118TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 118–743
Part 1

MEDICAID VBPS FOR PATIENTS ACT

NOVEMBER 18, 2024.—Ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

MINORITY VIEWS

[To accompany H.R. 2666]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2666) to amend title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

59–006

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicaid VBPs for Patients Act" or the "MVP Act".

SEC. 2. CODIFYING VALUE-BASED PURCHASING ARRANGEMENTS UNDER MEDICAID AND REFORMS RELATED TO PRICE REPORTING UNDER SUCH ARRANGEMENTS.

(a) CODIFYING MULTIPLE BEST PRICE POINTS.—

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

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

(B) in subclause (V), by striking the period and inserting "; and"; and

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

"(VI) may include multiple best price points for a single dosage form and strength of a drug of a manufacturer subject to a value-based purchasing arrangement (as defined in subsection (k)(12)), but only if such manufacturer offers such arrangement to all States.".

(2) RULE OF CONSTRUCTION.—Nothing in the amendments made by this subsection may be construed to prohibit a manufacturer from treating a value-based purchasing arrangement as a bundled sale.

(b) DEFINITION OF AVERAGE MANUFACTURER PRICE.—

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

(A) in subparagraph (B)(i)—

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

(ii) in subclause (VIII), by striking the period at the end and inserting "; and"; and

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

"(IX) with respect to such covered outpatient drug that is sold under a value-based purchasing arrangement (as defined in paragraph (12)) during the rebate period, including such drug that is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy—

"(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

"(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such value-based purchasing arrangement during the period for which such arrangement is effective."; and

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

"(D) SPECIAL RULE FOR CERTAIN VALUE-BASED PURCHASING ARRANGEMENTS.—For purposes of subparagraph (A), in determining the average price paid to the manufacturer for a covered outpatient drug that is sold under a value-based purchasing arrangement (as defined in paragraph (12)) that provides that payment for such drug is made in installments over the course of such agreement, such price shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.".

(2) RULEMAKING.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall implement the amendments made by this subsection through rulemaking.

(c) DEFINITION OF VALUE-BASED PURCHASING ARRANGEMENT.—Section 1927(k) of the Social Security Act (42 U.S.C. 1396r-8(k)) shall be amended by adding at the end the following paragraph:

"(12) VALUE-BASED PURCHASING ARRANGEMENT.—The term 'value-based purchasing arrangement' has the meaning given such term in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation).".

SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER MEDICARE.

Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended—

(1) by striking "In calculating" and inserting the following:

"(A) IN GENERAL.—Subject to subparagraph (B), in calculating"; and

(2) by adding at the end the following new subparagraph:

"(B) CERTAIN REMUNERATION UNDER VALUE-BASED PURCHASING ARRANGEMENTS EXCLUDED.—In calculating the manufacturer's average sales price under this subsection for a drug or biological that is sold under a value-

based purchasing arrangement (as defined in section 1927(k)(12)) and with respect to which the manufacturer of such drug or biological has elected to include multiple best price points (as described in section 1927(c)(1)(C)(ii)(VI)) in reporting the best price of such drug under section 1927(b), such price shall not include any amount that is excluded from the calculation of the average manufacturer price of such drug or biological under section 1927(k)(1)(B)(i)(IX).".

SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS UNDER MEDICAID.

Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidance to State Medicaid agencies on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part of, or as incident to and in the same setting as, inpatient hospital services furnished under a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), or under a waiver of such plan, where such drugs or biological products are reimbursed directly and not paid for as part of payment for such inpatient hospital services, including guidance on how multiple States may enter into agreements with one another and with manufacturers which permit the transfer of funds between the participating States so that individuals who reside in a State different from the State in which they receive a drug subject to a value-based purchasing arrangement as an inpatient may be treated as if they received such drug in the State in which they reside.

SEC. 5. EXCEPTION UNDER THE ANTIKICKBACK STATUTE.

(a) IN GENERAL.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) in subparagraph (J), by moving the left margin of such subparagraph 2 ems to the left;

(2) in subparagraph (K)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking "and" at the end;

(3) in subparagraph (L)(iii), by striking the period and inserting "; and"; and

(4) by adding at the end the following new subparagraph:

"(M) any remuneration provided by a manufacturer or third party on behalf of a manufacturer to a State under a value-based purchasing arrangement (as defined in section 1927(k)(12)) under a State plan under title XIX (or waiver of such plan) in the case a patient fails to achieve outcomes or measures defined in such arrangement following the administration of a covered outpatient drug (as defined in section 1927(k)(2)).".

(b) RULEMAKING.—Not later than 180 days after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall through rulemaking implement the amendments made by this section.

