STUDY AND REPORT TO CONGRESS ON IMPACT OF MEDICAID EXTENSION PROVISIONS

Pub. L. 100–485, title III, § 303(c), Oct. 13, 1988, 102 Stat. 2392, directed Secretary of Health and Human Services to conduct a study of impact of medicaid extension provisions under this section, with particular focus on costs of such provisions and impact on welfare dependency, and report to Congress on results of such study not later than Apr. 1, 1993.

### § 1396r–7. Repealed. Pub. L. 105–33, title IV, § 4713(a), Aug. 5, 1997, 111 Stat. 509

Section, act Aug. 14, 1935, ch. 531, title XIX, § 1926, as added Dec. 19, 1989, Pub. L. 101–239, title VI, § 6402(b), 103 Stat. 2260, related to adequate payment levels for obstetrical and pediatric services.

EFFECTIVE DATE OF REPEAL

Pub. L. 105–33, title IV, § 4713(b), Aug. 5, 1997, 111 Stat. 509, provided that: ''The repeal made by subsection (a) [repealing this section] shall apply to services furnished on or after October 1, 1997.''

### § 1396r–8. Payment for covered outpatient drugs

#### (a) Requirement for rebate agreement

##### (1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

##### (2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

##### (3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1–A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

##### (4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

##### (5) Limitation on prices of drugs purchased by covered entities

###### (A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

###### (B) "Covered entity" defined

In this subsection, the term ''covered entity'' means an entity described in section 256b(a)(4) of this title.

###### (C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

###### (i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

###### (ii) State agency

Each such single State agency shall provide a means by which a covered entity

shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

**(D) Effect of subsequent amendments**

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

**(E) Determination of compliance**

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

**(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies**

**(A) In general**

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

**(B) Effect of subsequent amendments**

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

**(C) Determination of compliance**

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

**(7) Requirement for submission of utilization data for certain physician administered drugs**

**(A) Single source drugs**

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a single source drug that is physician administered under this subchapter (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this subchapter.

**(B) Multiple source drugs**

**(i) Identification of most frequently physician administered multiple source drugs**

Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this subchapter. The Secretary may modify such list from year to year to reflect changes in such volume.

**(ii) Requirement**

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

**(C) Use of NDC codes**

Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

**(D) Hardship waiver**

The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

**(b) Terms of rebate agreement**

**(1) Periodic rebates**

**(A) In general**

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is

responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

**(B) Offset against medical assistance**

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter, including amounts received by a State under subsection (c)(4), shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

**(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 1396b(a) of this title 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 subchapter to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1396b(d)(2) of this title. Such a disallowance is not subject to a reconsideration under section 1316(d) of this title.

**(2) State provision of information**

**(A) State responsibility**

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

**(B) Audits**

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

**(3) Manufacturer provision of price and drug product information**

**(A) In general**

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)]); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1395w–3a(c) of this title) and the total number of units specified under section 1395w–3a(b)(2)(A) of this title;

(II) if required to make payment under section 1395w–3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or other-

wise described in section 1395w–3a(c)(2)(B) of this title;

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1395u(*o*)(1) of this title or section 1395rr(b)(13)(A)(ii) of this title, and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs;

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug; and

(v) not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices).

**(B) Verification surveys of average manufacturer price and manufacturer's average sales price**

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a–7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

**(C) Penalties**

**(i) Failure to provide timely information**

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

**(ii) False information**

Any manufacturer with an agreement under this section that knowingly provides false information, including information related to drug pricing, drug product information, and data related to drug pricing or drug product information, is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a–7a of this title (other than subsections (a), (b), (f)(3), and (f)(4)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

**(iii) Misclassified drug product or misreported information**

**(I) In general**

Any manufacturer with an agreement under this section that knowingly (as defined in section 1003.110 of title 42, Code of Federal Regulations (or any successor regulation)) misclassifies a covered outpatient drug, such as by knowingly submitting incorrect drug product information, is subject to a civil money penalty for each covered outpatient drug that is misclassified in an amount not to exceed 2 times the amount of the difference between—

(aa) the total amount of rebates that the manufacturer paid with respect to the drug to all States for all rebate periods during which the drug was misclassified; and

(bb) the total amount of rebates that the manufacturer would have been required to pay, as determined by the Secretary using drug product information provided by the manufacturer, with respect to the drug to all States for all rebate periods during which the drug was misclassified if the drug had been correctly classified.

**(II) Other penalties and recovery of underpaid rebates**

The civil money penalties described in subclause (I) are in addition to other penalties as may be prescribed by law and any other recovery of the underlying underpayment for rebates due under this section or the terms of the rebate agreement as determined by the Secretary.

**(iv) Increasing oversight and enforcement**

Each year the Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to the enforcement of the civil money penalties under this subparagraph and subsection (c)(4)(B)(ii)(III), an amount equal to 25 percent of the total amount of civil money penalties collected under this subparagraph and subsection (c)(4)(B)(ii)(III) for the year, and such retained amount shall be available to the Secretary, without further appropriation and until expended, for activities related to the oversight and enforcement of this section and agreements under this section, including—

(I) improving drug data reporting systems;

(II) evaluating and ensuring manufacturer compliance with rebate obligations; and

(III) oversight and enforcement related to ensuring that manufacturers accurately and fully report drug information, including data related to drug classification.

**(D) Confidentiality of information**

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1395w–3a of this title) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1395w–3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w–3b of this title,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this subchapter,

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f), and

(vi) in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before April 18, 2019.

The previous sentence shall also apply to information disclosed under section 1395w–102(d)(2) or 1395w–104(c)(2)(E)[1] of this title and drug pricing data reported under the first sentence of section 1395w–141(i)(1) of this title.

**(4) Length of agreement**

**(A) In general**

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

**(B) Termination**

**(i) By the Secretary**

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

**(ii) By a manufacturer**

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

**(iii) Effectiveness of termination**

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

**(iv) Notice to States**

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

**(v) Application to terminations of other agreements**

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of title 38.

**(C) Delay before reentry**

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

[1] See References in Text note below.

**(c) Determination of amount of rebate**

**(1) Basic rebate for single source drugs and innovator multiple source drugs**

**(A) In general**

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

**(B) Range of rebates required**

**(i) Minimum rebate percentage**

For purposes of subparagraph (A)(ii)(II), the ''minimum rebate percentage'' for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010[2] is 15.1 percent; and

(VI) except as provided in clause (iii), after December 31, 2009,[3] 23.1 percent.

**(ii) Temporary limitation on maximum rebate amount**

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

**(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 1395u(*o*)(5) of this title 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.

**(C) ''Best price'' defined**

For purposes of this section—

**(i) In general**

The term ''best price'' means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w–141 of this title; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII, by an MA–PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w–114a of this title.

**(ii) Special rules**

The term ''best price''—

[2] So in original. Probably should be followed by a comma.

[3] So in original. Probably should be followed by ''is''.

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

**(iii) Application of auditing and recordkeeping requirements**

With respect to a covered entity described in section 256b(a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b(a)(5)(C) of this title.

**(D) Limitation on sales at a nominal price**

**(i) In general**

For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 256b(a)(4) of this title.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and

(bb) would be a covered entity described in section 256b(a)(4)[1] of this title insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 300(a) of this title.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

**(ii) Factors**

The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

**(iii) Nonapplication**

Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38.

**(iv) Rule of construction**

Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 300a–6 of this title.

