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THE MEDICAID DRUG REBATE AMENDMENTS OF 1992
P.L. 102-585, *1 VETERANS HEALTH CARE ACT OF 1992
DATES OF CONSIDERATION AND PASSAGE
House: August 4, October 5, 1992
Senate: October 1, 8, 1992
Cong. Record Vol. 138 (1992)
House Report (Veterans' Affairs Committee) No. 102-714,
July 24, 1992 (To accompany **H.R. 5193**)
Senate Report (Veterans' Affairs Committee) No. 102-401,
Sept. 15, 1992 (To accompany S. 2575)
RELATED REPORTS
House Report (Veterans' Affairs Committee) No. 102-384(I),
Nov. 24, 1991 (To accompany H.R. 2890)
House Report (Energy and Commerce Committee) No. 102-384(II),
Sept. 22, 1992 (To accompany H.R. 2890)
House Report (Veterans' Affairs Committee) No. 102-622,
June 26, 1992 (To accompany H.R. 5192)
Senate Report (Veterans' Affairs Committee) No. 102-409,
Sept. 17, 1992 (To accompany S. 2973)
Senate Report (Veterans' Affairs Committee) No. 102-400,
Sept. 15, 1992 (To accompany S. 2974)

HOUSE REPORT NO. 102-384(II)
September 22, 1992
[To accompany H.R. 2890 which on July 15, 1991, was referred jointly to the Committee on Veterans' Affairs and the Committee on Energy and Commerce]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2890) to establish limits on the prices of drugs procured by the Department of Veterans Affairs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

The amendments are as follows:
Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicaid Drug Rebate Amendments of 1992".

***2** SEC. 2. TREATMENT OF PRESCRIPTION DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS OR PURCHASED BY CERTAIN CLINICS AND HOSPITALS.

(a) Exclusion of Prices From Calculation of Best Prices for Medicaid Rebate Agreements.-Section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r-8(c)(1)(C)) is amended by striking "(excluding" and inserting "(excluding any prices charged to the Indian Health Service or a covered entity described in subsection (a)(5)(D), any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under a State pharmaceutical assistance program by reference to prices charged to the Department of Veterans Affairs, and excluding".

(b) Agreements Required to Receive Payment.-

(1) In general.-The first sentence of section 1927(a)(1) of such Act (42 U.S.C. 1396r-8(a)(1)) is amended by striking "manufacturer)." and inserting "manufacturer) and an agreement described in paragraph (5) (with respect to drugs purchased by a covered entity on or after October 1, 1992), and must meet the requirements of paragraph (6).".

(2) Agreements described.-Section 1927(a) of such Act (42 U.S.C. 1396r-8(a)) is amended by adding at the end the following new paragraphs:

"(5) Limitation on prices of drugs procured by covered entities.-

"(A) Agreement with secretary.-An agreement described in this paragraph is an agreement between a manufacturer and the Secretary that provides that the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in subparagraph (C)) procured by a covered entity (as defined in subparagraph (D)) does not exceed an amount equal to the average manufacturer price for the drug under this title in the preceding calendar quarter, reduced by the rebate percentage described in subparagraph (B).

"(B) Rebate percentage defined.-For a covered outpatient drug procured in a calendar quarter, the 'rebate percentage' is the amount (expressed as a percentage) equal to-

"(i) the average total rebate required under subsection (c) with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

"(ii) the average manufacturer price for such a unit of the drug during such quarter.

"(C) Exception for drugs provided under state plans.-Drugs described in this subparagraph are drugs procured by the entity for which payment is made by the State under the State plan.

"(D) Covered entity defined.-In this subsection, the term 'covered entity' means an entity that meets the requirements described in subparagraph (E) and is one of the following:

"(i) A Federally-qualified health center (as defined in section 1905(l)(2)(B)).

"(ii) A family planning project receiving a grant or contract under section 1001 of the Public Health Service Act.

"(iii) An entity receiving a grant under subpart II of part C of title XXVI of the Public Health Service Act (relating to categorical grants for outpatient early intervention services for HIV disease).

"(iv) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act.

"(v) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

"(vi) A subsection (d) hospital (as defined in section 1886(d)(1)(B)) that the Secretary certifies-

"(I) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII or eligible for assistance under the State plan under this title;

"(II) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment***3** percentage (as determined under section 1886(d)(5)(F)) greater than 12.5 percent or was described in section 1886(d)(5)(F)(i)(II); and

"(III) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

"(E) Requirements for covered entities.-

"(i) Prohibiting duplicate rebates.-A covered entity shall not request payment under the State plan for medical assistance described in section 1905(a)(12) with respect to a drug that is subject to an agreement under this paragraph if the drug is subject to the payment of a rebate to the State under this section.

"(ii) Prohibiting resale of drugs.-With respect to any covered outpatient drug that is subject to an agreement under this paragraph, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

"(iii) Auditing.-A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this paragraph with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in clauses (i) or (ii) with respect to drugs of the manufacturer.

"(iv) Additional sanction for noncompliance.-If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in clause (i) or clause (ii), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

"(F) Treatment of distinct units of hospitals.-In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this paragraph.

"(G) Notice to manufacturers.-The Secretary shall notify manufacturers of covered outpatient drugs of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of subparagraph (E).

"(6) Requirements relating to drugs procured by department of veterans affairs.-

"(A) In general.-A manufacturer meets the requirements of this paragraph and applicable provisions of title 38, United States Code, if-

"(i) for each quarter beginning on or after January 1, 1993, the manufacturer makes available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product of the manufacturer which-

"(I) is an innovator multiple source drug,

"(II) would be an innovator multiple source drug but for the application of the first sentence of subsection (k)(3), or

"(III) is a covered drug (as defined in subparagraph (D)(ii)); and

"(ii) with respect to each covered drug of the manufacturer (as defined in subparagraph (D)(ii)) procured by the Department of Veterans Affairs on or after October 1, 1992, the manufacturer has entered into and has in effect an agreement with the Secretary of Veterans Affairs under which-

"(I) in the case of a drug purchased under the depot contracting system or listed on the Federal Supply Schedule, the price charged may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subparagraph (B)); and

"(II) the manufacturer is required to meet applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices and the Secretary's authority to audit the manufacturer's records.

"(B) Additional discount.-With respect to any covered drug the price of which is determined in accordance with an agreement under this paragraph, ***4** the manufacturer shall provide a discount in an amount equal to the amount by which-

"(i) the change in non-Federal price (as determined under subparagraph (D)(i)); exceeds

"(ii) the product of-

"(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the month during which the agreement goes into effect as the Secretary of Veterans Affairs considers appropriate); and

"(II) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in subclause (I) and the last month preceding the month during which the agreement goes into effect.

"(C) Application of survey requirements and sanctions.-The provisions of subparagraphs (B) and (C) of subsection (b)(3) shall apply to covered drugs and the Secretary of Veterans Affairs in the same manner as such provisions apply to covered outpatient drugs and the Secretary of Health and Human Services under such subparagraphs, except that references in such subparagraphs to prices or information reported or required under 'subparagraph (A)' shall be deemed to refer to information reported to the Secretary of Veterans Affairs pursuant to applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices.

"(D) Definitions.-In this paragraph:

"(i) Change in non-federal price.-The term 'change in non-Federal price' means, with respect to a covered drug that is subject to an agreement under this paragraph, an amount equal to-

"(I) the non-Federal average manufacturer price of the drug during the 3-month

period that ends with the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary of Veterans Affairs considers appropriate); minus

"(II) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the end of the period described in subclause (I) (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the period described in subparagraph (A) as the Secretary of Veterans Affairs considers appropriate).

"(ii) Covered drug.-The term 'covered drug' means a drug or product which-

"(I) is a single source drug (as defined in subsection (k)(7)(A)(iv));

"(II) would be a single source drug but for the application of the first sentence of subsection (k)(3);

"(III) is a biological product identified under section 600.3 of title 21, Code of Federal Regulations; or

"(IV) is insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(iii) Depot.-The term 'depot' means a storage system operated by an agency of the Federal Government or by an entity with which such an agency contracts, through which drugs from various manufacturers are received, stored, and held for distribution to multiple health care facilities of an agency of the Federal Government. The term includes any warehousing and distribution arrangement whether Government-owned and operated, Government-owned and privately operated, or privately-owned and operated.