SEC. 6. GAO STUDY AND REPORT ON USE OF VALUE-BASED PURCHASING ARRANGEMENTS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the extent to which value-based purchasing arrangements (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r-8(k)(12)) facilitate patient access to covered outpatient drugs, improve patient outcomes, lower overall health system costs, and lower costs for patients in Federal health care programs. In conducting such study, the Comptroller General shall—

(1) study the impact of this Act on—

(A) access to transformative therapies, including rare disease gene therapies, generally;

(B) mitigating socioeconomic disparities in accessing covered outpatient drugs sold under value-based purchasing arrangements through its requirement that State Medicaid programs have access to the same value-based purchasing arrangement pricing structure that are available in the commercial market for such drugs;

(C) the Medicaid drug rebate program under section 1927 of the Social Security Act (42 U.S.C. 1396r–8), the 340B drug pricing program under section 340B of the Public Health Service Act (42 U.S.C. 256b), and part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.), including compliance with such programs;

(D) expenditures under State Medicaid programs; and

(E) prices for such drugs under the Medicaid program in States that do not enter into such arrangements;

(2) analyze all the types of value-based purchasing arrangement pricing structures, which structures are working well (as measured by price and ease of implementing), and which need improvement; and

(3) study the potential long-term savings for States that enter into such arrangements under State Medicaid programs.

(b) REPORT.—Not later than June 30, 2028, the Comptroller General of the United States shall submit to Congress a report containing the results of the study conducted under subsection (a).

PURPOSE AND SUMMARY

The bill amends Medicare and Medicaid policies to support opportunities for States to enter into value-based purchasing arrangements with drug manufacturers to manage the costs of certain drugs in the Medicaid program.

BACKGROUND AND NEED FOR LEGISLATION

The current decade is poised to bring seismic changes to health care, as breakthrough treatments for cell and gene therapies come to market for the first time. Therapies to cure diseases like sickle cell disease and hemophilia, diseases where medicine could only help manage symptoms, could lead to opportunities where patients no longer need regular doctors' appointments and hospitalizations, saving them time and money and supporting a more secure future.

The Medicaid program, which disproportionately covers children and people with disabilities who stand to benefit the most from many of these potential treatments, will be integral in covering these therapeutics. However, many of these treatments will likely be high-cost, one-time treatments that will have significant budgetary implications for States in the short run that could disrupt State financing and an ability to cover these treatments, even if the eventual cures will save States money in the long run.

As such, value-based purchasing arrangements have emerged as a means for States to help manage these costs by allowing States to pay over multiple installments for a drug and by allowing States to pay for a drug only if the patient meets key clinical endpoints. However, statutory barriers in Medicare and Medicaid limit the ability for States to enter these types of agreements. Thus, H.R. 2666 would make necessary amendments to current law to facilitate these types of agreements.

COMMITTEE ACTION

On April 26, 2023, the Subcommittee on Health held a hearing on H.R. 2666. The title of the hearing was "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care." The Subcommittee received testimony from:

- Chiquita Brooks-LaSure, Administrator, U.S. Centers for Medicare and Medicaid Services;
- Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association;
- Kristin Bass, Chief Policy and External Affairs Officer, Pharmaceutical Care Management Association;
- Brian Connell, Executive Director, Federal Affairs, The Leukemia and Lymphoma Society;
- Sean Cavanaugh, Chief Policy Officer, Aledade, Inc.;

- Ilyse Schuman, Senior Vice President, Health Policy, American Benefits Council; and
- Loren Adler, Fellow and Associate Director, USC-Brookings Initiative for Health Policy, Economic Studies Program, Brookings Institution.

On May 17, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 2666, as amended, to the full Committee by a record vote of 16 yeas and 11 nays.

On May 24, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2666, as amended, favorably reported to the House by a record vote of 31 yeas and 19 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 3

BILL: H.R. 2666, "Medicaid VBPs for Patients Act" or the "MVP Act"

AMENDMENT: A motion by Chair Rodgers to order H.R. 2666 favorably reported to the House, as amended (Final Passage).

DISPOSITION: AGREED TO, by a roll call vote of 31 yeas to 19 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone		X	
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette			
Rep. Guthrie	X			Rep. Schakowsky		X	
Rep. Griffith	X			Rep. Matsui		X	
Rep. Bilirakis	X			Rep. Castor		X	
Rep. Johnson	X			Rep. Sarbanes		X	
Rep. Bucshon	X			Rep. Tonko		X	
Rep. Hudson	X			Rep. Clarke		X	
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz		X	
Rep. Duncan	X			Rep. Peters	X		
Rep. Palmer	X			Rep. Dingell		X	
Rep. Dunn	X			Rep. Veasey		X	
Rep. Curtis	X			Rep. Kuster		X	
Rep. Lesko	X			Rep. Kelly		X	
Rep. Pence	X			Rep. Barragán		X	
Rep. Crenshaw	X			Rep. Blunt Rochester		X	
Rep. Joyce	X			Rep. Soto		X	
Rep. Armstrong	X			Rep. Craig		X	
Rep. Weber	X			Rep. Schrier		X	
Rep. Allen	X			Rep. Trahan		X	
Rep. Balderson	X			Rep. Fletcher		X	
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte							

05/24/2023

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 2666 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to codify value-based purchasing arrangements under the Medicaid program.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2666 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 2666:

- On April 26, 2023, the Subcommittee on Health held a hearing on H.R. 2666. The title of the hearing was "Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care." The Subcommittee received testimony from:
  - Chiquita Brooks-LaSure, Administrator, U.S. Centers for Medicare and Medicaid Services;
  - Ashley Thompson, Senior Vice President, Public Policy Analysis and Development, American Hospital Association;
  - Kristin Bass, Chief Policy and External Affairs Officer, Pharmaceutical Care Management Association;
  - Brian Connell, Executive Director, Federal Affairs, The Leukemia and Lymphoma Society;
  - Sean Cavanaugh, Chief Policy Officer, Aledade, Inc.;

- Ilyse Schuman, Senior Vice President, Health Policy, American Benefits Council; and
- Loren Adler, Fellow and Associate Director, USC-Brookings Initiative for Health Policy, Economic Studies Program, Brookings Institution.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2666 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the "Medicaid VBPs for Patients Act" or the "MVP Act".

