards

(a) Deeming of individuals as eligible for medicare benefits

(1) In general

For purposes of eligibility for benefits under this subchapter, an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(2) shall be deemed to meet the conditions specified in section 426(a) of this title.

(2) Discretionary deeming

For purposes of eligibility for benefits under this subchapter, the Secretary may deem an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(3) to meet the conditions specified in section 426(a) of this title.

(3) Effective date of coverage

An Individual[1] who is deemed eligible for benefits under this subchapter under paragraph (1) or (2) shall be—

(A) entitled to benefits under the program under Part[1] A as of the date of such deeming; and

(B) eligible to enroll in the program under Part[1] B beginning with the month in which such deeming occurs.

(b) Pilot program for care of certain individuals residing in emergency declaration areas

(1) Program; purpose

(A) Primary pilot program

The Secretary shall establish a pilot program in accordance with this subsection to provide innovative approaches to furnishing comprehensive, coordinated, and cost-effective care under this subchapter to individuals described in paragraph (2)(A).

(B) Optional pilot programs

The Secretary may establish a separate pilot program, in accordance with this sub-

[1] So in original. Probably should not be capitalized.