"(iv) Non-federal average manufacturer price.-The term 'non-Federal average manufacturer price' means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers to the manufacturer, taking into ***5** account any cash discounts or similar price reductions during that period, but not taking into account any prices paid by the Federal Government.

"(v) Weighted average price.-The term 'weighted average price' means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs) an amount equal to-

"(I) the sum of the products of the average price per unit of each quantity of the drug sold during the period and the number of units of the drug sold during the period; divided by

"(II) the total number of units of the drug sold during the period.".

(3) Confidentiality of information.-Section 1927(b)(3)(D) of such Act (42 U.S.C. 1396r-8(b)(3)(D)) is amended-

(A) by striking "this paragraph" and inserting "this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii)"; and

(B) by striking "Secretary" each place it appears and inserting "Secretary or the Secretary of Veterans Affairs".

(4) Study of treatment of certain clinics as covered entities eligible for prescription drug discounts.-

(A) Study.-The Secretary of Health and Human Services shall conduct a study of the feasibility and desirability of including entities described in subparagraph (C) as covered entities eligible for limitations on the prices of covered outpatient drugs under section 1927(a)(5) of the Social Security Act (as added by paragraph (2)).

(B) Report.-Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under subparagraph (A), and shall include in the report-

(i) a description of the entities that are the subject of the study;

(ii) an analysis of the extent to which such entities procure prescription drugs; and

(iii) an analysis of the impact of the inclusion of such entities as covered entities under section 1927(a)(5) of the Social Security Act on the quality of care provided to and the health status of the patients of such entities.

(C) Entities described.-An entity described in this subparagraph is an entity-

(i) receiving funds from a State for the provision of mental health or substance abuse treatment services under subparts I or II of part B of title XIX of the Public Health Service Act or under title V of such Act;

(ii) receiving funds under section 318 of the Public Health Service Act (relating to treatment of sexually transmitted diseases) or section 317(j)(2) of such Act (relating to treatment of tuberculosis) through a State or unit of local government; or

(iii) receiving funds from a State under title V of the Social Security Act for the provision of maternal and child health services that are furnished on an outpatient basis.

(c) Budget Neutrality Adjustment.-Section 1927(c)(1)(B) of the Social Security Act (42 U.S.C. 1396r-8(c)(1)(B)) is amended-

(1) in clause (i), by striking "January 1, 1993," and inserting "October 1, 1992,";

(2) by striking "and" at the end of clause (i); and

(3) by striking clause (ii) and inserting the following:

"(ii) for quarters (or other periods) beginning after September 30, 1992, and before January 1, 1994, the greater of-

"(I) 15.7 percent of the average manufacturer price for the drug, or

"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;

"(iii) for quarters (or other periods) beginning after December 31, 1993, and before January 1, 1995, the greater of-

"(I) 15.4 percent of the average manufacturer price for the drug, or

"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;

"(iv) for quarters (or other periods) beginning after December 31, 1994, and before January 1, 1996, the greater of-

***6** "(I) 15.2 percent of the average manufacturer price for the drug, or

"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug; and

"(v) for quarters (or other periods) beginning after December 31, 1995, the greater of-

"(I) 15.1 percent of the average manufacturer price for the drug, or

"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug.".

(d) Reports on Best Price Changes and Payment of Rebates.-

(1) In general.-Not later than 180 days after the expiration of each calendar quarter that begins on or after October 1, 1992, and ends on or before December 31,

1995, the Secretary of Health and Human Services shall submit a report to Congress that contains the following information relating to prescription drugs dispensed in the quarter (subject to paragraph (2)):

(A) With respect to single source drugs and innovator multiple source drugs (as such terms are defined in section 1927(k)(7) of the Social Security Act)-

(i) the percentage of such drugs whose best price (as reported to the Secretary under section 1927(b) of the Social Security Act) increased compared to the best price during the previous calendar quarter;

(ii) the percentage of such drugs whose best price (as so reported) decreased compared to the best price during the previous calendar quarter;

(iii) the percentage of such drugs whose best price (as so reported) was the same as the best price during the previous calendar quarter;

(iv) the median and mean percentage increase (or decrease) in the best price of such single source drugs (as so reported) compared to the best price during the previous calendar quarter;

(v) the median and mean percentage increase (or decrease) in the best price of such innovator multiple source drugs (as so reported) compared to the best price during the previous calendar quarter; and

(vi) the median and mean percentage increase (or decrease) in the best price of all such drugs (as so reported) compared to the best price during the previous calendar quarter.

(B) With respect to all drugs for which manufacturers are required to pay rebates under section 1927(c) of the Social Security Act, the Secretary's estimate, on a State-by-State and a national aggregate basis, of-

(i) the total amount of all rebates paid under such section during the quarter, broken down by the portions of such total amount attributable to rebates described in paragraphs (1), (2), and (3) of such section;

(ii) the percentages of such total amount attributable to rebates described in paragraphs (1), (2), and (3) of such section; and

(iii) the amount of the portion of such total amount attributable to the rebate described in paragraph (1) of such section that is attributable to the application of clauses (i)(II) or (ii)(II) of such paragraph.

(2) Limitation on drugs subject to report.-No report submitted under paragraph (1) shall include any information relating to any prescription drug unless the Secretary finds that expenditures for the drug are significant expenditures under the medicaid program. In the previous sentence, expenditures for a drug are "significant" if the drug was one of the 1,000 drugs for which the greatest amount of the Federal financial assistance attributable to prescription drugs was paid under section 1903(a) of the Social Security Act during calendar year 1991.

(3) Special rule for initial report.-For purposes of the first report required to be submitted under paragraph (1)-

(A) the Secretary shall submit the report not later than July 1, 1993; and

(B) the information contained in the report shall include information on prescription drugs dispensed during each calendar quarter that began on or after January 1, 1991, and ended on or before December 31, 1992.

(e) Effective Date.-The amendments made by this section shall apply with respect to payments for calendar quarters (or periods) beginning on or after January 1, 1993 (without regard to whether or not regulations to carry out such amendments have been promulgated by such date).

Amend the title so as to read:

***7** A bill to amend title XIX of the Social Security Act to establish limits on the prices of prescription drugs procured by the Department of Veterans Affairs or purchased by certain clinics and hospitals, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 2890 is to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients.

Under current law, no Federal Medicaid matching funds are available for State spending on any of a manufacturer's outpatient prescription drugs unless the manufacturer agrees to provide a rebate on each drug to the State and the Federal government. With respect to single source drugs (drugs for which there is no generic competition) and innovator multiple source drugs (drugs that were once single source for which there is generic competition), the required rebate is the sum of (1) a basic rebate plus (2) an additional rebate. During calendar year 1992, the basic rebate is the greater of (1) 12.5 percent of the average manufacturer price (AMP) of the drug, or (2) the largest discount the manufacturer gives any U.S. purchaser as reflected in this "best price," so long as this discount does not exceed 50 percent of the AMP. In calculating the "best price," the Secretary must take into account the prices charged to the Department of Veterans Affairs and other agencies purchasing drugs from the Federal Supply Schedule. Beginning in calendar year 1993, the 12.5 percent minimum percentages will increase to 15.0 percent, and the 50 percent maximum discount will no longer apply.

The additional rebate applicable to single source and innovator multiple source drugs under current law is, through calendar year 1993, the difference between the AMP for the drug and the AMP for that drug on October 1, 1990, increased by the percentage increase in the consumer price index. Beginning in calendar year 1994, the additional rebate will be calculated on the basis of the weighted AMP for all of a manufacturer's single source and innovator multiple source drugs.

With respect to generic drugs (a copy of a single source drug that has been approved for marketing by the Food and Drug Administration), the required rebate is 10 percent of the AMP for a drug through calendar year 1993, and 11 percent thereafter.