**(2) Additional rebate for single source and innovator multiple source drugs**

**(A) In general**

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

**(B) Treatment of subsequently approved drugs**

In the case of a covered outpatient drug approved by the Food and Drug Administra-

tion after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting ''the first full calendar quarter after the day on which the drug was first marketed'' for ''the calendar quarter beginning July 1, 1990'' and ''the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed'' for ''September 1990''.

**(C) Treatment of new formulations**

**(i) In general**

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 for a rebate period with respect to such drug under this subsection shall be the greater of the amount described in clause (ii) for such drug or the amount described in clause (iii) for such drug.

**(ii) Amount 1**

For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the amount computed under subparagraph (A) and, as applicable, subparagraph (B) for such drug and rebate period.

**(iii) Amount 2**

For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the product of—

(I) the average manufacturer price for the rebate period 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 paragraph for the rebate period 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, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

**(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.

**(3) Rebate for other drugs**

**(A) In general**

Except as provided in subparagraph (C), the amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

**(B) "Applicable percentage" defined**

For purposes of subparagraph (A)(i), the ''applicable percentage'' for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent;[4] and

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

**(C) Additional rebate**

**(i) In general**

The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

**(ii) Special rules for application of provision**

In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

(I) the reference in subparagraph (A)(i) of such paragraph to ''1990'' shall be deemed a reference to ''2014'';

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to ''the calendar quarter beginning July 1, 1990'' shall be deemed a reference to ''the calendar quarter beginning July 1, 2014''; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to ''September 1990'' shall be deemed a reference to ''September 2014'';

(IV) the references in subparagraph (D) of such paragraph to ''paragraph (1)(A)(ii)'', ''this paragraph'', and ''December 31, 2009'' shall be deemed references to ''subparagraph (A)'', ''this subparagraph'', and ''December 31, 2014'', respectively; and

(V) any reference in such paragraph to a ''single source drug or an innovator

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

multiple source drug'' shall be deemed to be a reference to a drug to which clause (i) applies.

**(iii) Special rule for certain noninnovator multiple source drugs**

In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013, such paragraph shall be applied—

(I) by substituting ''the applicable quarter'' for ''the calendar quarter beginning July 1, 1990''; and

(II) by substituting ''the last month in such applicable quarter'' for ''September 1990''.

**(iv) Applicable quarter defined**

In this subsection, the term ''applicable quarter'' means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

**(4) Recovery of unpaid rebate amounts due to misclassification of covered outpatient drugs**

**(A) In general**

If the Secretary determines that a manufacturer with an agreement under this section paid a lower per-unit rebate amount to a State for a rebate period as a result of the misclassification by the manufacturer of a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made) than the per-unit rebate amount that the manufacturer would have paid to the State if the drug had been correctly classified, the manufacturer shall pay to the State an amount equal to the product of—

(i) the difference between—

(I) the per-unit rebate amount paid to the State for the period; and

(II) the per-unit rebate amount that the manufacturer would have paid to the State for the period, as determined by the Secretary, if the drug had been correctly classified; and

(ii) the total units of the drug paid for under the State plan in the period.

**(B) Authority to correct misclassifications**

**(i) In general**

If the Secretary determines that a manufacturer with an agreement under this section has misclassified a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made), the Secretary shall notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner.

**(ii) Enforcement**

If, after receiving notice of a misclassification from the Secretary under clause (i), a manufacturer fails to correct the misclassification by such time as the Secretary shall require, until the manufacturer makes such correction, the Secretary may do any or all of the following:

(I) Correct the misclassification, using drug product information provided by the manufacturer, on behalf of the manufacturer.

(II) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from Federal financial participation in accordance with section 1396b(i)(10)(E) of this title.

(III) Impose a civil money penalty (which shall be in addition to any other recovery or penalty which may be available under this section or any other provision of law) for each rebate period during which the drug is misclassified not to exceed an amount equal to the product of—

(aa) the total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

(bb) 23.1 percent of the average manufacturer price for the dosage form and strength of such misclassified drug.

**(C) Reporting and transparency**

**(i) In general**

The Secretary shall submit a report to Congress on at least an annual basis that includes information on the covered outpatient drugs that have been identified as misclassified, any steps taken to reclassify such drugs, the actions the Secretary has taken to ensure the payment of any rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in subsection (b)(3)(C)(iv), including an accounting of how such funds have been allocated and spent in accordance with such subsection.

**(ii) Public access**

The Secretary shall make the information contained in the report required under clause (i) available to the public on a timely basis.

**(D) Other penalties and actions**

Actions taken and penalties imposed under this clause shall be in addition to other remedies available to the Secretary including terminating the manufacturer's rebate agreement for noncompliance with the terms of such agreement and shall not exempt a manufacturer from, or preclude the Secretary from pursuing, any civil money penalty under this subchapter or subchapter XI, or any other penalty or action as may be prescribed by law.

**(d) Limitations on coverage of drugs**

**(1) Permissible restrictions**

(A) A State may subject to prior authorization any covered outpatient drug. Any such

prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

**(2) List of drugs subject to restriction**

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

**(3) Update of drug listings**

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

**(4) Requirements for formularies**

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

**(5) Requirements of prior authorization programs**

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

**(6) Other permissible restrictions**

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

**(7) Non-excludable drugs**

The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

**(e) Treatment of pharmacy reimbursement limits**

**(1) In general**

During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this subchapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

**(2) Special rule**

If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

**(3) Effect on State maximum allowable cost limitations**

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

**[(4)][5] Establishment of upper payment limits**

Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

**(5) Use of amp in upper payment limits**

The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1395w–3a of this title.

**(f) Survey of retail prices; State payment and utilization rates; and performance rankings**

**(1) Survey of retail prices**

**(A) Use of vendor**

The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

**(B) Secretary response to notification of availability of multiple source products**

If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).[1]

**(C) Use of competitive bidding**

In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

**(D) Additional provisions**

A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

[5] See 1993 Amendment note below.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

**(E) Availability of information to States**

Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1396a(a)(5) of this title with responsibility for the administration or supervision of the administration of the State plan under this subchapter of the retail survey price determined under this paragraph.

**(2) Annual State report**

Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this subchapter for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

**(3) Annual State performance rankings**

**(A) Comparative analysis**

The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this subchapter for each such drug for each State.

**(B) Availability of information**

The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

**(4) Appropriation**

Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

**(g) Drug use review**

**(1) In general**

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

**(2) Description of program**

Each drug use review program shall meet the following requirements for covered outpatient drugs:

**(A) Prospective drug review**

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

**(B) Retrospective drug use review**

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

**(C) Application of standards**

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection [6] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

**(D) Educational program**

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

**(3) State drug use review board**

**(A) Establishment**

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the ''DUR Board'') either directly or through a contract with a private organization.

**(B) Membership**

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ * * *[7] licensed and actively practicing pharmacists.

**(C) Activities**

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section [6] (2)(B).

(ii) Application of standards as defined in section [6] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified

[6] So in original. Probably should be ''paragraph''.

[7] So in original.

in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

**(D) Annual report**

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

**(h) Electronic claims management**

**(1) In general**

In accordance with chapter 35 of title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

**(2) Encouragement**

In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

**(i) Omitted**

**(j) Exemption of organized health care settings**

(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 1396b(m) of this title; and

(B) subject to discounts under section 256b of this title.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

**(k) Definitions**

In this section—

**(1) Average manufacturer price**

**(A) In general**

Subject to subparagraph (B), the term ''average manufacturer price'' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

**(B) Exclusion of customary prompt pay discounts and other payments**

**(i) In general**

The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail com-

munity pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and

(V) discounts provided by manufacturers under section 1395w–114a of this title.

