

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2239

To implement pharmaceutical marketplace reform, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

JUNE 24 (legislative day, JUNE 7), 1994

Mr. PRYOR (for himself and Mr. SASSER) introduced the following bill; which  
was read twice and referred to the Committee on Finance

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## A BILL

To implement pharmaceutical marketplace reform, and for  
other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCE TO ACT; TABLE OF**  
4 **CONTENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the  
6 “Pharmaceutical Marketplace Reform Act of 1994”.

7 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-  
8 cept as otherwise specifically provided, whenever in this  
9 Act an amendment is expressed in terms of an amendment  
10 to or repeal of a section or other provision, the reference

1 shall be considered to be made to that section or other  
2 provision of the Social Security Act.

3 (c) TABLE OF CONTENTS.—The table of contents for  
4 this Act is as follows:

- Sec. 1. Short title; reference to Act; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.

TITLE I—MEDICARE PROGRAM

Subtitle A—Covered Outpatient Prescription Drugs and Rebates

- Sec. 101. Covered outpatient prescription drugs.
- Sec. 102. Rebates for covered outpatient drugs.

Subtitle B—Drug Use Review

- Sec. 111. Medicare drug use review.

Subtitle C—Effective Date

- Sec. 121. Effective date.

TITLE II—MEDICAID PROGRAM

- Sec. 201. No Federal financial participation with respect to certain innovator multiple source drugs.
- Sec. 202. Rebate for certain covered outpatient drugs.
- Sec. 203. State regulation of outpatient prescription drug benefits covered by health care plans.

TITLE III—COMMISSIONS

- Sec. 301. Pharmaceutical Marketplace Information Commission.
- Sec. 302. Prescription Drug Payment Review Commission.

TITLE IV—ADDITIONS TO THE MASTER AGREEMENT

- Sec. 401. Equal access to discounts.
- Sec. 402. Provision of information to the Pharmaceutical Marketplace Information Commission.
- Sec. 403. Conforming amendments.
- Sec. 404. Effective date.

5 **SEC. 2. FINDINGS.**

6 The Congress finds that—

7 (1) any medicare outpatient prescription drug  
8 benefit should be structured to take advantage of

1 market forces and should use the same principles as  
2 other managed care pharmacy benefit programs;

3 (2) there is a lack of information in the health  
4 care system about the price and quality of pharma-  
5 ceutical products, resulting in a significant level of  
6 market distortions and a lack of price competition;

7 (3) the availability of more information about  
8 price and quality of medications would make the  
9 pharmaceutical marketplace more competitive, and  
10 minimize the need for more regulatory pharma-  
11 ceutical cost containment mechanisms;

12 (4) in the absence of competing new pharma-  
13 ceutical products in the market, there is a need for  
14 the health care system to have information about the  
15 price of new pharmaceutical products to assure that  
16 the prices are reasonable;

17 (5) price concessions and discounting offered by  
18 pharmaceutical manufacturers have not been offered  
19 on equal terms to all purchasers, resulting in higher  
20 prices for pharmaceutical products at the retail level,  
21 and ultimately for consumers; and

22 (6) under health care reform, all Americans  
23 should have access to high quality drug use review  
24 and coordinated pharmaceutical care services.

1 **SEC. 3. PURPOSES.**

2 The purposes of this Act are—

3 (1) to establish the medicare outpatient pre-  
4 scription drug program as a pharmaceutical care  
5 benefit using principles of managed care;

6 (2) to improve the quality and timeliness of in-  
7 formation provided in the health care marketplace  
8 about the relative price and value of currently mar-  
9 keted and new pharmaceutical products;

10 (3) to assure that prices for new breakthrough  
11 pharmaceutical products in the United States are  
12 reasonable;

13 (4) to provide that all pharmaceutical buyers  
14 have access to manufacturer price discounts and  
15 concessions on equal terms and conditions; and

16 (5) to assure that drug use review and pharma-  
17 ceutical care becomes an integral part of the delivery  
18 of prescription drugs in health care programs.