Under the Committee bill, no Federal Medicaid matching funds would be available for State spending on any of a manufacturer's covered outpatient prescription drugs unless the manufacturer (1) lists each of its drugs on the Federal Supply Schedule and (2) enters into, and complies with, an agreement with the Secretary of the Department of Veterans Affairs (DVA). Under this agreement, the Secretary may require that the price charged to DVA by a manufacturer for any single source drug not exceed 76 percent of the non-Federal average manufacturer price, less an additional discount to offset any price increases in excess of the increase in the consumer price index. The manufacturer would also have to meet reporting and auditing requirements specified in Title 38 of the U.S. Code. The bill would also exclude prices charged under the Federal Supply Schedule to the DVA (or any other Federal purchaser, including the Department of Defense and the Federal ***8** Bureau of Prisons) from the calculation of "best price" for purposes of determining the Medicaid basic rebate for single source and innovator multiple source drugs.

The Committee bill would also protect the following Federally-funded clinics and public hospitals: (1) Federally qualified health centers (FQHCs); (2) family planning programs; (3) Ryan White Act early intervention programs; (4) State AIDS drug purchase programs; (5) hemophilia treatment centers; and (6) certain public "disproportionate share" hospitals. Under the bill, Federal Medicaid matching funds would not be available for State spending on any of a manufacturer's covered outpatient prescription drugs unless the manufacturer enters into, and complies with, an

agreement with the Secretary of HHS under which these protected purchasers would pay the same amount for a covered outpatient drug that Medicaid pays (after the basic and additional rebates have been deducted from the drug's average manufacturer price). The Secretary would have the discretion to determine the mechanism (rebate, point-of-purchase discount, or otherwise) for assuring this price reduction, which would apply only to drugs for which payment is not made separately to the clinic or other protected purchaser by a State Medicaid program. The Committee bill would prohibit these protected purchasers from reselling or transferring drugs to individuals other than their patients and would give the Secretary and manufacturers access to directly pertinent records for audit purposes.

Exclusion of the prices charged to the DVA and other protected purchasers from the calculation of "best price" would result in a cost to the Federal government if no change is made in current law. In order to maintain budget neutrality, the Committee bill would raise the minimum rebate which manufacturers must pay on single source and innovator multiple source drugs to 15.7 percent during the last quarter of calendar year (CY) 1992 and all of CY 1993; to 15.4 percent during CY 1994; to 15.2 percent during CY 1995; and to 15.1 percent during CY 1996 and thereafter. The additional rebates required under current law with respect to single source and innovator multiple source drugs, as well as the current law rebate percentages applicable to generic drugs, would remain unchanged.

The Committee bill directs the Secretary to report, on a quarterly basis, information relating to (1) changes in the Medicaid "best prices" of the top (by Medicaid expenditures) 1,000 single source and innovator multiple source drugs and (2) total Medicaid rebates paid by all manufacturers, broken down by the amounts attributable to the basic rebate (both the amounts attributable to the minimum percentage and the amounts attributable to "best price"), to the additional rebate, and to the generic rebate. The first report, covering CY 1991 and 1992, would be due July 1, 1993.

BACKGROUND AND NEED FOR THE LEGISLATION

CURRENT LAW

Medicaid is a Federal-State means-tested entitlement program that purchases basic health care and long-term care services on behalf of over 30 million low-income women, children, and elderly ***9** and disabled individuals. In FY 1993, the Federal government will spend an estimated $80 billion on Medicaid, matching about $60 billion in State Medicaid expenditures.

Medicaid is the Nation's largest single purchaser of prescription drugs, paying for between 12 and 20 percent of all retail prescriptions in the U.S. In 1993, the Federal and State governments will spend an estimated $7.4 billion on outpatient prescription drugs, with Federal spending representing 57 percent, or about $4.2 billion of that total.

The Department of Veterans Affairs operates a health care system composed of 172 hospitals, some 350 outpatient clinics, and 127 nursing homes that deliver health and long-term care services to some 3 million veterans. In FY 1993, the DVA will spend an estimated $975 million, or 6.7 percent of its projected operating budget of $14.6 billion, purchasing prescription drugs. Because the DVA health system gives the products of manufacturers exposure to about half of the Nation's physicians-in-training, and because each medical center in the DVA system is urged to carefully limit its formulary to the most cost-effective drugs available, the DVA has negotiating leverage vis-a-vis manufacturers of competing products. Prior to

the enactment of the Medicaid drug rebate program in 1990, this negotiating leverage enabled the DVA to receive deep discounts on prescription drugs, varying from 22 percent to 90 percent of the average wholesale price (AWP) of single source products and 39 to 93 percent of AWP on multiple source drugs.

Under the terms of the Budget Summit agreement between the President and the Congress in September, 1990, the Committee on Energy and Commerce was directed to report changes in Medicaid law that would achieve savings of $1.6 billion over 5 years in the purchase of prescriptions drugs. This Committee responded by reporting legislation that imposed a rebate requirement on manufacturers of single source, innovator multiple source, and generic drugs. Under this proposal, which was included by the Committee in that year's budget reconciliation bill and estimated by CBO to save $2.1 billion over 5 years, a manufacturer could not receive Federal Medicaid matching funds on any of its covered outpatient drugs in any State unless it agreed to give rebates to all States on each of its drugs. The rebates for single source and innovator multiple source drugs were to be based on the "best price" given to any purchaser in the U.S. on each drug as of September 1, 1990. For purposes of calculating the rebate, this "best price" could not increase more than the percentage increase in the consumer price index (CPI-U, all items). The purpose of this indexing provision was to protect the savings to the Medicaid program against future price increases by manufacturers.

In the House-Senate conference on the Omnibus Budget Reconciliation Act (OBRA) of 1990, where the current Medicaid drug rebate program was crafted, the indexing provision was deleted. As a result, a rebate program was created under which manufacturers may have a disincentive to offer lower "best prices" on covered outpatient drugs that Medicaid patients use in any significant volume. If Medicaid represents, say, 20 percent of a manufacturer's sales on a particular drug, the manufacturer knows that a "best price" that is lower than 87.5 percent of the AMP for a drug will result in a ***10** rebate to the Medicaid program for that product which is greater than the minimum rebate percentage which the manufacturer would have to pay under current law. The lower the "best price" to that purchaser, the greater the rebate to Medicaid.

However, the disincentive created by the Medicaid rebate program is only one of many factors that manufacturers may take into account when they set prices for their products, and it may not necessarily determine a manufacturer's pricing strategy with respect to any particular drug. For example, a manufacturer may pursue a "best price" strategy irrespective of the Medicaid rebate program in order to maintain its share in a competitive market.

The Subcommittee on Health and Environment heard testimony that many manufacturers did in fact respond to the potential disincentive in the Medicaid drug rebate program enacted in OBRA 90. Chairman Montgomery of the Committee on Veterans' Affairs testified that manufacturers deleted numbers of drugs from the Federal Supply Schedule (FSS), a DVA-administered list of drugs available to Federal purchasers at prices negotiated by DVA authorities, and by raising FSS prices for many other drugs. "Overall, VA data showed a net increase in its post-OBRA pharmaceutical prices of 21 percent ... Factoring out 'normal' inflation, VA calculated OBRA's impact on an already fiscally-starved system to be $93 million annually," he stated.

The DVA is not the only Federal purchaser that has experienced price increases since the enactment of OBRA 90. Federally-funded clinics and public hospitals serving large numbers of low-income patients also testified to the loss of "best prices." The Director of an Association which represents the 28 community and migrant health centers in Texas that serve 270,000 low-income and uninsured patients testified that, since the enactment of OBRA 90, drug prices to the centers, which purchase drugs through a buying group, have risen "dramatically." He gave the exam-

ple of glyburide, an oral antidiabetic usually prescribed to adults who develop diabetes after age 30 and who do not require insulin. Health centers in Texas have been paying $153 for the 5 mg., 1,000 count of glyburide; they will spend nearly $108,000 this year for this size and strength of glyburide. The centers have been informed by the manufacturer that next year, the price for this size and strength will increase nearly 89 percent to $287; this would result in an expenditure of $202,000 by the centers for this same size and strength next year, which translates into nearly 2,800 clinic visits.

Testimony presented by the Chief Operating Officer of the Parkland Memorial Hospital in Dallas, Texas, describes the adverse impact of drug price increases on public hospitals which serve large numbers of low-income and uninsured patients. A detailed study of the most widely used outpatient drugs at 5 public hospitals, conducted by researchers at New York University, found that, after OBRA 90, manufacturers "promptly cancelled discount contracts, terminated special-price practices, and raised the prices they charged public hospitals." Hospital costs for the drugs included in the study increased, on average, by 32 percent, far in excess of the historical 5 to 9 percent annual increases in drug prices experienced by public hospitals.