**(ii) Inclusion of other discounts and payments**

Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

**(C) Exclusion of section 505(c) drugs**

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)], such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

**(2) Covered outpatient drug**

Subject to the exceptions in paragraph (3), the term ''covered outpatient drug'' means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (4)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] or 507[1] of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act [21 U.S.C. 355(j)];

(ii)(I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C. 331, 332(a), 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C. 352(f), 355(a)]; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506[1] of the Federal Food, Drug, and Cosmetic Act.

**(3) Limiting definition**

The term ''covered outpatient drug'' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological[8] used

[8] So in original. Probably should be ''biological product''.

for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

**(4) Nonprescription drugs**

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as ''over-the-counter'' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

**(5) Manufacturer**

The term ''manufacturer'' means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

**(6) Medically accepted indication**

The term ''medically accepted indication'' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

**(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug**

**(A) Defined**

**(i) Multiple source drug**

The term ''multiple source drug'' means, with respect to a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4), for which there[3] at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

**(ii) Innovator multiple source drug**

The term ''innovator multiple source drug'' means a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration, unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)).

**(iii) Noninnovator multiple source drug**

The term ''noninnovator multiple source drug'' means a multiple source drug that is not an innovator multiple source drug.

**(iv) Single source drug**

The term ''single source drug'' means a covered outpatient drug, including a drug product approved for marketing as a nonprescription drug that is regarded as a covered outpatient drug under paragraph (4), which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)). Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.

**(B) Exception**

Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

**(C) Definitions**

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

**(8) Rebate period**

The term ''rebate period'' means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

**(9) State agency**

The term ''State agency'' means the agency designated under section 1396a(a)(5) of this

title to administer or supervise the administration of the State plan for medical assistance.

**(10) Retail community pharmacy**

The term ''retail community pharmacy'' means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

**(11) Wholesaler**

The term ''wholesaler'' means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

(Aug. 14, 1935, ch. 531, title XIX, § 1927, as added Pub. L. 101–508, title IV, § 4401(a)(3), Nov. 5, 1990, 104 Stat. 1388–143; amended Pub. L. 102–585, title VI, § 601(a)–(c), Nov. 4, 1992, 106 Stat. 4962–4964; Pub. L. 103–18, § 2(a), Apr. 12, 1993, 107 Stat. 54; Pub. L. 103–66, title XIII, § 13602(a), Aug. 10, 1993, 107 Stat. 613; Pub. L. 105–33, title IV, §§ 4701(b)(2)(A)(x), 4756, Aug. 5, 1997, 111 Stat. 493, 527; Pub. L. 106–113, div. B, § 1000(a)(6) [title VI, §§ 606(a), 608(u)], Nov. 29, 1999, 113 Stat. 1536, 1501A–396, 1501A–398; Pub. L. 108–173, title I, §§ 101(e)(4), (9), 103(e)(1), 105(b), title III, § 303(i)(4), title IX, § 900(e)(1)(K), (L), title X, § 1002, Dec. 8, 2003, 117 Stat. 2151, 2152, 2159, 2166, 2254, 2372, 2431; Pub. L. 109–91, title I, § 104(a), Oct. 20, 2005, 119 Stat. 2092; Pub. L. 109–171, title VI, §§ 6001(a)–(c)(2), (d)–(f)(2), 6002(a), 6003(a), (b), 6004(a), Feb. 8, 2006, 120 Stat. 54–61; Pub. L. 109–432, div. B, title IV, § 405(c)(2)(A)(ii), Dec. 20, 2006, 120 Stat. 3000; Pub. L. 111–8, div. F, title II, § 221(a), Mar. 11, 2009, 123 Stat. 783; Pub. L. 111–148, title II, §§ 2501(a), (b), (c)(2), (d)(1), (e), 2502(a), 2503(a)–(c), title III, § 3301(d)(2), title IV, § 4107(b), Mar. 23, 2010, 124 Stat. 306–310, 312, 468, 560; Pub. L. 111–152, title I, §§ 1101(c), 1206(a), Mar. 30, 2010, 124 Stat. 1039, 1056; Pub. L. 111–226, title II, § 202, Aug. 10, 2010, 124 Stat. 2394; Pub. L. 111–309, title II, § 204(b), Dec. 15, 2010, 124 Stat. 3290; Pub. L. 114–74, title VI, § 602(a), Nov. 2, 2015, 129 Stat. 596; Pub. L. 114–198, title VII, § 705(a), July 22, 2016, 130 Stat. 753; Pub. L. 115–123, div. E, title XII, § 53104(a), Feb. 9, 2018, 132 Stat. 302; Pub. L. 115–271, title I, § 1004(b)(1), Oct. 24, 2018, 132 Stat. 3912; Pub. L. 116–16, § 6(a)(1), (2)(B)–(c), Apr. 18, 2019, 133 Stat. 859, 861, 863; Pub. L. 116–59, div. B, title VI, § 1603(a), (b), Sept. 27, 2019, 133 Stat. 1108.)

AMENDMENT OF SUBSECTION (g)

*Pub. L. 115–271, title I, § 1004(b), Oct. 24, 2018, 132 Stat. 3912, provided that, effective with respect to retrospective drug use reviews conducted on or after Oct. 1, 2020, subsection (g) of this section is amended:*

*(1) in paragraph (1)(A)–*

*(A) by striking ''of section 1396b(i)(10)(B)'' and inserting ''of section 1396a(a)(54)'';*

*(B) by striking '', by not later than January 1, 1993,'';*

*(C) by inserting after ''gross overuse,'' the following: ''excessive utilization,''; and*

*(D) by striking ''or inappropriate or medically unnecessary care'' and inserting ''inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization''; and*

*(2) in paragraph (2)(B)–*

*(A) by inserting after ''gross overuse,'' the following: ''excessive utilization,''; and*

*(B) by striking ''or inappropriate or medically unnecessary care'' and inserting ''inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization''.*

*See 2018 Amendment notes below.*

REFERENCES IN TEXT

The amendments made by subsections (a)(1), (b), (c), and (d) of section 2501 of the Patient Protection and Affordable Care Act, referred to in subsec. (b)(1)(C)(i)(II), mean the amendments made by section 2501(a)(1), (b), (c), and (d) of Pub. L. 111–148, which amended this section and section 1396b of this title.

Section 1395w–104(c)(2)(E) of this title, referred to in subsec. (b)(3)(D), was redesignated section 1395w–104(c)(2)(G) of this title by Pub. L. 111–148, title X, § 10328(a), Mar. 23, 2010, 124 Stat. 964.

The Internal Revenue Code of 1986, referred to in subsec. (c)(1)(D)(i)(IV)(aa), is classified generally to Title 26, Internal Revenue Code.

Section 256b(a)(4) of this title, referred to in subsec. (c)(1)(D)(i)(IV)(bb), was in the original ''section 340(B)(a)(4) of the Public Health Service Act'', and was translated as meaning section 340B(a)(4) of the Public Health Service Act, which defines ''covered entity'', to reflect the probable intent of Congress.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(4)(C) and (k)(6), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Paragraph (4) and subsection (e)(4), referred to in subsecs. (e)(5) and (f)(1)(B), probably means text that was editorially designated as par. (4) of subsec. (e). See 1993 Amendment note below.

