to reflect renumbering of corresponding section of original act.

**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 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.

**Preferential Services for Indians with Medicare Coverage Not Authorized**
Pub. L. 94–437, title IV, § 401(d), Sept. 30, 1976, 90 Stat. 1409, 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 of this subchapter 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-care 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) 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 1395l(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

1 See References in Text note below.
made for part B services furnished by such providers and facilities to such individuals.

(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 1395oo 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 the 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 renegotiated 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 meth-
od (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) of this section) for such organizations’ necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2) of this section. The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) of this section 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 a 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 1395rr 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. Payment for such vaccine and its administration shall be made separately in accordance with section 1395rr of this title.

(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 1395rr 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.

(ii) the difference between payment amounts under this subchapter for separately billed drugs and biologicals for which a billing code exists before January 1, 2009, by 1.6 percent above the amount of such composite rate component for such services furnished on December 31, 2009.

(iii) 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.

(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)(ii) 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 2006 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 1395oo 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 payments 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 (B), 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 furnished on or after January 1, 2011, in a form and manner specified by 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 under the payment system under this paragraph.

(i) 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, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014, such payment adjustment shall not be less than 10 percent; and

(ii) 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)(B), 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 ap-
applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such subparagraph.

(F)(i)(I) Subject to subclause (II) 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.

(II) For 2012 and each subsequent year, after determining the increase factor described in subparagraph (A), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1395w(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in such increase factor being less than 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.

(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 1395f of this title, section 1395oo 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 payments, 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.

(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)—
(A) encouraging, consistent with sound med-
ical practice, the use of those treatment set-
tings most compatible with the successful re-
habilitation of the patient and the participa-
tion of patients, providers of services, and
renal disease facilities in vocational rehabili-
tation programs;
(B) developing criteria and standards relat-
ing to the quality and appropriateness of pa-
tient care and with respect to working with
patients, facilities, and providers in encourag-
ing participation in vocational rehabilitation
programs; and network goals with respect to
the placement of patients in self-care settings
and undergoing or preparing for transplant-
tion;
(C) evaluating the procedure by which facili-
ties and providers in the network assess the
appropriateness of patients for proposed treat-
ment 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), utiliz-
ing standards of care established by the net-
work organization to assure proper medical
care;
(F) collecting, validating, and analyzing such
data as are necessary to prepare the re-
ports required by subparagraph (H) and to as-
sure the maintenance of the registry estab-
lished under paragraph (7);
(G) identifying facilities and providers that
are not cooperating toward meeting network
goals and assisting such facilities and provid-
ers in developing appropriate plans for correc-
tion and reporting to the Secretary on facili-
ties and providers that are not providing ap-
propriate medical care; and
(H) submitting an annual report to the Sec-
retary on July 1 of each year which shall in-
clude 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), identi-
fication of those facilities that have consist-
ently failed to cooperate with network goals,
and recommendations with respect to the need
for additional or alternative services or facili-
ties in the network in order to meet the net-
work goals, including self-dialysis training,
transplantation, and organ procurement facili-
ties.
(3) Where the Secretary determines, on the
basis of the data contained in the network’s an-
nual report and such other relevant data as may
be available to him, that a facility or provider
has consistently failed to cooperate with net-
work plans and goals or to follow the recom-
mandations of the medical review board, he may
terminate or withhold certification of such fa-
cility or provider (for purposes of payment for
services furnished to individuals with end stage
renal disease) until he determines that such pro-
vider or facility is making reasonable and ap-
propriate efforts to cooperate with the network’s
plans and goals. If the Secretary determines
that the facility’s or provider’s failure to co-
operate 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 facil-
ity and to the public, impose such other sanc-
tions 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 facili-
ty or provider, and graduated reduction in re-
imbursement for all patients.
(4) The Secretary shall, in determining wheth-
ner 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 ap-
propriate professional and planning organiza-
tions, shall provide such guidelines with respect
to the planning and delivery of renal disease
services as are necessary to assist network or-
ganizations in their development of their respec-
tive networks’ goals to promote the optimum
use of self-dialysis and transplantation by suit-
able 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 di-
alysis and transplantation.
(7) The Secretary shall establish a national
data collection activities, and such con-
solidation of existing end stage renal disease
data systems, as is necessary to achieve the pur-
pose of such registry, shall determine the ap-
propriate 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.

(9) A donor of 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.

(10) Reimbursement for the costs of artificial kidney and automated dialysis peritoneal machines for home dialysis

(11) 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.

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

(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 modifications 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.