***11** Hard evidence on the effect of OBRA 90 on prescription drug prices is still being compiled. The testimony received by the Subcommittee is not dispositive as to the impact of the OBRA 90 Medicaid rebate program. There is still uncertainty as to the extent to which manufacturers have raised prices to purchasers other than Medicaid, and the extent to which such increases were due to the provisions of OBRA 90. But two points seem clear. Prices paid for outpatient drugs by the DVA, and some Federally-funded clinics and public hospitals, have increased substantially over the last two years. Those price increases have in turn reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources.

While there is substantial disagreement about the effects of OBRA 90, there is no dispute that the Medicaid rebate program has generated significant savings for the State and Federal governments, and is expected to continue to do so. According to the Congressional Budget Office, the rebate program will reduce Federal Medicaid outlays by about $5.2 billion over the next 5 years.

It is evident that OBRA 90 has achieved its objective of generating savings for the Medicaid program. However, other entities-notably the DVA, Federally-funded clinics, and public hospitals, have continued to experience substantial increases in their outpatient drug costs. The Committee is persuaded that, without intervention, the DVA and Federally-funded clinics may continue to experience substantial drug price increases as manufacturers try to limit their rebates to Medicaid. In the view of the Committee, the Federal government simply cannot continue to allow the DVA, Federally-funded clinics, and their patients to remain unprotected against manufacturer price increases.

With respect to the DVA, the Committee bill attempts to restore a market environment in which the DVA can again negotiate effectively for favorable prices on prescription drugs, while offering manufacturers the assurance that, by giving DVA at least the discount specified (or providing a deeper discount), those favorable prices will not affect the calculation of Medicaid rebates. To accomplish this, the Committee bill would make three major changes.

First, the bill would require a manufacturer, as a condition of the availability of Medicaid matching funds with respect to its covered outpatient drugs, to make available for procurement on the Federal Supply Schedule (FSS) of the General Services Administration after December 31, 1992, each of its single source and innovator multiple source drugs, whether administered on an outpatient or inpatient ba-

sis. This will assure that the DVA has access to all the drugs that its patients may need, and will prevent manufacturers from refusing to negotiate or give discounts on particular drug products.

Second, the bill would exclude from the calculation of "best price" for determining the amount of the Medicaid rebate any prices charged under the FSS, thereby excluding all prices to the DVA. In doing so, the bill would further the economies which the DVA-administered FSS permits such Federal health care providers as the Department of Defense and the Bureau of Prisons, which also purchase drugs through the FSS. In addition, the Committee bill would clarify that prices paid under State pharmaceutical assistance ***12** programs such as that operating in the State of New York, which use DVA of FSS prices as a basis for determining rebates or discounts, are also excluded from the calculation of "best price."

Finally, the Committee bill would also condition the availability of Federal matching funds with respect to any covered outpatient drug of a manufacturer on the agreement of the manufacturer to provide the DVA a minimum discount on each drug and to comply with applicable reporting and auditing requirements. In the case of single source drugs (outpatient or inpatient) purchased under the DVA's depot contracting system or listed on the FSS, the DVA may not be charged more than 76 percent of the non-Federal average manufacturer price (less an additional discount to offset price increases in excess of inflation). The 24 percent discount represents the median "best price" rebate under the Medicaid program for the first quarter of 1991, which was the last quarter before manufacturers began substantially increasing prices to the DVA. The use of this percentage is intended to capture what the Committee on Veteran's Affairs believes to be the level of discounts the DVA was receiving before the Medicaid rebate program went into effect. The Committee bill requires that an additional discount be paid on a drug when the increase in the non-Federal AMP exceeds the increase that would have occurred if the CPI had been applied to the non-Federal AMP (measured in the 3-month period ending one year before the end of the 3-month period for which the discount is calculated).

The Committee bill also provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans. Like the prices charged to the DVA, prices charged to these "covered entities" would be exempt from the calculation of the Medicaid "best price" for purposes of determining the Medicaid rebate. The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals.

In addition, manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (whether through a discount, rebate, or other mechanism) to these "covered entities" on covered outpatient drugs. These price reductions would be at least as great as those which Medicaid receives under the rebate program. They would be implemented, at the discretion of the Secretary, either by a point-of-purchase discount, a rebate, or other mechanism. "Covered entities" receiving these price reductions would be prohibited from obtaining payment for these drugs under Medicaid or from reselling or transferring the drugs to individuals other than their patients, and they would be subject to audit to verify compliance with these requirements. In giving these "covered entities" access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

***13** The Committee bill specifies 6 types of "covered entities":

(1) Federally qualified health centers (FQHCs), a category which includes ap-

proximately 1,500 Community Health Center sites, 425 Migrant Health Center sites, and 300 Health Care for the Homeless sites, as well as those clinic sites recognized by the Secretary as "look-alikes";

(2) Family planning clinics receiving Federal funds under Title X of the Public Health Service (PHS) Act, a category which includes approximately 85 grantees, encompassing almost 5,000 sites for delivery of services;

(3) AIDS early intervention sites receiving Federal funds under title XXVI of the PHS Act, a category which includes approximately 120 grantees (some of which are also Federally qualified health centers or Federally funded hemophilia treatment programs);

(4) State-operated AIDS drug purchasing assistance programs receiving Federal funds under title XXVI of the Public Health Service Act, a category which includes 54 programs;

(5) Comprehensive hemophilia diagnostic treatment centers receiving funds under the "Federal set-aside" in the Maternal and Child Health Block Grant, a category that includes a network of centers that are direct recipients of grant under this section, as well as nearly 150 facilities with which they subcontract; and

(6) Certain public hospitals that for the most recent cost reporting period had a Medicare disproportionate share adjustment greater than 12.5 or received more than 30 percent of their inpatient revenues from State or local indigent care funds, a category that encompasses approximately 90 hospitals.

With respect to clinics providing mental health, substance abuse treatment, maternal and child health, sexually transmitted disease treatment, or tuberculosis treatment services with Federal block grant funds, the bill directs the Secretary to report to the Congress within a year of enactment on the feasibility and desirability of treating these programs as "covered entities."

SECTION-BY-SECTION ANALYSIS AND DISCUSSION

SECTION 1. SHORT TITLE

The short title of the bill is the "Medicaid Drug Rebate Amendments of 1992."

SECTION 2. TREATMENT OF PRESCRIPTION DRUGS PROCURED BY THE DEPARTMENT OF VETERANS^AFFAIRS OR PURCHASED BY CERTAIN CLINICS AND HOSPITALS

(a) Exclusion of prices from calculation of best prices for Medicaid rebate agreements

The Committee bill would exclude from the calculation of "best price" for purposes of determining the Medicaid basic rebate with respect to single source or innovator multiple source drugs any of the following: (1) prices charged to the Department of Veterans Affairs (DVA), the Department of Defense, the Federal Bureau of Prisons, or any other purchaser under the Federal Supply Schedule of the General Services Administration; (2) prices charged to the ***14** Indian Health Service; (3) prices used under a State pharmaceutical assistance program by reference to prices charged to the DVA; and (4) prices charged to a "covered entity." For this purpose, a "covered entity" means (a) a Federally-qualified health center; (b) a family planning project receiving a grant or contract under section 1001 of the Public Health Service (PHS) Act; (c) an entity receiving a categorical grant to provide outpatient early intervention services for HIV disease under title XXVI of the PHS

Act; (d) a State-operated AIDS drug purchasing assistance program receiving Federal funds under title XXVI of the PHS Act; (e) a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act; and (5) a "disproportionate share" hospital that meets certain requirements. As defined under current Medicaid law, a Federally-qualified health center includes entities receiving Federal funds through the Community Health Center, Migrant Health Center, and Health Care for the Homeless programs under the PHS Act, as well as certain entities which do not actually receive Federal funds but are certified by the Secretary meet the requirements for doing so, and outpatient programs or facilities operated by Indian tribes or tribal organizations. In order to qualify as a "covered entity," a clinic, program, or project falling into one of these five categories must also meet requirements relating to the prohibition of duplicate rebates, the prohibition of resale of drugs, and auditing.