Section 507 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (k)(2)(A)(i), was repealed by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

Section 107(c)(3) of the Drug Amendments of 1962, referred to in subsec. (k)(2)(A)(iii)(I), is section 107(c)(3) of Pub. L. 87–781 which is set out in an Effective Date of 1962 Amendment note under section 321 of Title 21, Food and Drugs.

Section 506 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (k)(2)(C), was repealed and a new section 506 enacted by Pub. L. 105–115, title I, §§ 112(a), 125(a)(1), Nov. 21, 1997, 111 Stat. 2309, 2325, which no longer relates to insulin.

CODIFICATION

Subsec. (i) of this section, which required the Secretary to transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives

an annual report on the operation of this section in the preceding fiscal year, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, set out as a note under section 1113 of Title 31, Money and Finance. See, also, item 9 on page 93 of House Document No. 103–7.

PRIOR PROVISIONS

A prior section 1927 of act Aug. 14, 1935, was renumbered section 1939 and is classified to section 1396v of this title.

AMENDMENTS

2019—Subsec. (b)(1)(B). Pub. L. 116–16, §6(b)(2), inserted '', including amounts received by a State under subsection (c)(4),'' after ''in any quarter''.

Subsec. (b)(3). Pub. L. 116–16, §6(a)(1)(A), inserted ''and drug product'' after ''price'' in heading.

Subsec. (b)(3)(A)(ii), (iii). Pub. L. 116–16, §6(a)(1)(B)(i), (ii), struck out ''and'' at end of cl. (ii) and substituted semicolon for period at end of cl. (iii).

Subsec. (b)(3)(A)(v). Pub. L. 116–16, §6(a)(1)(B)(iii), (iv), added cl. (v).

Subsec. (b)(3)(C)(ii). Pub. L. 116–16, §6(a)(1)(C)(i), (2)(B), inserted '', including information related to drug pricing, drug product information, and data related to drug pricing or drug product information,'' after ''provides false information'' and substituted ''subsections (a), (b), (f)(3), and (f)(4)'' for ''subsections (a) and (b)''.

Subsec. (b)(3)(C)(iii), (iv). Pub. L. 116–16, §6(a)(1)(C)(ii), added cls. (iii) and (iv).

Subsec. (b)(3)(D)(vi). Pub. L. 116–16, §6(a)(1)(C)(iii), added cl. (vi).

Subsec. (c)(4). Pub. L. 116–16, §6(b)(1), added par. (4).

Subsec. (k)(1)(C). Pub. L. 116–59, §1603(a), substituted ''Exclusion'' for ''Inclusion'' in heading and ''the manufacturer's new drug application'' for ''a new drug application'' and ''exclusive'' for ''inclusive'' in text.

Subsec. (k)(2)(A). Pub. L. 116–16, §6(c)(1), substituted ''paragraph (4)'' for ''paragraph (5)'' in introductory provisions.

Subsec. (k)(7)(A)(i). Pub. L. 116–16, §6(c)(2)(B), substituted '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),'' for ''(not including any drug described in paragraph (5))''.

Subsec. (k)(7)(A)(ii). Pub. L. 116–16, §6(c)(2)(A), (C), substituted ''is marketed'' for ''was originally marketed'' and ''a new drug application'' for ''an original new drug application'' and inserted '', unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation))'' before period at end.

Subsec. (k)(7)(A)(iv). Pub. L. 116–16, §6(c)(2)(A), (D), substituted ''a new drug application'' for ''an original new drug application'' and inserted '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),'' after ''covered outpatient drug'', ''unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation))'' after ''under the new drug application'', and ''Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.'' at end.

Subsec. (k)(11). Pub. L. 116–59, §1603(b), struck out ''manufacturers,'' before ''repackers,'' and ''manufacturer's and'' before ''distributor's warehouses,''.

2018—Subsec. (c)(2)(C). Pub. L. 115–123 added cls. (i) to (iii) and struck out introductory provisions and former cls. (i) to (iii) which read as follows: ''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).''

Subsec. (g)(1)(A). Pub. L. 115–271, §1004(b)(1)(A), substituted ''of section 1396a(a)(54)'' for ''of section 1396b(i)(10)(B)'', struck out '', by not later than January 1, 1993,'' after ''shall provide'', and substituted ''gross overuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization'' for ''gross overuse, or inappropriate or medically unnecessary care''.

Subsec. (g)(2)(B). Pub. L. 115–271, §1004(b)(1)(B), substituted ''gross overuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization'' for ''gross overuse, or inappropriate or medically unnecessary care''.

2016—Subsec. (c)(2)(C). Pub. L. 114–198 inserted before period at end of concluding provisions '', but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation''.

2015—Subsec. (c)(3)(A). Pub. L. 114–74, §602(a)(1), substituted ''Except as provided in subparagraph (C), the amount'' for ''The amount''.

Subsec. (c)(3)(C). Pub. L. 114–74, §602(a)(2), added subpar. (C).

2010—Subsec. (a)(5)(B). Pub. L. 111–309 substituted a period for ''and a children's hospital described in section 1395ww(d)(1)(B)(iii) of this title which meets the requirements of clauses (i) and (iii) of section 256b(b)(4)(L) of this title and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this subchapter.''

Subsec. (b)(1)(A). Pub. L. 111–148, §2501(c)(2)(A)(i), inserted '', including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs'' after ''for such period''.

Subsec. (b)(1)(C). Pub. L. 111–148, §2501(a)(2), added subpar. (C).

Subsec. (b)(2)(A). Pub. L. 111–148, §2501(c)(2)(A)(ii), inserted ''including such information reported by each medicaid managed care organization,'' after ''for which payment was made under the plan during the period,''.

Subsec. (b)(3)(A). Pub. L. 111–148, §2503(b)(1)(B), which directed insertion, in the second sentence, of ''(relating to the weighted average of the most recently reported monthly average manufacturer prices)'' after ''(D)(v)'' was executed by making the insertion in concluding provisions to reflect the probable intent of Congress.

Subsec. (b)(3)(A)(iv). Pub. L. 111–148, §2503(b)(1)(A), which directed, in the first sentence, addition of cl. (iv) after cl. (iii), was executed by adding cl. (iv) after cl. (iii) to reflect the probable intent of Congress.

Subsec. (b)(3)(D)(v). Pub. L. 111–148, §2503(b)(2), substituted ''the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f)'' for ''average manufacturer prices''.

Subsec. (c)(1)(B)(i)(IV) to (VI). Pub. L. 111–148, §2501(a)(1)(A), struck out ''and'' at end of subcl. (IV), inserted ''and before January 1, 2010'' after ''December 31, 1995,'' and substituted ''; and'' for period at end in subcl. (V), and added subcl. (VI).

Subsec. (c)(1)(B)(iii). Pub. L. 111–148, § 2501(a)(1)(B), added cl. (iii).

Subsec. (c)(1)(C)(i)(VI). Pub. L. 111–148, § 3301(d)(2), inserted '', or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w–114a of this title'' before period at end.

Subsec. (c)(2)(C). Pub. L. 111–152, § 1206(a), amended subpar. (C) generally. Prior to amendment, text read as follows:

''(i) IN GENERAL.—Except as provided in clause (ii), in the case of a drug that is a new formulation, such as an extended-release formulation, of a single source drug or an innovator multiple source drug, the rebate obligation with respect to the drug under this section shall be the amount computed under this section for the new formulation of the drug or, if greater, the product of—

''(I) the average manufacturer price for each dosage form and strength of the new formulation of the single source drug or innovator multiple source drug;

''(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 new formulation paid for under the State plan in the rebate period (as reported by the State).

