SEC. 2501. PRESCRIPTION DRUG REBATES.

(a) INCREASE IN MINIMUM REBATE PERCENTAGE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(1) IN GENERAL.—Section 1927(c)(1)(B) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(B)) is amended—

(A) in clause (i)—

(i) in subclause (IV), by striking "and" at the end;

(ii) in subclause (V)—

(I) by inserting "and before January 1, 2010" after "December 31, 1995,"; and

(II) by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following new subclause:

"(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent."; and

(B) by adding at the end the following new clause:

"(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

"(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

"(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

"(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

"(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.".

(2) RECAPTURE OF TOTAL SAVINGS DUE TO INCREASE.—Section 1927(b)(1) of such Act (42 U.S.C. 1396r–8(b)(1)) is amended by adding at the end the following new subparagraph:

"(C) SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.—

"(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

"(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

"(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

"(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).".

(b) INCREASE IN REBATE FOR OTHER DRUGS.—Section 1927(c)(3)(B) of such Act (42 U.S.C. 1396r–8(c)(3)(B)) is amended—

(1) in clause (i), by striking "and" at the end;

(2) in clause (ii)—

(A) by inserting "and before January 1, 2010," after "December 31, 1993,"; and

(B) by striking the period and inserting "; and"; and

(3) by adding at the end the following new clause:

"(iii) after December 31, 2009, is 13 percent.".

(c) EXTENSION OF PRESCRIPTION DRUG DISCOUNTS TO ENROLLEES OF MEDICAID MANAGED CARE ORGANIZATIONS.—

(1) IN GENERAL.—Section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) in clause (xi), by striking "and" at the end;

(B) in clause (xii), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than covered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.".

(2) CONFORMING AMENDMENTS.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (b)—

(i) in paragraph (1)(A), in the first sentence, by inserting ", including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs" before the period; and

(ii) in paragraph (2)(A), by inserting "including such information reported by each medicaid managed care organization," after "for which payment was made under the plan during the period,"; and

(B) in subsection (j), by striking paragraph (1) and inserting the following:

"(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

"(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and

"(B) subject to discounts under section 340B of the Public Health Service Act.".

(d) ADDITIONAL REBATE FOR NEW FORMULATIONS OF EXISTING DRUGS.—

(1) IN GENERAL.—Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended by adding at the end the following new subparagraph:

"(C) TREATMENT OF NEW FORMULATIONS.—[*Replaced by section 1206(a) of HCERA*] In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

"(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

"(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

"(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term 'line extension' means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to drugs that are paid for by a State after December 31, 2009.

(e) MAXIMUM REBATE AMOUNT.—Section 1927(c)(2) of such Act (42 U.S.C. 1396r–8(c)(2)), as amended by subsection (d), is amended by adding at the end the following new subparagraph:

"(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.".

(f) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(A) in subsection (a)(2)(B)(i), by striking "1927(c)(4)" and inserting "1927(c)(3)"; and

(B) by striking subsection (c); and

(C) redesignating subsection (d) as subsection (c).

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2010.