Section 2. Codifying value-based purchasing arrangements under Medicaid and reforms related to price reporting under such arrangements

Section 2 codifies the ability for drug manufacturers to report multiple best prices in Medicaid for a drug, if the manufacturer is engaged in a value-based purchasing arrangement for the drug.

This section also amends the calculation of Average Manufacturer Price to account for multiple best prices reported for drugs in value-based purchasing arrangements, and requires rulemaking to implement this provision.

The section also defines value-based purchasing arrangements in statute.

Section 3. Calculation of average sales price under Medicare

Section 3 amends the calculation of Average Sales Price to account for multiple best prices reported for drugs in value-based purchasing arrangements.

Section 4. Guidance on value-based purchasing arrangements for inpatient drugs under Medicaid

Section 4 requires the Department of Health and Human Services (HHS) to issue guidance clarifying the ability for States and manufacturers to enter into value-based purchasing arrangements for drugs dispensed in inpatient settings.

Section 5. Exception under the Antikickback Statute

Section 5 creates an exception in the Antikickback Statute for payments made by manufacturers to States when the manufacturer is in a value-based purchasing agreement with a State and when a patient in such an arrangement fails to achieve outcomes or measures specified by the arrangement.

The section also requires rulemaking to implement this section.

Section 6. GAO Study and report on use of value-based purchasing arrangements

Section 6 requires the Comptroller General to study the extent to which value-based purchasing agreements facilitate access to respective drugs.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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PART A—GENERAL PROVISIONS

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CRIMINAL PENALTIES FOR ACTS INVOLVING FEDERAL HEALTH CARE PROGRAMS

SEC. 1128B. (a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit

or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c),

shall (i) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1861(u)), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of title XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act;

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1860D–3(e)(6);

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agree-

ment, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4);

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1860D–14A(g)) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A;

(K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish; [and]

(L) a bona fide mental health or behavioral health improvement or maintenance program, if—

(i) such program—

(I) consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

(II) is made available to a physician or other clinician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician or other clinician;

(III) is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial

changes to the operation of such program), that includes—

(aa) a description of the content and duration of the program;

(bb) a description of the evidence-based support for the design of the program;

(cc) the estimated cost of the program;

(dd) the personnel (including the qualifications of such personnel) implementing the program; and

(ee) the method by which such entity will evaluate the use and success of the program;

(IV) is offered by an entity described in clause (ii) with a formal medical staff to all physicians and other clinicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

(V) is offered to all such physicians and clinicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician or clinician for such entity;

(VI) is evidence-based and conducted by a qualified health professional; and

(VII) meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

(ii) such entity is—

(I) a hospital;

(II) an ambulatory surgical center;

(III) a community health center;

(IV) a rural emergency hospital;

(V) a skilled nursing facility; or

(VI) any similar entity, as determined by the Secretary; and

(iii) neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician or other clinician to such entity or the amount or value of other business generated by such physician for the entity**[**.**]***; and*

(M) any remuneration provided by a manufacturer or third party on behalf of a manufacturer to a State under a value-based purchasing arrangement (as defined in section 1927(k)(12)) under a State plan under title XIX (or waiver of such plan) in the case a patient fails to achieve outcomes or measures defined in such arrangement following the administration of a covered outpatient drug (as defined in section 1927(k)(2)).

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under title XVIII, title XIX, or title XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, or other entity (including an eligible organization under section 1876(b)) for which certification is required under title XVIII or a State health care program (as defined in section 1128(h)), or with respect to information required to be provided under section 1124A, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Whoever knowingly and willfully—

(1) charges, for any service provided to a patient under a State plan approved under title XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under title XIX under a contract under section 1903(m) or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under title XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Whoever accepts assignments described in section 1842(b)(3)(B)(ii) or agrees to be a participating physician or supplier under section 1842(h)(1) and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) For purposes of this section, the term "Federal health care program" means—

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or

(2) any State health care program, as defined in section 1128(h).

(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.

(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

SEC. 1847A. (a) APPLICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

(2) ELECTION.—This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

(b) PAYMENT AMOUNT.—

(1) IN GENERAL.—Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4) or in the case of such a drug or biological product that is a selected drug (as referred to in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(3)) applicable for such drug and a year during such period; or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) SPECIFICATION OF UNIT.—

(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable.