The requirements that a hospital must meet in order to be a "covered entity" are as follows. First, the hospital must meet the definition of a hospital set forth in section 1886(d)(1)(B) of the Social Security Act, which in general excludes psychiatric, rehabilitation, children's, chronic care, and cancer treatment or research hospitals. Second, the hospital must be owned or operated by a unit of State or local government. The Committee recognizes that some "public" hospitals are not owned or operated by a unit of State or local government. The bill would therefore also extend "covered entity" status to a public or private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, and to a private nonprofit hospital which has a contract with a State or local government health care to low-income individuals who are not eligible for Medicaid or Medicare. The Committee does not intend to extend "covered entity" status to a private nonprofit hospital that has a minor contract to provide indigent care which represents an insignificant portion of its operating revenues. Third, the hospital, for the most recent cost reporting period ending before the calendar quarter involved, must have had a Medicare disproportionate share adjustment percentage greater than 12.5 percent or, in the alternative, be located in an urban area, have 100 or more beds, and receive more than 30 percent of its inpatient care revenues (excluding Medicare and Medicaid payments) from State and local government payments for indigent care.

Finally, a hospital may not be a "covered entity" under the Committee bill if it obtains covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. The Committee recognizes that the public disproportionate share hospitals which the Committee is seeking to protect from high drug ***15** prices may participate in, or themselves maintain, group purchasing arrangements for a variety of purposes, including the purchase of supplies and equipment as well as pharmaceuticals. The Committee does not intend to disturb these arrangements or to require the withdrawal of these hospitals from these organizations or arrangements. However, the Secretary may not certify a hospital as a "covered entity" for purposes of the Committee bill if the hospital purchases any covered outpatient drug through a group purchasing organization or other group purchasing arrangement during the period for which certification is sought.

The Committee emphasizes that, in defining "covered entities" for purposes of both the exclusion from "best price" and the receipt of price reductions under manufacturer agreements with the Secretary, the bill does not require the receipt of any specified amount of Federal funding. In the case of "look alike" FQHCs and public hospital, an entity need not receive any Federal grants funds to qualify as a "covered entity." With respect to the other categories of "covered entity," the level of Federal grant funds that the entity receives is immaterial to a determination of its status as a "covered entity."

(b) Agreements required to receive payment

Under the Committee bill, in order for Federal Medicaid matching funds to be available for a manufacturer's covered outpatient drugs, the manufacturer must have entered into, and have in effect, an agreement with the Secretary of DVA, and a separate agreement with the Secretary of HHS, relating to the prices charged for drugs to the DVA and to certain Federally-funded clinics. These agreements are independent of, and additional to, the agreement into which manufacturers must enter into with the Secretary of HHS under current law regarding the provision of rebates to States for drugs purchased by Medicaid.

Limitation on prices of drugs procured by "covered entities"

In order to receive Federal Medicaid matching funds with respect to its covered outpatient drugs, a manufacturer must enter into an agreement with the Secretary of HHS that provides that the amount required to be paid to the manufacturer for covered outpatient drugs procured by a "covered entity" (as described above) does not exceed a specified amount. That amount is equal to the average manufacturer price for the drug in the preceding calendar quarter, reduced by an amount (expressed as a percentage) equal to the average total rebate (both basic and additional rebates) required under the Medicaid rebate program during the preceding calendar quarter, divided by the AMP for the drug (for a unit of the dosage form and strength involved). Thus, if the average manufacturer price for a unit of a drug (of a particular dosage form and strength) is $1.00, and the average Medicaid basic rebate for that unit of the drug is 17 cents, and the average Medicaid additional rebate is 3 cents, then no "covered entity" may be required to pay an amount in excess of 80 cents in the following quarter for that unit of the drug. The Committee bill does not preclude either the Secretary, on behalf of "covered entities," or "covered entities" ***16** themselves, from negotiating greater price reductions with manufacturers on one or more covered outpatient drugs.

The Committee emphasizes that the bill does not limit the amount of drugs that a "covered entity" may procure for purposes of receiving price reductions under this agreement. Unlike the general treatment of entities under the CDC-administered consolidated purchase price for vaccines, a "covered entity" under this bill is not limited to purchasing drugs with its Federal grant funds. Instead, it may use any revenues or funds available to it to procure drugs. The Committee bill does not authorize the Secretary to limit in any way the volume of purchases that can be made at the price reduction provided under the Secretary's agreements with manufacturers.

The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity." The Committee further expects that if, in order to implement these agreements, the Secretary finds it necessary to disclose to a contractor any confidential information provided to the Secretary by a manufacturer, the Secretary shall take such steps as may be necessary to prevent re-disclosure of such information by the contractor.

In order to assure that manufacturers that enter into these agreements with the Secretary do not extend price discounts on the same unit of the same drug twice-once to the "covered entity" in the form of a discount and again to the State Medicaid program in the form of a rebate-the Committee bill specifies that drugs procured by a "covered entity" for which payment is made by a State under the Medicaid program are not subject to the limitation on prices provided under this agreement. (The manufacturer would still owe a rebate on such a drug to the State Medicaid agency).

The Committee bill imposes three requirements on "covered entities" to assure the integrity of the drug price limitation program under these agreements. First, the Committee bill prohibits a "covered entity" from billing Medicaid separately for a prescription drug dispensed to a Medicaid patient if that unit of the drug was obtained by the "covered entity" for an amount specified under the manufacturer's agreement with the Secretary and if that unit of the drug would be subject to payment of a rebate under the Medicaid program. However, the Committee emphasizes that the bill does not prohibit the entity from dispensing a drug procured under the terms of this agreement in connection with a clinic visit and including the drug in the cost of the clinic visit for which the clinic bills the State Medicaid program. Because the State receives no separate claim for reimbursement for the prescription, the State will not claim a rebate on that unit of the drug from the manufacturer under the Medicaid rebate agreement, and the manufacturer ***17** is not required to make a price reduction twice on the same unit of drug.

Second, the Committee bill prohibits "covered entities" from reselling or otherwise transferring a drug subject to this agreement to a person who is not a patient of the entity. If the Secretary finds, after notice and hearing, that a "covered entity" is in violation of either the prohibition against billing Medicaid separately for a drug subject to price limitation under this agreement or the prohibition against transfer or resale, the Committee bill provides that the "covered entity" is liable to the manufacturer for an amount equal to the price reduction for the drug which the entity received under the agreement.

Finally, the Committee bill requires that a "covered entity" permit the Secretary and the manufacturer of a covered outpatient drug subject to this agreement to audit, at the Secretary's or the manufacturer's expense, the records of the entity that directly pertain to its compliance with the prohibitions against duplicate rebates and against resale or transfer with respect to the drugs of the manufacturer. The audits are to be conducted in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits. The Committee expects that, in developing these procedures, the Secretary will make every effort to minimize the administrative and financial burdens that these audits impose on "covered entities," and to limit the allowable scope of these audits to records directly pertinent to a determination of compliance with the specific prohibitions. The Committee emphasizes that participation by a "covered entity" in the price reductions under these agreements is completely at the option of each entity.

Requirements relating to drugs procured by Department of Veterans Affairs

In order to receive Federal Medicaid matching funds with respect to its covered outpatient drugs, a manufacturer must, effective January 1, 1993, make available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product which is (1) a single source drug (whether administered on an outpatient or inpatient basis), (2) a biological product described in 21 C.F.R. section 600.3, (3) insulin certified under section 506 of the Federal Food,

Drug, and Cosmetic Act, or (4) an innovator multiple source drug (whether administered on an outpatient or inpatient basis). In addition, the manufacturer must enter into, and have in effect, an agreement with the Secretary of DVA relating to "covered drugs" procured by the DVA on or after October 1, 1992. For purposes of this agreement, the term "covered drug" means (1) a single source drug (whether administered on an outpatient or inpatient basis) and (2) a biological product described in 21 C.F.R. section 600.3.