''(ii) NO APPLICATION TO NEW FORMULATIONS OF ORPHAN DRUGS.—Clause (i) shall not apply to a new formulation of a covered outpatient drug that is or has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, without regard to whether the period of market exclusivity for the drug under section 527 of such Act has expired or the specific indication for use of the drug.''

Pub. L. 111–148, § 2501(d)(1), added subpar. (C).

Subsec. (c)(2)(D). Pub. L. 111–148, § 2501(e), added subpar. (D).

Subsec. (c)(3)(B). Pub. L. 111–148, § 2501(b), struck out ''and'' at end of cl. (i), inserted ''and before January 1, 2010,'' after ''December 31, 1993,'' and substituted ''; and'' for period at end in cl. (ii), and added cl. (iii).

Subsec. (d)(2)(E). Pub. L. 111–148, § 2502(a)(1), redesignated subpar. (F) as (E) and struck out former subpar. (E) which read as follows: ''Agents when used to promote smoking cessation.''

Subsec. (d)(2)(F). Pub. L. 111–148, § 4107(b), inserted '', except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation'' before period at end.

Pub. L. 111–148, § 2502(a)(1)(B), redesignated subpar. (G) as (F). Former subpar. (F) redesignated (E).

Subsec. (d)(2)(G) to (K). Pub. L. 111–148, § 2502(a)(1), redesignated subpars. (H) and (K) as (G) and (H), respectively, and struck out subpars. (I) and (J) which read as follows:

''(I) Barbiturates.

''(J) Benzodiazepines.''

Subsec. (d)(7). Pub. L. 111–148, § 2502(a)(2), added par. (7).

Subsec. (e)(4). Pub. L. 111–148, § 2503(a)(1)(A), struck out ''(or, effective January 1, 2007, two or more)'' after ''three or more''.

Subsec. (e)(5). Pub. L. 111–148, § 2503(a)(1)(B), added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: ''Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.''

Subsec. (f)(1)(A)(i). Pub. L. 111–148, § 2503(c)(1), inserted ''with respect to a retail community pharmacy,'' before ''the determination''.

Subsec. (f)(1)(C)(ii). Pub. L. 111–148, § 2503(c)(2), substituted ''retail community pharmacies'' for ''retail pharmacies''.

Subsec. (j)(1). Pub. L. 111–148, § 2501(c)(2)(B), added par. (1) and struck out former par. (1) which read as follows: ''Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) of this title, are not subject to the requirements of this section.''

Subsec. (k)(1)(A). Pub. L. 111–148, § 2503(a)(2)(A), substituted ''by—'' for ''by wholesalers for drugs distributed to the retail pharmacy class of trade.'' and added cls. (i) and (ii).

Subsec. (k)(1)(B). Pub. L. 111–148, § 2503(a)(2)(B), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: ''The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.''

Subsec. (k)(1)(B)(i)(IV). Pub. L. 111–226 inserted at end '', unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and''.

Subsec. (k)(1)(B)(i)(V). Pub. L. 111–152, § 1101(c), added subcl. (V).

Subsec. (k)(1)(C). Pub. L. 111–148, § 2503(a)(2)(C), substituted ''retail community pharmacies'' for ''the retail pharmacy class of trade''.

Subsec. (k)(7)(A)(i)(III). Pub. L. 111–148, § 2503(a)(3)(A), substituted ''the United States'' for ''the State''.

Subsec. (k)(7)(C). Pub. L. 111–148, § 2503(a)(3)(B), inserted ''and'' after semicolon at end of cl. (i), substituted period for ''; and'' at end of cl. (ii), and struck out cl. (iii) which read as follows: ''a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.''

Subsec. (k)(10), (11). Pub. L. 111–148, § 2503(a)(4), added pars. (10) and (11).

2009—Subsec. (c)(1)(D)(i)(IV) to (VI). Pub. L. 111–8, § 221(a)(1), added subcls. (IV) and (V) and redesignated former subcl. (IV) as (VI).

Subsec. (c)(1)(D)(iv). Pub. L. 111–8, § 221(a)(2), added cl. (iv).

2006—Subsec. (a)(5)(B). Pub. L. 109–171, § 6004(a), inserted before period at end ''and a children's hospital described in section 1395ww(d)(1)(B)(iii) of this title which meets the requirements of clauses (i) and (iii) of section 256b(b)(4)(L) of this title and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this subchapter''.

Subsec. (a)(7). Pub. L. 109–171, § 6002(a), added par. (7).

Subsec. (b)(3)(A). Pub. L. 109–171, § 6001(b)(1)(B), inserted ''Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).'' at end of concluding provisions.

Subsec. (b)(3)(A)(i). Pub. L. 109–171, § 6003(a)(1), added cl. (i) and struck out former cl. (i) which read as follows: ''not later than 30 days after the last day of each month of a rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section), customary prompt pay discounts extended to wholesalers, and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement,;''.

Pub. L. 109–171, § 6001(b)(1)(A), (c)(2), inserted ''month of a'' after ''last day of each'' and '', customary prompt

pay discounts extended to wholesalers,'' after ''(k)(1) of this section)''.

Subsec. (b)(3)(A)(ii). Pub. L. 109–171, §6003(a)(2), inserted ''(including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)'' after ''drugs''.

Subsec. (b)(3)(A)(iii). Pub. L. 109–171, §6001(d)(1), inserted '', and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs'' before period at end.

Subsec. (b)(3)(D)(iv), (v). Pub. L. 109–171, §6001(b)(2), added cls. (iv) and (v).

Subsec. (c)(1)(C)(i). Pub. L. 109–171, §6003(b)(1)(A), inserted ''(including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)'' after ''or innovator multiple source drug of a manufacturer'' in introductory provisions.

Subsec. (c)(1)(C)(ii)(IV). Pub. L. 109–171, §6003(b)(1)(B), added subcl. (IV).

Subsec. (c)(1)(D). Pub. L. 109–171, §6001(d)(2), added subpar. (D).

Subsec. (e)(4). Pub. L. 109–171, §6001(a)(1), which directed substitution of ''Subject to paragraph (5), the Secretary'' for ''The Secretary'' and insertion of ''(or, effective January 1, 2007, two or more)'' after ''three or more'' in subsec. (e)(4), was executed to the last par. of subsec. (e) to reflect the probable intent of Congress. See 1993 Amendment note below.

Subsec. (e)(5). Pub. L. 109–171, §6001(a)(2), added par. (5).

Subsec. (f). Pub. L. 109–171, §6001(e), added subsec. (f).

Subsec. (g)(1)(B)(i)(II). Pub. L. 109–171, §6001(f)(1), which directed insertion of ''(or its successor publications)'' after ''United States Pharmacopoeia-Drug Information'', was executed by making insertion after ''United States Pharmacopeia-Drug Information'' to reflect the probable intent of Congress.

Subsec. (g)(2)(A)(ii). Pub. L. 109–171, §6001(f)(2), inserted '', or to require verification of the offer to provide consultation or a refusal of such offer'' before period at end of concluding provisions.