(B) UNIT DEFINED.—In this section, the term "unit" means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable, determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) AVERAGE SALES PRICE.—The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) BASIS FOR PAYMENT AMOUNT.—The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) USE OF VOLUME-WEIGHTED AVERAGE SALES PRICES IN CALCULATION OF AVERAGE SALES PRICE.—

(A) IN GENERAL.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable, determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) BILLING UNIT DEFINED.—For purposes of this subsection, the term "billing unit" means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) SPECIAL RULE.—Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) BIOSIMILAR BIOLOGICAL PRODUCT.—

(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(i) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(ii) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(B) TEMPORARY PAYMENT INCREASE.—

(i) IN GENERAL.—In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting "8 percent" for "6 percent".

(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a qualifying biosimilar biological product is—

(I) in the case of such a product for which payment was made under this paragraph as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning October 1, 2022, and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For purposes of this subparagraph, the term "qualifying biosimilar biological product" means a biosimilar biological product described in paragraph (1)(C) with respect to which—

(I) in the case of a product described in clause (ii)(I), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product; and

(II) in the case of a product described in clause (ii)(II), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product.

(c) MANUFACTURER'S AVERAGE SALES PRICE.—

(1) IN GENERAL.—For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of "best price' under section 1927(c)(1)(C)(i).

(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

(3) SALE PRICE NET OF DISCOUNTS.—[In calculating]

(A) IN GENERAL.—Subject to subparagraph (B), in calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under subsection (i), section 1927, or section 1860D–14B). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(B) CERTAIN REMUNERATION UNDER VALUE-BASED PURCHASING ARRANGEMENTS EXCLUDED.—In calculating the manufacturer's average sales price under this subsection for a drug or biological that is sold under a value-based purchasing arrangement (as defined in section 1927(k)(12)) and with respect to which the manufacturer of such drug or biological has elected to include multiple best price points (as described in section 1927(c)(1)(C)(ii)(VI)) in reporting the best price of such drug under section 1927(b), such price shall not include any amount that is excluded from the calculation of the average manufacturer price of such drug or biological under section 1927(k)(1)(B)(i)(IX).

(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE.—

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section—

(i) in the case of a drug or biological furnished prior to January 1, 2019, based on—

(I) the wholesale acquisition cost; or

(II) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals; and

(ii) in the case of a drug or biological furnished on or after January 1, 2019—

(I) at an amount not to exceed 103 percent of the wholesale acquisition cost; or

(II) based on the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2024, during the initial period described in subparagraph (A) with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.

(5) FREQUENCY OF DETERMINATIONS.—

(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) UPDATES IN PAYMENT AMOUNTS.—The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) DEFINITIONS AND OTHER RULES.—In this section:

(A) MANUFACTURER.—The term "manufacturer" means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5)), except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.

(B) WHOLESALE ACQUISITION COST.—The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States,

not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) MULTIPLE SOURCE DRUG.—

(i) IN GENERAL.—The term "multiple source drug" means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are 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 (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term "single source drug or biological" means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and 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.

(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—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.

(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, "other than a vaccine" is deemed deleted from section 1927(k)(2)(B).

(H) BIOSIMILAR BIOLOGICAL PRODUCT.—The term "biosimilar biological product" means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.

(I) REFERENCE BIOLOGICAL PRODUCT.—The term "reference biological product" means the biological product licensed under such section 351 that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) MONITORING OF MARKET PRICES.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

(3) LIMITATION ON AVERAGE SALES PRICE.—

(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term "applicable threshold percentage" means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter,

substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

(4) CIVIL MONEY PENALTY.—

(A) MISREPRESENTATION.—If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false 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.

(D) INCREASING OVERSIGHT AND ENFORCEMENT.—For calendar quarters beginning on or after January 1, 2022, section 1927(b)(3)(C)(iv) shall be applied as if—

(i) each reference to "under this subparagraph and subsection (c)(4)(B)(ii)(III)" were a reference to "under this subparagraph, subsection (c)(4)(B)(ii)(III), and subparagraphs (A), (B), and (C) of section 1847A(d)(4)"; and

(ii) the reference to "activities related to the oversight and enforcement of this section and agreements under this section" were a reference to "activities related to the oversight and enforcement of this section and under subsection (f)(2) of section 1847A and subparagraphs (A), (B), and (C) of section 1847A(d)(4) and, if applicable, agreements under this section".

(E) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A), (B), or (C) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(5) WIDELY AVAILABLE MARKET PRICE.—

(A) IN GENERAL.—In this subsection, the term "widely available market price" means the price that a prudent physician or supplier would pay for the drug or biological.

In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) CONSIDERATIONS.—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

(i) Manufacturers.
(ii) Wholesalers.
(iii) Distributors.
(iv) Physician supply houses.
(v) Specialty pharmacies.
(vi) Group purchasing arrangements.
(vii) Surveys of physicians.
(viii) Surveys of suppliers.
(ix) Information on such market prices from insurers.
(x) Information on such market prices from private health plans.

(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—

(1) IN GENERAL.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3).

(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning on January 1, 2022, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs or biologicals described in subparagraph (A), 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 such a drug or biological 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 1128A (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 1128A(a).

(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs or biologicals by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

(ii) to permit the Comptroller General of the United States to review the information provided;

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

(iv) to permit the Medicare Payment Advisory Commission to review the information provided; and

(v) to permit the Medicaid and CHIP Payment and Access Commission to review the information provided.