Under this agreement, the price charged by a manufacturer to the DVA with respect to a "covered drug" purchased under the DVA depot contracting system or listed on the Federal Supply Schedule may not exceed 76 percent of the non-Federal average manufacturer price, less the amount of any "additional discount" required. The "additional discount" with respect to a drug is an ***18** amount equal to the amount by which the change in the non-Federal price exceeds the product of (1) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month during which the agreement goes into effect and (2) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the 3-month period and the last month preceding the month during which the agreement goes into effect. The non-Federal average manufacturer price is defined as the weighted average price of a single form and dosage unit of a "covered drug" that is paid (during a period of time specified by the Secretary of DVA) by wholesalers to the manufacturer, taking into account any cash discounts or similar price reductions, but not taking into account any prices paid by the Federal Government.

The Committee bill also requires that, under this agreement, the manufacturer meeting applicable requirements (under Title 38 of the U.S. Code) relating to reporting information on drug prices to the Secretary of DVA and to the Secretary's authority to audit the manufacturer's records. The Secretary of DVA is authorized to survey wholesalers and manufacturers that directly distribute their "covered drugs" to verify manufacturer prices reported to the Secretary of DVA. The Secretary of DVA is authorized to impose a civil monetary penalty of up to $100,000 on a wholesaler, manufacturer, or direct seller of a "covered drug" that refuses a request for information about charges or prices by the Secretary, or that knowing provides false information to the Secretary. Manufacturers with an agreement with the Secretary of DVA that fail to provide information relating to prices of "covered drugs" to the Secretary of DVA on a timely basis are subject to an increase in the civil monetary penalty that the Secretary imposes of $10,000 per day in which the information is not provided. A manufacturer with an agreement with the Secretary of DVA that knowingly provides false information is subject to a civil money penalty of up to $100,000 for each item of false information.

Under the Committee bill, information disclosed by a manufacturer or a wholesaler under an agreement with the Secretary of DVA is confidential and shall not be disclosed by the Secretary of DVA (or a contractor with the DVA) in a form which discloses the identify of a specific manufacturer or wholesaler, except as the Secretary of DVA determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

Study of treatment of certain clinics as "covered entities"

The Committee bill directs the Secretary of HHS to report to Congress, within one year after enactment, on the feasibility and desirability of allowing the following entities to qualify as "covered entities" an receive manufacturer discounts or rebates on covered outpatient drugs under the terms of the agreement with the Secre-

tary of HHS: (1) entities receiving Federal funds from a State for the provision of mental health or substance abuse treatment services under titles V or XIX of the Public Health Service (PHS) Act; (2) entities providing treatment for sexually transmitted diseases or tuberculosis and receiving Federal funds through a State or unit of ***19** local government under section 317(j) or 318 of the PHS Act; and (3) entities receiving Federal funds from a State under the Title V Maternal and Child Health Block Grant for the provision of maternal and child health services furnished on an outpatient basis. The report is to include a description of these entities, an analysis of the extent to which they procure prescription drugs, and an analysis of the impact of the inclusion of such entities as "covered entities" on the quality of care provided to, and the health status of, the patients of such entities.

(c) Budget neutrality adjustment

Under current law, the basic rebate which a manufacturer must pay on single source and innovator multiple source drugs is a minimum of 12.5 percent of the average manufacturer price (AMP) for a drug in CY 1992, and 15 percent in CY 1993 and thereafter. To assure that the exclusion of prices charged under the Federal Supply Schedule and prices charged to "covered entities" will not increase Federal Medicaid outlays, the Committee bill raises these minimum percentages to 15.7 percent for the period October 1, 1992, through December 31, 1993; to 15.4 percent for quarters during CY 1994; to 15.2 percent for quarters during CY 1995; and to 15.1 percent for quarters during CY 1996 and thereafter.

(d) Reports on best price changes and payment of rebates

The Committee bill would direct the Secretary of HHS to submit reports to the Congress, on a quarterly basis, regarding the trends in "best prices" for single source and innovator multiple source drugs and the relative contribution that "best prices" make to the total rebates received by States. This reporting requirement is designed to give Congress the information necessary to determine whether the "best price" method of calculating the Medicaid basic rebate will continue to generate significant savings for the Federal and State governments over time, or whether the use of a flat percentage rebate would yield greater savings.

The Congressional Budget Office, working with the prices of a sample of the 100 single source and innovator multiple source drugs representing the largest Medicaid expenditures, found that the median "best price" discount-i.e., the percentage by which "best price" is below the average manufacturer price for a drug-fell from 24 percent in the first quarter of 1991 to 18 percent in the first quarter of 1992. CBO expects "best price" discounts to continue to decline until, by 1997, most will fall below the level of the minimum rebate (15.0 percent of AMP under current law, 15.1 percent under the Committee bill).

The National Governors Association and State Medicaid Directors do not share this assumption. They make 3 arguments in opposition to the CBO analysis. First, the NGA argues that the CBO analysis is based on a faulty assumption that "best prices" will disappear over time. Working from that assumption in a circular fashion, the NGA argues, CBO has arrived at estimates showing that the portion of Medicaid rebates attributable to "best price" will disappear. Second, the NGA argues that not enough information is available at this point to draw a firm conclusion regarding the future of "best prices." Third, the State Medicaid Directors point ***20** out that rebate revenues to the States increased between 1991 and 1992 to an extent they be-

lieve cannot be fully explained by increased utilization or inflation. The quarterly reports required under the Committee bill will enable the Congress and the States to determine whether the CBO projection is accurate, and, if so, whether a change in the methodology for calculating the basic rebate would be appropriate.

Each quarterly report must contain the following information relating to the 1,000 drugs for which the greatest amount of Federal Medicaid matching payments were made during calendar year 1991. With respect to single source and innovator multiple source drugs among this group, the report must provide (1) the percentage of such drugs the "best price" of which increased from the previous calendar quarter; (2) the percentage of such drugs the "best price" of which decreased from the previous calendar quarter; (3) the percentage of such drugs the "best price" of which did not increase or decrease from the previous calendar quarter; (4) the median and mean percentage increase (or decrease) in the "best price" of the single source drugs within this group of 1,000 from the previous quarter; (5) the median and mean percentage increase (or decrease) in the "best price" of the innovator multiple source drugs within this group of 1,000 from the previous quarter; and (6) the median and mean percentage increase (or decrease) in the "best price" of the entire group of 1,000 from the previous quarter.

Each quarterly report must also contain information with respect to the total amount of rebates which the Secretary estimates will be received by each State (and the District of Columbia), and by the Medicaid program nationally, on all covered outpatient drugs (currently about 45,000 drug products are covered under rebate agreements). These estimates must include the total amount of rebates paid in the quarter, as well as the percentages of the total paid, broken down by the portion attributable to the basic rebate, the additional rebate, and the generic rebate, respectively. The amounts attributable to the basic rebate must be further broken down by the amounts attributable to the minimum rebate percentage and the amounts attributable to the "best price."

The first of these reports would be due on July 1, 1993, and would apply to drugs dispensed during the 8 quarters in calendar years 1991 and 1992. Reports relating to subsequent quarters would be due no later than 180 days after the close of the quarter. The Committee expects that each of these reports will be made available to it and the other committees of jurisdiction in a timely manner.

(e) Effective date

The amendments made by the Committee bill would apply to Medicaid payments made on or after January 1, 1993, whether or not regulations to implement these amendments have been proposed or published in final form by such date. Thus, the requirements that manufacturers enter into agreements with the Secretary of DVA and the Secretary of HHS would be effective on January 1, 1993, although the agreements with the Secretary of HHS would apply to drugs purchased by "covered entities" on or after October 1, 1992, and the agreements with the Secretary of DVA ***21** would apply with respect to drugs procured on or after October 1, 1992. The requirement that manufacturers list all their single source and innovator multiple source drugs on the Federal Supply Schedule would apply January 1, 1993.

HEARINGS

On September 11, 1991, the Subcommittee on Hospitals and Health Care of the Committee on Veterans' Affairs held a hearing on H.R. 2890 and received testimony from representatives of the Department of Veterans Affairs and pharmaceutical manufac-

turers (Ser. No. 102-21).

On July 31, 1992, the Subcommittee on Health and the Environment held a hearing on legislative proposals to reform the Medicaid drug rebate program: H.R. 2890; H.R 3405, introduced by Mr. Wyden and Mr. Cooper; and H.R. 5614, introduced by Mr. Slattery. Testimony was received from Senators Kennedy, Pryor, and Rockefeller; Mr. Slattery; Chairman Montgomery and Representative Stump on behalf of the Committee on Veterans' Affairs; five veterans' organizations; representatives of community health centers, public hospitals, and State AIDS drug purchasing programs; representatives of Governors and State Medicaid agencies; representatives of group purchasing organizations; representatives of brand name drug manufacturers; and representatives of generic drug manufacturers.