Subsec. (k)(1). Pub. L. 109–171, §6001(c)(1), designated existing provisions as subpar. (A), inserted heading, substituted ''Subject to subparagraph (B), the term'' for ''The term'', struck out '', after deducting customary prompt pay discounts'' before period at end, and added subpar. (B).

Subsec. (k)(1)(C). Pub. L. 109–171, §6003(b)(2), as amended by Pub. L. 109–432, added subpar. (C).

Subsec. (k)(7)(A)(i). Pub. L. 109–171, §6001(a)(4), substituted ''is'' for ''are'' in subcls. (I), (II), and (III).

Pub. L. 109–171, §6001(a)(3), substituted ''at least 1 other drug product'' for ''are 2 or more drug products'' in introductory provisions.

2005—Subsec. (d)(2)(K). Pub. L. 109–91 added subpar. (K).

2003—Subsec. (a)(1). Pub. L. 108–173, §303(i)(4)(A), inserted ''or under part B of subchapter XVIII'' after ''section 1396b(a) of this title''.

Subsec. (b)(3)(A). Pub. L. 108–173, §303(i)(4)(B), added cl. (iii) and concluding provisions.

Subsec. (b)(3)(B). Pub. L. 108–173, §303(i)(4)(C), inserted ''and manufacturer's average sales price'' after ''average manufacturer price'' in heading and ''and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment'' after ''manufacturer prices'' in text.

Subsec. (b)(3)(D). Pub. L. 108–173, §303(i)(4)(D)(i), inserted ''(other than the wholesale acquisition cost for purposes of carrying out section 1395w–3a of this title)'' after ''subsection (a)(6)(A)(ii)'' in introductory provisions.

Pub. L. 108–173, §105(b), which directed insertion of ''and drug pricing data reported under the first sentence of section 1395w–141(i)(1) of this title'' after ''section 1395w–104(c)(2)(E) of this title'' in last sentence, was executed by making the insertion after ''or 1395w–104(c)(2)(E) of this title'' in concluding provisions to reflect the probable intent of Congress.

Pub. L. 108–173, §101(e)(4), inserted concluding provisions.

Subsec. (b)(3)(D)(i). Pub. L. 108–173, §303(i)(4)(D)(ii), inserted '', to carry out section 1395w–3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w–3b of this title'' after ''this section''.

Subsec. (c)(1)(C)(i)(I). Pub. L. 108–173, §1002(a), inserted ''(including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title)'' before semicolon at end.

Subsec. (c)(1)(C)(i)(V), (VI). Pub. L. 108–173, §103(e)(1), added subcls. (V) and (VI).

Subsec. (c)(1)(C)(iii). Pub. L. 108–173, §1002(b), added cl. (iii).

Subsec. (e)[(4)]. Pub. L. 108–173, §900(e)(1)(K), (L), which directed substitution of ''The Secretary'' for ''HCFA'' in subsecs. (e)(4) and (f)(2), was executed to the last par. of subsec. (e) to reflect the probable intent of Congress. See 1993 Amendment note below.

Subsec. (g)(1)(B)(i)(II). Pub. L. 108–173, §101(e)(9)(A), inserted ''and'' at end.

Subsec. (g)(1)(B)(i)(IV). Pub. L. 108–173, §101(e)(9)(B), struck out subcl. (IV) which read as follows: ''American Medical Association Drug Evaluations; and''.

1999—Subsec. (a)(1). Pub. L. 106–113, §1000(a)(6) [title VI, §606(a)], substituted ''shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before'' for ''shall not be effective until''.

Subsec. (g)(2)(A)(ii)(II)(cc). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(1)], substituted ''individual's'' for ''individuals''.

Subsec. (i)(1). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(2)], substituted ''the operation of this section'' for ''the the operation of this section''.

Subsec. (k)(7)(A)(iv). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(3)(A)], substituted ''distributors'' for ''distributers''.

Subsec. (k)(7)(C)(i). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(3)(B)], substituted ''pharmaceutically'' for ''pharmaceuutically''.

1997—Subsec. (g)(1)(B)(i)(III), (IV). Pub. L. 105–33, §4756, added subcl. (III) and redesignated former subcl. (III) as (IV).

Subsec. (j)(1). Pub. L. 105–33, §4701(b)(2)(A)(x), substituted ''health maintenance organizations, including medicaid managed care organizations'' for ''* * * Health Maintenance Organizations, including those organizations''.

1993—Subsec. (b)(1)(A). Pub. L. 103–66, §13602(a)(2)(A)(i)(II), which directed amendment of subpar. (A) by substituting ''dispensed after December 31, 1990, for which payment was made under the State plan for such period'' for ''dispensed under the plan during the quarter (or other period as the Secretary may specify)'', was executed by making the substitution for ''dispensed under the plan during the quarter (or such other period as the Secretary may specify)'' to reflect the probable intent of Congress.

Pub. L. 103–66, §13602(a)(2)(A)(i)(I), substituted ''for a rebate period'' for ''each calendar quarter (or periodically in accordance with a schedule specified by the Secretary)''.

Subsec. (b)(2)(A). Pub. L. 103–66, §13602(a)(2)(A)(ii), substituted ''each rebate period'' for ''each calendar quarter'' and ''units of each dosage form and strength and package size'' for ''dosage units'', inserted ''after December 31, 1990, for which payment was made'' after ''dispensed'', and substituted ''during the period'' for ''during the quarter''.

Subsec. (b)(3)(A)(i). Pub. L. 103–66, §13602(a)(2)(A)(iii), substituted ''rebate period under the agreement'' for ''quarter'' in two places.

Subsec. (c). Pub. L. 103–66, §13602(a)(1), added subsec. (c) and struck out former subsec. (c) which related to determination of amount of rebate for certain drugs.

Pub. L. 103–18 substituted ''such drug, except that for the calendar quarter beginning after September 30, 1992, and before January 1, 1993, the amount of the rebate may not exceed 50 percent of such average manufacturer price;'' for ''such drug;'' in par. (1)(B)(ii)(II).

Subsecs. (d) to (f). Pub. L. 103–66, § 13602(a)(1), added subsecs. (d) and (e), struck out former subsecs. (d) consisting of pars. (1) to (8) relating to limitations on coverage of drugs, (e) relating to denial of Federal financial participation in certain cases, and (f)(1) relating to reductions in pharmacy reimbursement limits, and struck out par. designation for former par. (2) of subsec. (f) without supplying a new designation. The text of former subsec. (f)(2) is now the last par. of subsec. (e).

Subsec. (k)(1). Pub. L. 103–66, § 13602(a)(2)(B)(i), substituted ''rebate period'' for ''calendar quarter'' and inserted before period at end '', after deducting customary prompt pay discounts''.

Subsec. (k)(3). Pub. L. 103–66, § 13602(a)(2)(B)(ii)(III), in concluding provisions, substituted ''for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used'' for ''which is used'' and inserted at end ''Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.''

Subsec. (k)(3)(E). Pub. L. 103–66, § 13602(a)(2)(B)(ii)(I), struck out ''* * * *emergency room visits'' after ''services''.

Subsec. (k)(3)(F). Pub. L. 103–66, § 13602(a)(2)(B)(ii)(II), which directed amendment of subpar. (F) by substituting ''services and services provided by an intermediate care facility for the mentally retarded'' for ''services'', was executed by making the substitution for ''sevices'' to reflect the probable intent of Congress because the word ''services'' did not appear.

Subsec. (k)(6). Pub. L. 103–66, § 13602(a)(2)(B)(iii), substituted ''or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).'' for '', which appears in peer-reviewed medical literature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.''