(g) PAYMENT ADJUSTMENT FOR CERTAIN DRUGS FOR WHICH THERE IS A SELF-ADMINISTERED NDC.—

(1) OIG STUDIES.—The Inspector General of the Department of Health and Human Services shall conduct periodic studies to identify National Drug Codes for drug or biological products that are self-administered for which payment may not be made under this part because such products are not covered pursuant to section 1861(s)(2) and which the Inspector General determines (based on the same or similar methodologies to the methodologies used in the final recommendation followup report of the Inspector General described in paragraph (3) or in the November 2017 final report of the Inspector General entitled "Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries") should be excluded

from the determination of the payment amount under this section.

(2) PAYMENT ADJUSTMENT.—If the Inspector General identifies a National Drug Code for a drug or biological product under paragraph (1), the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this paragraph) and the Secretary shall, to the extent the Secretary deems appropriate, apply as the amount of payment under this section for the applicable billing and payment code the lesser of—

(A) the amount of payment that would be determined under this section for such billing and payment code if such National Drug Code for such product so identified under paragraph (1) were excluded from such determination; or

(B) the amount of payment otherwise determined under this section for such billing and payment code without application of this subsection.

(3) APPLICATION TO CERTAIN IDENTIFIED PRODUCTS.—In the case of a National Drug Code for a drug or biological product that is self-administered for which payment is not made under this part because such product is not covered pursuant to section 1861(s)(2) that was identified by the Inspector General of the Department of Health and Human Services in the final recommendation followup report of the Inspector General published July 2020, entitled Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars, beginning July 1, 2021, the amount of payment under this section for the applicable billing and payment code shall be the lesser of—

(A) the amount of payment that would be determined under this section for such billing and payment code if such National Drug Code for such drug or biological products so identified were excluded from such determination; or

(B) the amount of payment otherwise determined under this section for such billing and payment code without application of this subsection.

(h) REFUND FOR CERTAIN DISCARDED SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.—

(1) SECRETARIAL PROVISION OF INFORMATION.—

(A) IN GENERAL.—For each calendar quarter beginning on or after January 1, 2023, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that in-

cludes such data as determined appropriate by the Secretary).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (3).

(B) DETERMINATION OF DISCARDED AMOUNTS.—For purposes of subparagraph (A)(i), with respect to a refundable single-dose container or single-use package drug furnished during a quarter, the amount of such drug that was discarded shall be determined based on the amount of such drug that was unused and discarded for each drug on the date of service.

(C) EXCLUSION OF UNITS OF PACKAGED DRUGS.—The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(2) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund that is equal to the amount specified in paragraph (3) for such drug for such quarter.

(3) REFUND AMOUNT.—

(A) IN GENERAL.—The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(i) the product of—

(I) the total number of units of the billing and payment code for such drug that were discarded during such quarter (as determined under paragraph (1)); and

(II)(aa) in the case of a refundable single-dose container or single-use package drug that is a single source drug or biological, the amount of payment determined for such drug or biological under subsection (b)(1)(B) for such quarter; or

(bb) in the case of a refundable single-dose container or single-use package drug that is a biosimilar biological product, the amount of payment determined for such product under subsection (b)(1)(C) for such quarter; exceeds

(ii) an amount equal to the applicable percentage (as defined in subparagraph (B)) of the estimated total allowed charges for such drug under this part during the quarter.

(B) APPLICABLE PERCENTAGE DEFINED.—

(i) IN GENERAL.—For purposes of subparagraph (A)(ii), the term "applicable percentage" means—

(I) subject to subclause (II), 10 percent; and

(II) if applicable, in the case of a refundable single-dose container or single-use package drug described in clause (ii), a percentage specified by the Secretary pursuant to such clause.

(ii) TREATMENT OF DRUGS THAT HAVE UNIQUE CIRCUMSTANCES.—In the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in paragraph (8)(B)(ii), the Secretary, through notice and comment rulemaking, may increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

(4) FREQUENCY.—Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

(5) REFUND DEPOSITS.—Amounts paid as refunds pursuant to paragraph (2) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

(6) ENFORCEMENT.—

(A) AUDITS.—

(i) MANUFACTURER AUDITS.—Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this subsection shall be subject to periodic audit with respect to such drug and such refunds by the Secretary.

(ii) PROVIDER AUDITS.—The Secretary shall conduct periodic audits of claims submitted under this part with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) to ensure compliance with the requirements applicable under this subsection.

(B) CIVIL MONEY PENALTY.—

(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (2) for such drug for a calendar quarter in an amount equal to the sum of—

(I) the amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(II) 25 percent of such amount.

(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) 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 1128A(a).

(7) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

(8) DEFINITION OF REFUNDABLE SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUG.—

(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term "refundable single-dose container or single-use package drug" means a single source drug or biological (as defined in section 1847A(c)(6)(D)) or a biosimilar biological product (as defined in section 1847A(c)(6)(H)) for which payment is made under this part and that is furnished from a single-dose container or single-use package.