(13) 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 participation 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 dialyzer filters for those facilities and providers which voluntarily elect to reuse such filters.

(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) of this section 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) of this section,

(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) of this section, 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(i) 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 a protocol or requirement subjects such a protocol or facility under the system under the year, payments otherwise made to such

(B) Use of endorsed measures

(i) In general

Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(i) 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.

(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 subparagraph (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 1395oo 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 pa-
tient 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, 1995, ch. 531, title XVIII, §1881, as added Pub. L. 100–203, title IV, §4036(b), inserted subject to paragraph (14), in lieu of payment,, for such services furnished by renal dialysis facilities, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

Subsec. (b)(12)(F). Pub. L. 110–275 inserted “subject to paragraph (14), the payment amounts” for “The payment amounts” in introductory provisions.

Subsec. (b)(13)(A). Pub. L. 110–275 inserted “subject to paragraph (14), the payment amounts” for “The payment amounts” in introductory provisions.

References in Text

Parts A and B, referred to in text, are classified to sections 1395ct and 1395q of this title, respectively.

Section 1395xx(a)(2)(P) of this title, related to index under this section.

Section 1395xx(a)(2)(O) of this title, referred to in subsec. (b)(1), is section 1147(f)(6)(B)(ii)(II) of Pub. L. 103–422, title V, §5106, 120 Stat. 485, 496, for such services furnished on or after January 1, 2006, if provider of services 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)(II)(v), redesignated section 1395u(3) of this title, as amended Pub. L. 104–193, renumbered subpar. (1) as (2), and added subpar. (3).


Subsec. (h). Pub. L. 110–275, §153(c), redesignated subpar. (h) as (i).


Subsec. (b)(12)(G). Pub. L. 110–432 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 payment system under subparagraph (B) for dialysis services furnished on or after January 1, 2006, if provider of services 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. (h). Pub. L. 110–275, §153(c), redesignated subpar. (h) as (i).


Subsec. (b)(12)(F). Pub. L. 110–432 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 payment system under subparagraph (B) for dialysis services furnished on or after January 1, 2006, if provider of services 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.”


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Subsec. (b)(12)(F). Pub. L. 110–432 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 payment system under subparagraph (B) for dialysis services furnished on or after January 1, 2006, if provider of services 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. (c)(6). Pub. L. 99–509, §8335(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, §8335(l)(1), added par. (7). Pub. L. 99–509, §8335(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.


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

Subsec. (c)(3). Pub. L. 98–369, §2323(a), inserted proviso 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 1395(v) of this title".

1981—Subsec. (b)(2)(B). Pub. L. 97–35, §2145(a)(1), (2), substituted "any regulations promulgated under paragraph (7)" for "section 1395(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 "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)(6). Pub. L. 97–35, §2145(a)(5), (6), substituted "except as may be provided in regulations under paragraph (7)" for "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 75 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 non-profit entities which the Secretary finds can furnish equipment economically and efficiently," for "services and renal dialysis facilities" and such providers, facilities, and non-profit 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 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 13565 of this title.

Effective Date of 1990 Amendment
Section 4201(c)(2) of Pub. L. 101–508 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 13565 of this title.

Effective Date of 1989 Amendment
Section 6203(b)(3) of Pub. L. 101–239 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 Amendments
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 13565 of this title.

Amendment by Pub. L. 100–53 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 1330a–7 of this title.

Effective Date of 1986 Amendment
Section 9335(a)(3) of Pub. L. 99–509 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].""

Section 9335(j)(2) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, §4085(j)(21)(C), Dec. 22, 1987, 101 Stat. 1330–133, provided that: "$The amendments 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 [subsec. (c)(1)(A) of this section] (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."


Section 9335(j) of Pub. L. 99–509 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 Amendments
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 13565 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 13565 of this title.
Section 2352(b) of Pub. L. 98–369 provided that: "The amendment 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, 1981]."

Amendment by section 2354(b)(4) of Pub. L. 98–369 effective July 18, 1981, 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 604(a)(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. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1981 Amendment**

Section 2145(b) of Pub. L. 97–33 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 1885(b)(7) of the Social Security Act [subsec. (b)(7) of this section] 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 1395ww of this title.

**Construction of 2008 Amendment**

Pub. L. 110–275, title I, §153(b)(4), July 15, 2008, 122 Stat. 2315, 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)(ii) of section 1811(b)(1) 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]."

**Inspector General Studies on ESRD Drugs**

Pub. L. 108–173, title VI, §623(c), Dec. 8, 2003, 117 Stat. 2315, provided that: "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.

