

“(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section;”

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2010.

**SEC. 153. RENAL DIALYSIS PROVISIONS.**

(a) COMPOSITE RATE.—

(1) UPDATE.—Section 1881(b)(12)(G) of the Social Security Act (42 U.S.C. 1395rr(b)(12)(G)) is amended—

(A) in clause (i), by striking “and” at the end;

(B) in clause (ii)—

(i) by inserting “and before January 1, 2009,” after “April 1, 2007;” and

(ii) by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new clauses:

“(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.”

(2) SITE NEUTRAL COMPOSITE RATE.—Section 1881(b)(12)(A) of the Social Security Act (42 U.S.C. 1395rr(b)(12)(A)) is amended by adding at the end the following new sentence: “Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.”

(b) DEVELOPMENT OF ESRD BUNDLED PAYMENT SYSTEM.—

(1) IN GENERAL.—Section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraph:

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

“(ii) In implementing the system under this paragraph the Secretary shall ensure that the estimated total amount of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (i), the Secretary shall

use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

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

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

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

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

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

Such term does not include vaccines.

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

“(D) Such system—

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

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

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

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

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

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

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

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

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

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

“(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

“(F)(i) Subject to 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 minus 1.0 percentage point.

“(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) The Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i) minus 1.0 percentage point.

“(G) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

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

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

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

(2) PROHIBITION OF UNBUNDLING.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)), as amended by section 135(a)(2), is amended—

(A) in paragraph (22), by striking “or” at the end;

(B) in paragraph (23), by striking the period at the end and inserting “; or”; and

(C) by inserting after paragraph (23) the following new paragraph:

“(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.”

(3) CONFORMING AMENDMENTS.—(A) Section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended—

(i) in paragraph (12)(A), by striking “In lieu of payment” and inserting “Subject to paragraph (14), in lieu of payment”;

(ii) in the second sentence of paragraph (12)(F)—

(I) by inserting “or paragraph (14)” after “this paragraph”; and

(II) by inserting “or under the system under paragraph (14)” after “subparagraph (B)”; and

(iii) in paragraph (13)—

(I) in subparagraph (A), in the matter preceding clause (i), by striking “The payment amounts” and inserting “Subject to paragraph (14), the payment amounts”; and

(II) in subparagraph (B)—

(aa) in clause (i), by striking “(i)” after “(B)” and by inserting “, subject to paragraph (14)” before the period at the end; and

(bb) by striking clause (ii).

(B) Section 1861(s)(2)(F) of the Social Security Act (42 U.S.C. 1395x(s)(2)(F)) is amended by inserting “, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B))” before the semicolon at the end.

(C) Section 623(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (42 U.S.C. 1395rr note) is repealed.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act.

(c) QUALITY INCENTIVES IN THE END-STAGE RENAL DISEASE PROGRAM.—Section 1881 of the Social Security Act (42 U.S.C. 1395rr) is amended by adding at the end the following new subsection:

“(h) QUALITY INCENTIVES IN THE END-STAGE RENAL DISEASE PROGRAM.—

“(1) QUALITY INCENTIVES.—

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

“(B) REQUIREMENT.—The requirement described in this subparagraph is that the provider or facility meets (or

exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

“(C) NO EFFECT IN SUBSEQUENT YEARS.—The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

“(2) MEASURES.—

“(A) IN GENERAL.—The measures specified under this paragraph with respect to the year involved shall include—

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

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

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

“(I) iron management;

“(II) bone mineral metabolism; and

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

“(B) USE OF ENDORSED MEASURES.—

“(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iii) must have been endorsed by the entity with a contract under section 1890(a).

“(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 1890(a), 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 paragraph (4)(D) (in this subsection referred to as the ‘total performance score’).

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

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

“(B) PERFORMANCE SCORE WITH RESPECT TO INDIVIDUAL MEASURES.—The Secretary shall also calculate separate performance scores for each measure, including for dialysis adequacy and anemia management.

“(4) PERFORMANCE STANDARDS.—

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

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

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

“(D) PERFORMANCE PERIOD.—The Secretary shall establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.

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

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

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

“(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

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

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

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

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

“(6) PUBLIC REPORTING.—

“(A) IN GENERAL.—The Secretary shall establish procedures for making information regarding performance under this subsection available to the public, including—

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

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

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

“(C) CERTIFICATES.—

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

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

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

(d) GAO REPORT ON ESRD BUNDLING SYSTEM AND QUALITY INITIATIVE.—Not later than March 1, 2013, the Comptroller General of the United States shall submit to Congress a report on the implementation of the payment system under subsection (b)(14) of section 1881 of the Social Security Act (as added by subsection (b)) for renal dialysis services and related services (defined in subparagraph (B) of such subsection (b)(14)) and the quality initiative under subsection (h) of such section 1881 (as added by subsection (b)). Such report shall include the following information:

(1) The changes in utilization rates for erythropoiesis stimulating agents.

(2) The mode of administering such agents, including information on the proportion of individuals receiving such agents intravenously as compared to subcutaneously.

(3) An analysis of the payment adjustment under subparagraph (D)(iii) of such subsection (b)(14), including an examination of the extent to which costs incurred by rural, low-volume providers and facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other providers and facilities in furnishing such services, and a recommendation regarding the appropriateness of such adjustment.

(4) The changes, if any, in utilization rates of drugs and biologicals that the Secretary identifies under subparagraph (B)(iii) of such subsection (b)(14), and any oral equivalent or oral substitutable forms of such drugs and biologicals or of drugs and biologicals described in clause (ii), that have occurred after implementation of the payment system under such subsection (b)(14).

(5) Any other information or recommendations for legislative and administrative actions determined appropriate by the Comptroller General.

**SEC. 154. DELAY IN AND REFORM OF MEDICARE DMEPOS COMPETITIVE ACQUISITION PROGRAM.**

**(a) TEMPORARY DELAY AND REFORM.—**

(1) **IN GENERAL.**—Section 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w-3(a)(1)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (B)(i), in the matter before subclause (I), by inserting “consistent with subparagraph (D)” after “in a manner”;

(ii) in subparagraph (B)(i)(II), by striking “80” and “in 2009” and inserting “an additional 70” and “in 2011”, respectively;

(iii) in subparagraph (B)(i)(III), by striking “after 2009” and inserting “after 2011 (or, in the case of national mail order for items and services, after 2010)”; and

(iv) by adding at the end the following new subparagraphs:

“(D) **CHANGES IN COMPETITIVE ACQUISITION PROGRAMS.—**

“(i) **ROUND 1 OF COMPETITIVE ACQUISITION PROGRAM.**—Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

“(I) the contracts awarded under this section before the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1841;