Subsec. (k)(7)(A)(i). Pub. L. 103–66, § 13602(a)(2)(B)(iv), substituted ''rebate period'' for ''calendar quarter'' in introductory provisions.

Subsec. (k)(8), (9). Pub. L. 103–66, § 13602(a)(2)(B)(v), added par. (8) and redesignated former par. (8) as (9).

1992—Subsec. (a)(1). Pub. L. 102–585, § 601(b)(1), substituted ''manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6)'' for ''manufacturer)''.

Subsec. (a)(5), (6). Pub. L. 102–585, § 601(b)(2), added pars. (5) and (6).

Subsec. (b)(3)(D). Pub. L. 102–585, § 601(b)(3), substituted ''this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii)'' for ''this paragraph'', ''Secretary or the Secretary of Veterans Affairs'' for ''Secretary'', and ''except—'' and cls. (i) to (iii) for ''except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.''

Subsec. (b)(4)(B)(ii). Pub. L. 102–585, § 601(b)(4)(i), (ii), substituted ''the calendar quarter beginning at least 60 days'' for ''such period'' and ''the manufacturer provides notice to the Secretary.'' for ''of the notice as the Secretary may provide (but not beyond the term of the agreement).''

Subsec. (b)(4)(B)(iv), (v). Pub. L. 102–585, § 601(b)(4)(iii), added cls. (iv) and (v).

Subsec. (c)(1)(B)(i). Pub. L. 102–585, § 601(c)(1), which directed the substitution of ''October 1, 1992,'' for ''January 1, 1993,'', was executed by making the substitution in introductory provisions and in subcl. (II), to reflect the probable intent of Congress.

Subsec. (c)(1)(B)(ii) to (v). Pub. L. 102–585, § 601(c)(2), (3), added cls. (ii) to (v) and struck out former cl. (ii) which read as follows: ''for quarters (or other periods) beginning after December 31, 1992, the greater of—

''(I) the difference between the average manufacturer price for a drug and 85 percent of such price, or

''(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug.''

Subsec. (c)(1)(C). Pub. L. 102–585, § 601(a), substituted ''(excluding any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section, any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under a State pharmaceutical assistance program, and excluding'' for ''(excluding''.

EFFECTIVE DATE OF 2019 AMENDMENT

Pub. L. 116–59, div. B, title VI, § 1603(c), Sept. 27, 2019, 133 Stat. 1108, provided that: ''The amendments made by this section [amending this section] shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act [Sept. 27, 2019].''

Amendment by Pub. L. 116–16 effective on Apr. 18, 2019, and applicable to covered outpatient drugs supplied by manufacturers under agreements under this section on or after that date, see section 6(e) of Pub. L. 116–16, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–271, title I, § 1004(b)(2), Oct. 24, 2018, 132 Stat. 3912, provided that: ''The amendments made by paragraph (1) [amending this section] shall take effect with respect to retrospective drug use reviews conducted on or after October 1, 2020.''

Pub. L. 115–123, div. E, title XII, § 53104(b), Feb. 9, 2018, 132 Stat. 302, provided that: ''The amendments made [by] subsection (a) [amending this section] shall apply with respect to rebate periods beginning on or after October 1, 2018.''

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title VII, § 705(b), July 22, 2016, 130 Stat. 753, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to drugs that are paid for by a State in calendar quarters beginning on or after the date of the enactment of this Act [July 22, 2016].''

EFFECTIVE DATE OF 2015 AMENDMENT

Pub. L. 114–74, title VI, § 602(b), Nov. 2, 2015, 129 Stat. 597, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to rebate periods beginning after the date that is one year after the date of the enactment of this Act [Nov. 2, 2015].''

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–226, title II, § 202, Aug. 10, 2010, 124 Stat. 2394, provided that the amendment made by Pub. L. 111–226 is effective as if included in the enactment of Pub. L. 111–148.

Pub. L. 111–152, title I, § 1206(b), Mar. 30, 2010, 124 Stat. 1057, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of the Patient Protection and Affordable Care Act [Pub. L. 111–148].''

Pub. L. 111–148, title II, § 2501(d)(2), Mar. 23, 2010, 124 Stat. 309, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to

drugs that are paid for by a State after December 31, 2009.''

Pub. L. 111–148, title II, §2502(b), Mar. 23, 2010, 124 Stat. 310, provided that: ''The amendments made by this section [amending this section] shall apply to services furnished on or after January 1, 2014.''

Pub. L. 111–148, title II, §2503(d), Mar. 23, 2010, 124 Stat. 312, provided that: ''The amendments made by this section [amending this section] shall take effect on the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of this Act [Mar. 23, 2010], without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.''

Amendment by section 3301(d)(2) of Pub. L. 111–148 applicable to drugs dispensed on or after July 1, 2010, see section 3301(d)(3) of Pub. L. 111–148, set out as a note under section 1320a–7b of this title.

Amendment by section 4107(b) of Pub. L. 111–148 effective Oct. 1, 2010, see section 4107(d) of Pub. L. 111–148, set out as a note under section 1396d of this title.

EFFECTIVE DATE OF 2009 AMENDMENT

Pub. L. 111–8, div. F, title II, §221(b), Mar. 11, 2009, 123 Stat. 783, provided that: ''The amendments made by this subsection [probably means this section, amending this section] shall take effect as if included in the amendment made by section 6001(d)(2) of the Deficit Reduction Act of 2005 [Pub. L. 109–171].''

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title IV, §405(c)(2)(A), Dec. 20, 2006, 120 Stat. 2999, provided that the amendment made by section 405(c)(2)(A) is effective as if included in the enactment of the Deficit Reduction Act of 2005 (Public Law 109–171).

Pub. L. 109–171, title VI, §6001(f)(3), Feb. 8, 2006, 120 Stat. 58, provided that: ''The amendments made by this subsection [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Feb. 8, 2006].''

Pub. L. 109–171, title VI, §6001(g), Feb. 8, 2006, 120 Stat. 58, provided that: ''Except as otherwise provided, the amendments made by this section [amending this section and section 1395x of this title] shall take effect on January 1, 2007, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.''

Pub. L. 109–171, title VI, §6003(c), Feb. 8, 2006, 120 Stat. 61, provided that: ''The amendments made by this section [amending this section] take effect on January 1, 2007.''

Pub. L. 109–171, title VI, §6004(b), Feb. 8, 2006, 120 Stat. 61, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to drugs purchased on or after the date of the enactment of this Act [Feb. 8, 2006].''

EFFECTIVE DATE OF 2005 AMENDMENT

Amendment by Pub. L. 109–91 applicable to drugs dispensed on or after Jan. 1, 2006, see section 104(d) of Pub. L. 109–91, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title I, §103(e)(2), Dec. 8, 2003, 117 Stat. 2160, provided that: ''Section 1927(c)(1)(C)(i)(VI) of the Social Security Act [42 U.S.C. 1396r–8(c)(1)(C)(i)(VI)], as added by paragraph (1), shall apply to prices charged for drugs dispensed on or after January 1, 2006.''

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(6) [title VI, §606(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–396, provided that: ''The amendment made by subsection (a) [amending this section] applies to agreements entered into on or after the date of enactment of this Act [Nov. 29, 1999].''