COMMITTEE CONSIDERATION

The bill H.R. 2890 was introduced on July 15, 1991 by Mr. Montgomery, Mr. Stump, and Mr. Hammerschmidt. It was jointly referred to the Committee on Veterans' Affairs and the Committee on Energy and Commerce. On November 13, 1991, the Committee on Veterans' Affairs ordered reported H.R. 2890 without amendment, by voice vote.

On September 15, 1992, the Subcommittee on Health and the Environment of the Committee on Energy and Commerce met in open session and ordered reported the bill H.R. 2890, as amended, by voice vote, a quorum being present.

On September 17, 1992, the Committee on Energy and Commerce met in open session and ordered reported the bill H.R. 2890, as amended, by voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Subcommittee on Health and the Environment has made no oversight findings on the operation of the Medicaid drug rebate program or its impact on the Department of Veterans Affairs.

COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings on the subject of the Medicaid drug rebate program or its impact on the Department of Veterans ***22** Affairs have been submitted to the Committee by the Committee on Government Operations.

COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XXIII of the Rules of the House of Representatives, the Committee agrees with the Congressional Budget Office that no cost will be incurred by the Federal Government in carrying out the Committee bill in fiscal years 1993 through 1997.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of Rules of the House of Representatives, the Committee states that the enactment of this bill into law will not have an in-

flationary impact on prices and costs in the operation of the national economy. The bill will give the Department of Veterans Affairs and certain Federally-funded clinics and public hospitals the ability to obtain the same (or lower) prices on covered outpatient drugs as Medicaid (net of rebates) receives. This will reduce the costs of operation of these providers. If drug manufacturers respond to these changes by increasing their prices to other customers that the bill does not protect, such as hospital and HMO group purchasing organizations, then these entities may experience an increase in their costs of operation. However, the Committee has no evidence that the bill will cause the prices of covered outpatient drugs overall to rise faster than they would have increased in its absence.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. Congress,

Congressional Budget Office,

Washington, DC, September 21, 1992.

Hon. John D. Dingell,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2890, the Medicaid Drug Rebate Amendments of 1992, as ordered reported by the House Committee on Energy and Commerce on September 17, 1992.

The bill would affect direct spending or receipts and thus would be subject to pay-as-you-go procedures under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985. As a result, the estimate required under clause 8 of House Rule XXI also is enclosed.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,
James L. Blum

(For Robert D. Reischauer.)

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 2890.

***23** 2. Bill title: Medicaid Drug Rebate Amendments of 1992.

3. Bill status: As ordered reported by the House Committee on Energy and Commerce on September 17, 1992.

4. Bill purpose: H.R. 2890 would amend title XIX of the Social Security Act to make amendments to the prescription drug rebate portion of the Medicaid program and for other purposes.

5. Estimated cost to the Federal Government:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

The costs of the bill fall within budget function 550.

Basis of estimate

Direct spending

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) required that pharmaceutical manufacturers give rebates to the state Medicaid programs for the purchase of outpatient prescription drugs. The rebates are calculated as the product of the rebate percentage, the average manufacturer price (AMP), and the total number of units of the drug purchased by Medicaid. For single-source and innovator multiple-source drugs (SS/IMS), the rebate percentage is the greater of the minimum rebate percentage, and the percentage by which the so-called best price for the drug is lower than the AMP. The minimum rebate percentage is set at fifteen percent for SS/IMS drugs sold in 1993 and thereafter. The best price of a drug is the lowest price for which the drug is available to any purchaser in the United States during the calendar quarter.

H.R. 2890 would affect the prescription drug rebates collected by state Medicaid programs in two ways. First, the minimum rebate percentage for SS/IMS drugs would be increased to the following levels: 15.7 percent for the last quarter in 1992 and all of 1993, 15.4 percent in 1994, 15.2 percent in 1995, and 15.1 percent thereafter.

Second H.R. 2890 would exempt certain prices from the calculation required by current law to determine the best price. OBRA-90 already has exempted prices received by agencies of the federal government through depot arrangements and single-award contract prices, as well as prices negotiated by individual state Medicaid plans. H.R. 2890 would exempt prices on the Federal Supply Schedule (FSS), which is an important drug purchasing mechanism used primarily by the Department of Veterans Affairs (VA) and the Department of Defense (DoD), from the calculation of the best price. The bill also would exempt prices paid by certain entities that receive grants under the Public Health Service Act and under Maternal and Child Health Block grants. Finally, H.R. 2890 would exempt prices paid by public hospitals that treat a disproportionate ***24** share of the poor and that do not purchase outpatient drugs through a buying group.

To estimate the costs of the bill, CBO has assembled a data base consisting of information about the 100 SS/IMS drugs on which Medicaid spends the most. The Inspector General's Office of the Health and Human Services Department (IG) provided the list of 100 drugs. The IG, based on its survey of drug use in the Medicaid program during the first quarter of 1991, estimated that these 100 drugs accounted for about half of all Medicaid spending for outpatient drugs. In addition, the Health Care Financing Administration (HCFA), provided manufacturer pricing data, including the AMP, the best price, and the unit rebate amount. Finally, the VA provided FSS price information, although not all of our sample drugs were included on the FSS.

In addition to the data described in the previous paragraph, CBO used information gathered in interviews with health industry experts to estimate the costs of the bill. We estimate that the loss in rebates from exempting certain prices from the best price calculation would be offset by the increase in rebates from the higher minimum rebate percentages. Therefore, we estimate that H.R. 2890 would have no net effect on direct spending.

Other effects

This bill also would establish a mechanism to control the prices paid by federal agencies to purchase drugs and biologicals from the Federal Supply Schedule (FSS). In general, the FSS price paid for a brand name drug would be limited to 76 percent of the average price paid by wholesalers. The FSS price would be further reduced to reflect the extent to which drug price increases exceed increases in the Producer Price Index. Drug manufacturers would be required to enter into pricing agreements complying with this formula in order to receive payment for drugs or biological under the Medicaid program or to sell drugs or biologicals to VA, the DoD, the Public Health Service (PHS), or any entity that receives funds from the PHS.

CBO is unable to provide a precise estimate of the savings in the pharmaceutical costs of VA, DoD, and PHS that would result from this measure because of limitations on the data available to compare current federal drug prices to wholesale prices. Based on a comparison of 1991 FSS prices and wholesale prices for a sample of 24 drugs commonly used by VA, it is estimated that savings could amount to $40-60 million a year for VA and $30-40 million annually for DoD. Nevertheless, spending on pharmaceuticals for these agencies is financed through appropriations and net federal savings from this provision would only occur if future appropriation levels are reduced in response to the reduction in pharmaceutical costs.

6. Pay-as-you-go considerations: The Budget Enforcement Act of 1990 set up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1995. The pay-as-you-go effects of the bill are as follows.

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***25** 7. Estimated cost to State and local government: None.

8. Estimate comparison: None.

9. Previous CBO estimate: None.

10. Estimate prepared by: Scott Harrison and K.W. Shepherd.

11. Estimate approved by: C.G. Nuckols, Assistant Director for Budget Analysis.

CONGRESSIONAL BUDGET OFFICE ESTIMATE [FN1]

The applicable cost estimate of this Act for all purposes of sections 252 and 253 of the Balanced Budget and Emergency Deficit Control Act of 1985 shall be as follows:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

AGENCY VIEWS

No views were received from the Department of Health and Human Services.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 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, existing law in which no change is proposed is shown in roman):

SECTION 1927 OF THE SOCIAL SECURITY ACT

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) 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).] ***26** manufacturer) and an agreement described in paragraph (5) (with respect to drugs purchased by a covered entity on or after October 1, 1992), and must meet the requirements of 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 of such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and 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 not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into

* * * * * * *

(5) Limitation on prices of drugs procured by covered entities.-

(A) Agreement with secretary.-An agreement described in this paragraph is an agreement between a manufacturer and the Secretary that provides that the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in subparagraph (C)) procured by a covered entity (as defined in subparagraph (D)) does not exceed an amount equal to the average manufacturer price for the drug under this title in the preceding calendar quarter, reduced by the rebate percentage described in subparagraph (B).