(B) EXCLUSIONS.—The term "refundable single-dose container or single-use package drug" does not include—

(i) a drug or biological that is either a radiopharmaceutical or an imaging agent;

(ii) a drug or biological approved by the Food and Drug Administration for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process; or

(iii) a drug or biological approved by the Food and Drug Administration on or after the date of enactment of this subsection and with respect to which payment has been made under this part for fewer than 18 months.

(9) REPORT TO CONGRESS.—Not later than 3 years after the date of enactment of this subsection, the Office of the Inspector General, after consultation with the Centers for Medicare & Medicaid Services and the Food and Drug Administration, shall submit to the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, a report on any impact this section is reported to have on the licensure, market entry, market retention, or marketing of biosimilar biological products. Such report shall be updated periodically at the direction of the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives.

(i) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS AND BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.—

(1) REQUIREMENTS.—

(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after January 1, 2023, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph

(A)(ii) of such paragraph for such drug and calendar quarter.

(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

(B) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

(C) TRANSITION RULE FOR REPORTING.—The Secretary may, for each part B rebatable drug, delay the timeframe for reporting the information described in subparagraph (A) for calendar quarters beginning in 2023 and 2024 until not later than September 30, 2025.

(2) PART B REBATABLE DRUG DEFINED.—

(A) IN GENERAL.—In this subsection, the term "part B rebatable drug" means a single source drug or biological (as defined in subparagraph (D) of subsection (c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such subsection) but excluding a qualifying biosimilar biological product (as defined in subsection (b)(8)(B)(iii)), for which payment is made under this part, except such term shall not include such a drug or biological—

(i) if, as determined by the Secretary, the average total allowed charges for such drug or biological under this part for a year per individual that uses such a drug or biological are less than, subject to subparagraph (B), $100; or

(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

(i) for 2024, shall be the dollar amount specified under such subparagraph for 2023, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year (without application of subparagraph (C)), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

(C) ROUNDING.—Any dollar amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(3) REBATE AMOUNT.—

(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to subparagraphs (B) and (G) and paragraph (4), the estimated amount equal to the product of—

(i) the total number of units determined under subparagraph (B) for the billing and payment code of such drug; and

(ii) the amount (if any) by which—

(I) the amount equal to—

(aa) in the case of a part B rebatable drug described in paragraph (1)(B) of subsection (b), 106 percent of the amount determined under paragraph (4) of such section for such drug during the calendar quarter; or

(bb) in the case of a part B rebatable drug described in paragraph (1)(C) of such subsection, the payment amount under such paragraph for such drug during the calendar quarter; exceeds

(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

(B) TOTAL NUMBER OF UNITS.—For purposes of subparagraph (A)(i), the total number of units for the billing and payment code with respect to a part B rebatable drug furnished during a calendar quarter described in subparagraph (A) is equal to—

(i) the number of units for the billing and payment code of such drug furnished during such calendar quarter, minus

(ii) the number of units for such billing and payment code of such drug furnished during such calendar quarter—

(I) with respect to which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act or a rebate under section 1927; or

(II) that are packaged into the payment amount for an item or service and are not separately payable.

(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term "payment amount benchmark quarter" means the calendar quarter beginning July 1, 2021.

(E) BENCHMARK PERIOD CPI–U.—The term "benchmark period CPI–U" means the consumer price index for all urban consumers (United States city average) for January 2021.

(F) REBATE PERIOD CPI–U.—The term "rebate period CPI–U" means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

(G) REDUCTION OR WAIVER FOR SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part B rebatable drug and a calendar quarter—

(i) in the case of a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the calendar quarter; or

(ii) in the case of a biosimilar biological product, when the Secretary determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event.

(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020, clause (i) of paragraph (3)(C) shall be applied as if the term "payment amount benchmark quarter" were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term "benchmark period CPI–U" were defined under paragraph (3)(E) as if the reference to "January 2021" under such paragraph were a reference to "the first month of the first full calendar quarter after the day on which the drug was first marketed".

(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020, paragraph (1)(B) shall be applied as if the reference to "January 1, 2023" under such paragraph were a reference to "the later of the 6th full calendar quarter after the day on which the drug was first marketed or January 1, 2023".

(C) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) with respect to a price applicability period (as defined in section 1191(b)(2)), in the case such drug is no longer considered to be a selected drug under section 1192(c), for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect

to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term "payment amount benchmark quarter" were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term "benchmark period CPI–U" were defined under paragraph (3)(E) as if the reference to "January 2021" under such paragraph were a reference to "the July of the year preceding such last year".

(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug furnished on or after April 1, 2023, if the payment amount described in paragraph (3)(A)(ii)(I) (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)), the payment amount described in subsection (b)(1)(B) for such drug) for a calendar quarter exceeds the inflation adjusted payment for such quarter—

(A) in computing the amount of any coinsurance applicable under this part to an individual to whom such drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

(B) the amount of such coinsurance for such calendar quarter, as computed under subparagraph (A), shall be applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply under subparagraphs (B) or (C) of subsection (b)(1).

(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(8) LIMITATION ON ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review of any of the following:

(A) The determination of units under this subsection.

(B) The determination of whether a drug is a part B rebatable drug under this subsection.

(C) The calculation of the rebate amount under this subsection.

(D) The computation of coinsurance under paragraph (5) of this subsection.