Amendment by section 1000(a)(6) [title VI, §608(u)] of Pub. L. 106–113 effective Nov. 29, 1999, see section 1000(a)(6) [title VI, §608(bb)] of Pub. L. 106–113, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–33 effective Aug. 5, 1997, and applicable to contracts entered into or renewed on or after Oct. 1, 1997, see section 4710 of Pub. L. 105–33, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–66, title XIII, §13602(d), Aug. 10, 1993, 107 Stat. 619, provided that:

''(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 1396a and 1396b of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].

''(2) The amendment made by subsection (a)(1) [amending this section] (insofar as such subsection amends section 1927(d) of the Social Security Act [42 U.S.C. 1396r–8(d)]) and the amendment made by subsection (c) [amending section 1396a of this title] shall apply to calendar quarters beginning on or after October 1, 1993, without regard to whether or not regulations to carry out such amendments have been promulgated by such date.''

Pub. L. 103–18, §2(b), Apr. 12, 1993, 107 Stat. 54, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 601(c) of the Veterans Health Care Act of 1992 [Pub. L. 102–585].''

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–585, title VI, §601(e), Nov. 4, 1992, 106 Stat. 4966, provided that: ''The amendments made by this section [amending this section] shall apply with respect to payments to State plans under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for calendar quarters (or periods) beginning on or after January 1, 1993 (without regard to whether or not regulations to carry out such amendments have been promulgated by such date).''

REGULATIONS

Pub. L. 109–171, title VI, §6001(c)(3), Feb. 8, 2006, 120 Stat. 55, provided that:

''(A) INSPECTOR GENERAL RECOMMENDATIONS.—Not later than June 1, 2006, the Inspector General of the Department of Health and Human Services shall—

''(i) review the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act [42 U.S.C. 1396r–8], as amended by this section; and

''(ii) shall submit to the Secretary of Health and Human Services and Congress such recommendations for changes in such requirements or manner as the Inspector General determines to be appropriate.

''(B) DEADLINE FOR PROMULGATION.—Not later than July 1, 2007, the Secretary of Health and Human Services shall promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act, taking into consideration the recommendations submitted to the Secretary in accordance with subparagraph (A)(ii).''

PHARMACY REIMBURSEMENT UNDER MEDICAID

Pub. L. 110–275, title II, §203, July 15, 2008, 122 Stat. 2592, provided that:

''(a) DELAY IN APPLICATION OF NEW PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS UNDER MEDICAID.—Notwithstanding paragraphs (4) and (5) of subsection (e) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8) or part 447 of title 42, Code of Federal Regulations, as published on July 17, 2007 (72 Federal Register 39142)—

''(1) the specific upper limit under section 447.332 of title 42, Code of Federal Regulations (as in effect on December 31, 2006) applicable to payments made by a

State for multiple source drugs under a State Medicaid plan shall continue to apply through September 30, 2009, for purposes of the availability of Federal financial participation for such payments; and

''(2) the Secretary of Health and Human Services shall not, prior to October 1, 2009, finalize, implement, enforce, or otherwise take any action (through promulgation of regulation, issuance of regulatory guidance, use of Federal payment audit procedures, or other administrative action, policy, or practice, including a Medical Assistance Manual transmittal or letter to State Medicaid directors) to impose the specific upper limit established under section 447.514(b) of title 42, Code of Federal Regulations as published on July 17, 2007 (72 Federal Register 39142).

''(b) TEMPORARY SUSPENSION OF UPDATED PUBLICLY AVAILABLE AMP DATA.—Notwithstanding clause (v) of section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)), the Secretary of Health and Human Services shall not, prior to October 1, 2009, make publicly available any AMP disclosed to the Secretary.

''(c) DEFINITIONS.—In this subsection:

''(1) The term 'multiple source drug' has the meaning given that term in section 1927(k)(7)(A)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(7)(A)(i)).

''(2) The term 'AMP' has the meaning given 'average manufacturer price' in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)) and 'AMP' in section 447.504(a) of title 42, Code of Federal Regulations as published on July 17, 2007 (72 Federal Register 39142).''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under subchapter XVIII of this chapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

REPORTS ON BEST PRICE CHANGES AND PAYMENT OF REBATES

Pub. L. 102–585, title VI, § 601(d), Nov. 4, 1992, 106 Stat. 4965, provided that not later than 90 days after the expiration of each calendar quarter beginning on or after Oct. 1, 1992, and ending on or before Dec. 31, 1995, Secretary of Health and Human Services was to submit to Congress a report containing information as to percentage of single source drugs whose best price either increased, decreased, or stayed the same in comparison to best price during previous calendar quarter, median and mean percentage increase or decrease of such price, and, with respect to drugs for which manufacturers were required to pay rebates under subsec. (c) of this section, Secretary's best estimate, on State-by-State and national aggregate basis, of total amount of rebates paid under subsec. (c) of this section and percentages of such total amounts attributable to rebates paid under pars. (1) to (3) of subsec. (c) of this section, limited consideration to drugs which are considered significant expenditures under medicaid program, and contained requirements for initial report.

DEMONSTRATION PROJECTS TO EVALUATE EFFICIENCY AND COST-EFFECTIVENESS OF PROSPECTIVE DRUG UTILIZATION REVIEW

Pub. L. 101–508, title IV, § 4401(c), Nov. 5, 1990, 104 Stat. 1388–159, directed Secretary of Health and Human Services to establish statewide demonstration projects to evaluate efficiency and cost-effectiveness of prospective drug utilization review and to evaluate impact on quality of care and cost-effectiveness of paying pharmacists under this subchapter whether or not drugs were dispensed for drug use review services, with two reports to be submitted to Congress, the first not later than Jan. 1, 1994, and the second not later than Jan. 1, 1995.

STUDY OF DRUG PURCHASING AND BILLING PRACTICES IN HEALTH CARE INDUSTRY; REPORT

Pub. L. 101–508, title IV, § 4401(d), Nov. 5, 1990, 104 Stat. 1388–160, as amended by Pub. L. 104–316, title I, § 122(i), Oct. 19, 1996, 110 Stat. 3837, provided for various studies and reports as follows: (1) directed Comptroller General to conduct study of drug purchasing and billing activities of various health care systems, and to submit report to Secretary of Health and Human Services and to Congress by not later than May 1, 1991; (2) directed Comptroller General to submit to Secretary and Congress report on changes in prices charged by manufacturers for prescription drugs to Department of Veterans Affairs, other Federal programs, hospital pharmacies, and other purchasing groups and managed care plans; (3) directed Secretary, acting in consultation with Comptroller General, to study prior approval procedures utilized by State medical assistance programs conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; (4) directed Secretary to conduct study on adequacy of current reimbursement rates to pharmacists under each State medical assistance program conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; and (5) directed Secretary to undertake study of relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and accessibility of vaccinations and immunization to children, and to report to Congress not later than one year after Nov. 5, 1990.

## § 1396s. Program for distribution of pediatric vaccines

### (a) Establishment of program

#### (1) In general

In order to meet the requirement of section 1396a(a)(62) of this title, each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section, under which—

(A) each vaccine-eligible child (as defined in subsection (b)), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8)) from a program-registered provider (as defined in subsection (c)) on or after October 1, 1994, is entitled to receive the immunization without charge for the cost of such vaccine; and

(B)(i) each program-registered provider who administers such a pediatric vaccine to a vaccine-eligible child on or after such date is entitled to receive such vaccine under the program without charge either for the vaccine or its delivery to the provider, and (ii) no vaccine is distributed under the program to a provider unless the provider is a program-registered provider.