"(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct 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.

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

"(D) RURAL AREAS.—The appropriate provision of the amendments 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


“(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 conduct 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 component 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 [this subchapter] 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.”

RENAI 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

Section 4201(b) of Pub. L. 101–508 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 [this subchapter].

"(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 and 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


"(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 [this subchapter] 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 [subsec. (b)(7) of this section] 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 pre-dialysis patient care).

"(iii) For purposes of clause (ii)(I)—

"(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 [this subchapter];

"(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 [subsec. (f)(2) of this section] 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 (section 1395t of this title)) 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

Section 4038(d)(1)–(4) of Pub. L. 101-203 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 non-profit 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


"(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.

"(6) For fiscal year 1996, $1,000,000.

"(7) For fiscal year 1997, $1,000,000.

"(8) For fiscal year 1998, $1,000,000.

"(9) For fiscal year 1999, $1,000,000.

"(10) For fiscal year 2000, $1,000,000.

"(11) For fiscal year 2001, $1,000,000.

"(12) For fiscal year 2002, $1,000,000.

"(13) For fiscal year 2003, $1,000,000.

"(14) For fiscal year 2004, $1,000,000.

"(15) For fiscal year 2005, (A) for fiscal year 2005, $1,000,000.

"(16) For fiscal year 2006, $1,000,000.

"(17) For fiscal year 2007, $1,000,000.

"(18) For fiscal year 2008, $1,000,000.

"(19) For fiscal year 2009, $1,000,000.

"(20) For fiscal year 2010, $1,000,000.

"(21) For fiscal year 2011, $1,000,000.

"(22) For fiscal year 2012, $1,000,000.

"(23) For fiscal year 2013, $1,000,000.

"(24) For fiscal year 2014, $1,000,000.

"(25) For fiscal year 2015, $1,000,000.

"(26) For fiscal year 2016, $1,000,000.

"(27) For fiscal year 2017, $1,000,000.

"(28) For fiscal year 2018, $1,000,000.

"(29) For fiscal year 2019, $1,000,000.

"(30) For fiscal year 2020, $1,000,000.

"(31) For fiscal year 2021, $1,000,000.

"(32) For fiscal year 2022, $1,000,000.

"(33) For fiscal year 2023, $1,000,000.

"(34) For fiscal year 2024, $1,000,000.

"(35) For fiscal year 2025, $1,000,000.

"(36) For fiscal year 2026, $1,000,000.

"(37) For fiscal year 2027, $1,000,000.

"(38) For fiscal year 2028, $1,000,000.

"(39) For fiscal year 2029, $1,000,000.

"(40) For fiscal year 2030, $1,000,000.

"(41) For fiscal year 2031, $1,000,000.

"(42) For the fiscal year 2031, $1,000,000.

"(43) For the fiscal year 2032, $1,000,000.

"(44) For the fiscal year 2033, $1,000,000.

"(45) For the fiscal year 2034, $1,000,000.

"(46) For the fiscal year 2035, $1,000,000.

"(47) The amendment made by paragraph (1) (amending sec-
DEADLINE FOR ESTABLISHING NEW END STAGE RENAL DISEASE NETWORK AREAS; TRANSITION


“(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.”

DEADLINE FOR ESTABLISHMENT OF NATIONAL END STAGE RENAL DISEASE REGISTRY

Section 3335(i)(2) of Pub. L. 99–509 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


(Section 4036(c)(1)(B) of Pub. L. 100–203 provided that: “The amendment made by subparagraph (A) [amending section 3335(k)(2) of Pub. L. 99–509, set out above] shall be effective as if included in the enactment of section 3335(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 [subsec. (c) of this section], 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)(2) to meet the conditions specified in section 426(a) of this title.

(3) Effective date of coverage

An Individual1 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 A as of the date of such deeming; and

(B) eligible to enroll in the program under Part 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 subsection, with respect to each geographic area subject to an emergency declaration (other than the declaration of June 17, 2009), in order to furnish such comprehensive, coordinated and cost-effective care to individuals described in paragraph (2)(B) who reside in such area.

(2) Individual described

For purposes of paragraph (1), an individual described in this paragraph is an individual who enrolls in part B, submits to the Secretary an application to participate in the applicable pilot program under this subsection, and—

(A) is an environmental exposure affected individual described in subsection (e)(2) who resides in or around the geographic area subject to an emergency declaration made as of June 17, 2009; or

1 So in original. Probably should not be capitalized.