(E) The computation of amounts paid under section 1833(a)(1)(EE).

(j) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2);

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title 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 the date of the enactment of title VI of the Veterans Health Care Act of 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 title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), 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 rat-

ing 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. The preceding sentence shall not apply to a single source drug or innovator multiple source drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, 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 title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section 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 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) COVERED ENTITY DEFINED.—In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act.

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section, the following requirements shall apply:

(i) ENTITIES.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(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 340B of such Act, 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 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 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 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, 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 the date of the enactment of this paragraph.

(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, United States Code, 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, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 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, United States Code (as in effect immediately after the enactment of this paragraph) 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 the date of the enactment of this paragraph.

(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 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (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 title.

(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 title. 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 1903(a) 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 title, 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 1903(a)(1).

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

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

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

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

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

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

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title 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); 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 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, 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 otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(14)(B), 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). For purposes of applying clause (iii), for calendar quarters beginning on or after January 1, 2022, a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under part B of title XVIII as a drug or biological.

(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 1128A (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 1128A(a).

(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 sus-

pended 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 1128A (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 1128A(a).

(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, 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) (other than the wholesale acquisition cost for purposes of carrying out section 1847A) 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 1847A (including the determination and implementation of the payment amount and the rebate), or to carry out section 1847B, section 1192(f), including rebates under paragraph (4) of such section, or section 1860D–14B,

(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 title,

(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),

(vi) in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before the date of the enactment of this clause, and

(vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.

The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(G) and drug pricing data reported under the first sentence of section 1860D–31(i)(1). Any information disclosed to the

Executive Director of the Medicare Payment Advisory Commission or the Executive Director of the Medicaid and CHIP Payment and Access Commission pursuant to this subparagraph shall not be disclosed by either such Executive Director in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler. Such information also shall not be disclosed by either such Executive Director to individual Commissioners of the Medicare Payment Advisory Commission or of the Medicaid and CHIP Payment and Access Commission in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler.

(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 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.

(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.

(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,

of or 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 is 15.1 percent;and

(VI) except as provided in clause (iii), after December 31, 2009, 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 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

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

(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), 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, United States Code, 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 340B(a)(4)(L) of the Public Health Service Act);

(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 1860D–31; and

(VI) subject to clause (ii)(V), any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or any discounts provided by manufacturers under the Medicare coverage gap

discount program under section 1860D–14A or under the manufacturer discount program under section 1860D–14C.

(ii) SPECIAL RULES.—The term "best price"—

(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, section 1847A(i), or section 1860D–14B);

(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

(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, 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); **[**and**]**

(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as referred to in section 1192(c)) during such rebate period, shall be inclusive of the maximum fair price (as defined in section 1191(c)(3)) for such drug with respect to such period**[**.**]***; and*

(VI) may include multiple best price points for a single dosage form and strength of a drug of a manufacturer subject to a value-based purchasing arrangement (as defined in subsection (k)(12)), but only if such manufacturer offers such arrangement to all States.

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(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 340B(a)(4) of the Public Health Service Act.

(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 340(B)(a)(4) of the Public Health Service Act 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 1001(a) of the Public Health Service Act, 42 U.S.C. 300.

(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, United States Code.

(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 1008 of the Public Health Service Act.

(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 Administration 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, and before January 1, 2024, 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; 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 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 1903(i)(10)(E).

(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 title or title 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 1905(bb)(2)(A), 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 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 title may require, as a condition of coverage or payment for a covered outpatient drug for which Fed-

eral 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 Act.

(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.

(D) Drugs and biological products described in subsection (ee)(1)(A) of section 1905 that are furnished as medical assistance in accordance with subsection (a)(29) of such section and section 1902(a)(10)(A).

(E) Drugs and biological products to which section 1905(a)(4)(F) and subclause (XVIII) in the matter following subparagraph (G) of section 1902(a)(10) apply that are furnished as medical assistance in accordance with such section or clause, respectively, for the treatment or prevention, of COVID–19, as described in such subparagraph or subclause, respectively, and section 1902(a)(10)(A).

(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 title 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) 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 1847A.

(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).

(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.

(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 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title 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 title 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 title 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 1903(i)(10)(B), 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.

(A) In order to meet the requirement of section 1902(a)(54), a State shall provide 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, excessive utilization,inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization, 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 1903, 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 1919, 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 title, 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 title by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title 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 title:

(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 title 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 1903(r)) 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 title, or associated with specific drugs or groups of drugs.

(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 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, excessive utilization,inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization, among physicians, pharmacists and individuals receiving benefits under this title, 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 (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 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 (2)(B).

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

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified 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, United States Code (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 title, 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 1903(a)(3)(A)(i) (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) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall 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 a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title.

(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 1903(m); and

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

(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 the 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 community 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

(V) discounts provided by manufacturers under section 1860D–14A or under section 1860D–14C;

(VI) any reduction in price paid during the rebate period to the manufacturer for a drug by reason of application of part E of title XI;

(VII) rebates paid by manufacturers under section 1847A(i); **[**and**]**

(VIII) rebates paid by manufacturers under section 1860D–14B**[**.**]***; and*

(IX) with respect to such covered outpatient drug that is sold under a value-based purchasing arrangement (as defined in paragraph (12)) during the rebate period, including such drug that is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy—

(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such value-based purchasing arrangement during the period for which such arrangement is effective.