(B) Rebate percentage defined.-For a covered outpatient drug procured in a calendar quarter, the "rebate percentage'' is the amount (expressed as a percentage) equal to-

(i) the average total rebate required under subsection (c) with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(C) Exception for drugs provided under state plans.-Drugs described in this subparagraph are drugs procured by the entity for which payment is made by the State under the State plan.

(D) Covered entity defined.-In this subsection, the term "covered entity" means an entity that meets the requirements described in subparagraph (E) and is one of the following:

(i) A Federally-qualified health center (as defined in section 1905(l)(2)(B)).

(ii) A family planning project receiving a grant or contract under section 1001 of the Public Health Service Act.

(iii) An entity receiving a grant under subpart II of part C of title XXVI of the Public Health Service Act ***27** (relating to categorical grants for outpatient early intervention services for HIV disease).

(iv) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act.

(v) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(vi) A subsection (d) hospital (as defined in section 1886(d)(1)(B)) that the Secretary certifies-

(I) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII or eligible for assistance under the State plan under this title;

(II) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F))) greater than 12.5 percent or was described in section 1886(d)(5)(F)(i)(II); and

(III) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(E) Requirements for covered entities.-

(i) Prohibiting duplicate rebates.-A covered entity shall not request payment under the State plan for medical assistance described in section 1905(a)(12) with respect to a drug that is subject to an agreement under this paragraph if the drug is subject to the payment of a rebate to the State under this section.

(ii) Prohibiting resale of drugs.-With respect to any covered outpatient drug that is subject to an agreement under this paragraph, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(iii) Auditing.-A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this paragraph with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in clauses (i) or (ii) with respect to drugs of the manufacturer.

(iv) Additional sanction for noncompliance.-If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described ***28** in clause (i) or clause (ii), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(F) Treatment of distinct units of hospitals.-In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this paragraph.

(G) Notice to manufacturers.-The Secretary shall notify manufacturers of covered outpatient drugs of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of subparagraph (E).

(6) Requirements relating to drugs procured by department of veterans affairs.-

(A) In general.-A manufacturer meets the requirements of this paragraph and applicable provisions of title 38, United States Code, if-

(i) for each quarter beginning on or after January 1, 1993, the manufacturer makes available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product of the manufacturer which-

(I) is an innovator multiple source drug,

(II) would be an innovator multiple source drug but for the application of the first sentence of subsection (k)(3), or

(III) is a covered drug (as defined in subparagraph (D)(ii)); and

(ii) with respect to each covered drug of the manufacturer (as defined in subparagraph (D)(ii)) procured by the Department of Veterans Affairs on or after October 1, 1992, the manufacturer has entered into and has in effect an agreement with the Secretary of Veterans Affairs under which-

(I) in the case of a drug purchased under the depot contracting system or listed on the Federal Supply Schedule, the price charged may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subparagraph (B)); and

(II) the manufacturer is required to meet applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices and the Secretary's authority to audit the manufacturer's records.

(B) Additional discount.-With respect to any covered drug the price of which is determined in accordance with an agreement under this paragraph, the manufacturer ***29** shall provide a discount in an amount equal to the amount by which-

(i) the change in non-Federal price (as determined under subparagraph (D)(i)); exceeds

(ii) the product of-

(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the month during which the agreement goes into effect as the Secretary of Veterans Affairs considers appropriate); and

(II) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in subclause (I) and the last month preceding the month during which the agreement goes into effect.

(C) Application of survey requirements and sanctions.-The provisions of subparagraphs (B) and (C) of subsection (b)(3) shall apply to covered drugs and the Secretary of Veterans Affairs in the same manner as such provisions apply to covered outpatient drugs and the Secretary of Health and Human Services under such subparagraphs, except that references in such subparagraphs to prices or information reported or required under "subparagraph (A)" shall be deemed to refer to information reported to the Secretary of Veterans Affairs pursuant to applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices.

(D) Definitions.-In this paragraph:

(i) Change in non-federal price.-The term "change in non-Federal price" means, with respect to a covered drug that is subject to an agreement under this paragraph, an amount equal to-

(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends with the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary of Veterans Affairs considers appropriate); minus

(II) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the end of the period described in subclause (I) (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such ***30** period is not available, during such period preceding the period described in subparagraph (A) as the Secre-

tary of Veterans Affairs considers appropriate).

(ii) Covered drug.-The term "covered drug" means a drug or product which-

(I) is a single source drug (as defined in subsection (k)(7)(A)(iv));

(II) would be a single source drug but for the application of the first sentence of subsection (k)(3);

(III) is a biological product identified under section 600.3 of title 21, Code of Federal Regulations; or

(IV) is insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(iii) Depot.-The term "depot" means a storage system operated by an agency of the Federal Government or by an entity with which such an agency contracts, through which drugs from various manufacturers are received, stored, and held for distribution to multiple health care facilities of an agency of the Federal Government. The term includes any warehousing and distribution arrangement whether Government-owned and operated, Government-owned and privately operated, or privately-owned and operated.

(iv) Non-federal average manufacturer price.-The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account any prices paid by the Federal Government.

(v) Weighted average price.-The term "weighted average price" means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs) an amount equal to-

(I) the sum of the products of the average price per unit of each quantity of the drug sold during the period and the number of units of the drug sold during the period; divided by

(II) the total number of units of the drug sold during the period.

(b) Terms of Rebate Agreement.-

(1) ***

* * * * * * *

(3) Manufacturer provision price information.-

(A) ***

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***31** (D) Confidentiality of information.-Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under [this paragraph] this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) 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 as the Secretary or the Secretary of Veterans Affairs determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

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(c) Amount of Rebate.-

(1) Basic rebate for single source drugs and innovator multiple source drugs.-With respect to single source drugs and innovator multiple source drugs, each manu-

facturer shall remit a basic rebate to the State medical assistance plan. Except as otherwise provided in this subsection, the amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to each dosage form and strength of single source drugs and innovator multiple source drugs shall be equal to the product of-

(A) ***

(B)(i) for quarters (or periods) beginning after December 31, 1990, and before [January 1, 1993,] October 1, 1992, the greater of-

(I) the difference between the average manufacturer price (after deducting customary prompt payment discounts) and 87.5 percent of such price for the quarter (or other period), or

(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(b)) for such quarter (or period) for such drug (except that for calendar quarters beginning after December 31, 1990, and ending before January 1, 1992, the rebate shall not exceed 25 percent of the average manufacturer price, and for calendar quarters beginning after December 31, 1991, and ending before January 1, 1993, the rebate shall not exceed 50 percent of the average manufacturer price); [and]

[(ii) for quarters (or other periods) beginning after December 31, 1992, the greater of-

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

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

(ii) for quarters (or other periods) beginning after September 30, 1992, and before January 1, 1994, the greater of-

***32** (I) 15.7 percent of the average manufacturer price for the drug, or

(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;

(iii) for quarters (or other periods) beginning after December 31, 1993, and before January 1, 1995, the greater of-

(I) 15.4 percent of the average manufacturer price for the drug, or

(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;

(iv) for quarters (or other periods) beginning after December 31, 1994, and before January 1, 1996, the greater of-

(I) 15.2 percent of the average manufacturer price for the drug, or

(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug; and

(v) for quarters (or other periods) beginning after December 31, 1995, the greater of-

(I) 15.1 percent of the average manufacturer price for the drug, or

(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug.

(C) For the purposes of this paragraph, the term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States [(excluding] (ex-

cluding any prices charged to the Indian Health Service or a covered entity described in subsection (a)(5)(D), any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under State pharmaceutical assistance program by reference to prices charged to the Department of Veterans Affairs, and excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section) and shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount;

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FN1 An estimate of H.R. 2890, the Medicaid Drug Rebate Amendments of 1992, as ordered reported by the House Committee on Energy and Commerce on September 17, 1992. This estimate was transmitted by the Congressional Budget Office on September 21, 1992

H.R. REP. 102-384(II), H.R. Rep. No. 384(II), 102ND Cong., 2ND Sess. 1992, 1992 WL 239341 (Leg.Hist.)

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