(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, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(D) SPECIAL RULE FOR CERTAIN VALUE-BASED PURCHASING ARRANGEMENTS.—For purposes of subparagraph (A), in determining the average price paid to the manufacturer for a covered outpatient drug that is sold under a value-based purchasing arrangement (as defined in paragraph (12)) that provides that payment for such drug is made in installments over the course of such agreement, such price shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.

(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 1905(a)(12), 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 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 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) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; 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 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 351 of the Public Health Service Act, and

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

(C) insulin certified under section 506 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 title 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 used 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 title includes coverage of prescribed drugs as described in section 1905(a)(12) 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, 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 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 non-prescription 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 excep-

tion 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 1902(a)(5) 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.

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MINORITY VIEWS

H.R. 2666, the Medicaid VBPs for Patients Act, would not expand access or increase affordability of drugs or gene therapies in Medicaid. Instead, it would create a loophole in federal law that would increase drug costs to Medicaid, further straining state budgets and making it harder for states to care for their most vulnerable populations.

Federal law generally requires state Medicaid programs to cover all Food and Drug Administration (FDA)-approved drugs and biologics of manufacturers that have a signed rebate agreement in place. In exchange for this coverage requirement, drug manufacturers are required to pay statutory rebates that are shared between the states and the federal government.[1] These statutory rebates are a large source of revenue that help states offset the costs of their Medicaid programs.[2]

The Medicaid drug rebate program is highly effective at reducing drug costs.[3] Medicaid consistently has among the lowest net drug costs of all federal health programs.[4] A drug's rebate is made up of a base rebate, which is the greater of either 23.1 percent of the average manufacturer price (AMP) for a brand drug, or the best price at which the drug is available on the private market. Additionally, if the quarterly AMP of the drug has increased over the base AMP of the drug at a rate that exceeds inflation, manufacturers must pay an inflationary rebate. Taken together, the Medicaid best price and inflationary rebates are a substantial source of rebates in Medicaid.

H.R. 2666 would create multiple loopholes in federal law that would undermine both the Medicaid best price policy and the inflationary rebates, resulting in decreased rebates and increased drug costs to states and the federal government. First, the bill would codify a regulation that allows drug manufacturers to report multiple best prices for drugs in value-based payment (VBP) arrangements. State Medicaid programs would only be able to receive these discounts if they entered into the same VBP that generated the best price. In other words, if a drug's non-VBP best price results in a 25 percent discount and the VBP best price results in a 50 percent discount, a state would need to enter into that VBP arrangement in order to receive the 50 percent discount.

Unfortunately, most, if not all states lack the financial resources and administrative capabilities to participate in VBPs, which means that under this structure, states will not benefit from these

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[1] Medicaid and CHIP Payment and Access Commission (MACPAC), *Strengthening Evidence Under Medicaid Drug Coverage* (March 2023).

[2] Id.

[3] Georgetown University Center for Children and Families, *How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs* (Jan. 2019).

[4] U.S. Government Accountability Office, *Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices* (June 2014).

VBP discounts. Accordingly, drug manufacturers will be able to structure their most generous discount agreements as VBPs with terms that make them inaccessible to state Medicaid programs and, therefore, result in reduced rebates and increased costs to Medicaid. This will put further strain on state budgets.

In addition to the best price loophole, H.R. 2666 would undermine Medicaid inflationary rebates by excluding VBP prices from the calculation of AMP. A manufacturer launching a new product would be able to structure some or all of its sales as VBPs, which would artificially increase the AMP. By artificially increasing the AMP, manufacturers will be able to delay the onset of inflationary rebates. This will deprive states and the federal government of yet another important source of rebates and further strain state budgets.

Multiple commenters echoed these concerns and others in their comments on the regulation that H.R. 2666 would codify. The National Association of Medicaid Directors (NAMD), a bipartisan association that represents all the state Medicaid directors, said "the rule's proposals would greatly favor manufacturers over states in terms of financial benefit, have significant impacts on the Medicaid pharmacy benefit, undermine best price protections that ensure the sustainability of Medicaid pharmacy budgets, and place substantial strain on state administrative resources." [5] Similarly, the Medicaid and CHIP Payment and Access Commission (MACPAC) wrote "[t]he proposed definition of VBP and changes to Medicaid best price could lead to decreased rebates, and thus increased Medicaid spending, while also increasing administrative burden on states. Specifically, the Commission is concerned that while these changes could incentivize the use of VBP in the commercial market, they would also negatively affect the Medicaid program and do little to address concerns about the impact of high-cost specialty drugs on Medicaid program spending." [6]

H.R. 2666 would codify harmful changes to the Medicaid drug rebate program that would increase costs to states and the federal government. It would create multiple loopholes, increase administrative burdens on states, and fail to increase access or reduce the cost of drugs to state Medicaid programs.

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[5] National Association of Medicaid Directors, *Comments on Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements*" [CMS–2482–P] (July 20, 2020).

[6] MACPAC, *Comments on Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements* (July 20, 2020).