19 **TITLE I—MEDICARE PROGRAM**  
20 **Subtitle A—Covered Outpatient**  
21 **Prescription Drugs and Rebates**

22 **SEC. 101. COVERED OUTPATIENT PRESCRIPTION DRUGS.**

23 (a) COVERED OUTPATIENT DRUGS AS MEDICAL AND  
24 OTHER HEALTH SERVICES.—

1           (1) IN GENERAL.—Section 1861(s)(2)(J) (42  
2 U.S.C. 1395x(s)(2)(J)) is amended to read as fol-  
3 lows:

4           “(J) covered outpatient drugs;”.

5           (2) DEFINITION OF COVERED OUTPATIENT  
6 DRUGS.—Section 1861(t) (42 U.S.C. 1395x(t)), as  
7 amended by section 13553(b) of the Omnibus Budg-  
8 et Reconciliation Act of 1993 (hereafter in this sub-  
9 title referred to as “OBRA-1993”), is amended—

10           (A) in the heading, by adding at the end  
11 the following: “; Covered Outpatient Drugs”;

12           (B) in paragraph (1), by striking “para-  
13 graph (2)” and inserting “the succeeding para-  
14 graphs of this subsection”; and

15           (C) by inserting after paragraph (2) the  
16 following new paragraph:

17           “(3) The term ‘covered outpatient drugs’ means—

18           “(A) drugs and biologicals (which cannot, as  
19 determined in accordance with regulations, be self-  
20 administered) furnished as incident to a physician’s  
21 professional service, of kinds which are commonly  
22 furnished in physicians’ offices and are commonly ei-  
23 ther rendered without charge or included in the phy-  
24 sician’s bill;

1           “(B) prescription drugs used in immuno-  
2           suppressive therapy furnished to an individual who  
3           receives an organ transplant for which payment is  
4           made under this title, but only in the case of drugs  
5           furnished—

6                   “(i) before 1995, within 12 months after  
7                   the date of the transplant procedure,

8                   “(ii) during 1995, within 18 months after  
9                   the date of the transplant procedure,

10                   “(iii) during 1996, within 24 months after  
11                   the date of the transplant procedure,

12                   “(iv) during 1997, within 30 months after  
13                   the date of the transplant procedure, and

14                   “(v) during any year after 1997, within 36  
15                   months after the date of the transplant proce-  
16                   dure;

17           “(C) erythropoietin—

18                   “(i) for dialysis patients competent to use  
19                   such drug without medical or other supervision  
20                   with respect to the administration of such drug,  
21                   subject to methods and standards established  
22                   by the Secretary by regulation for the safe and  
23                   effective use of such drug; and

24                   “(ii) administered in a renal dialysis facil-  
25                   ity.

1           “(D) an oral drug (which is approved by the  
2 Federal Food and Drug Administration) prescribed  
3 for use as an anticancer chemotherapeutic agent for  
4 a given indication, and containing an active ingredi-  
5 ent (or ingredients), which is the same indication  
6 and active ingredient (or ingredients) as a drug  
7 which the carrier determines would be covered pur-  
8 suant to subparagraph (A) or section 1861(s)(2)(B)  
9 if the drug could not be self-administered; and

10           “(E) any other outpatient drug or biological de-  
11 scribed in section 1927(k) for which payment may  
12 be specially allowed.”.

13           (3) CONFORMING AMENDMENTS.—(A) Section  
14 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by  
15 section 13553 of OBRA-1993, is amended—

16           (i) in subparagraph (A), by striking “(in-  
17 cluding drugs and biologicals which cannot, as  
18 determined in accordance with regulations, be  
19 self-administered)”.

20           (ii) by adding “and” at the end of sub-  
21 paragraph (O),

22           (iii) by amending subparagraph (P) to  
23 read as follows:

24           “(P) items related to the administration of  
25 erythropoietin.”, and

1 (iv) by striking subparagraph (Q).

2 (B) Section 1881(b)(1)(C) (42 U.S.C.  
3 1395rr(b)(1)(C)), as amended by section 13566(a)  
4 of OBRA-1993, is amended by striking “section  
5 1861(s)(2)(P)” and inserting “section  
6 1861(t)(3)(C)(i)”.

7 (b) ADDITION OF MEDICARE TO MASTER PLAN RE-  
8 QUIREMENTS.—Section 8126(a)(4) of title 38, United  
9 States Code, is amended—

10 (1) by striking “or” at the end of subparagraph  
11 (B);

12 (2) by striking the period at the end of sub-  
13 paragraph (C) and inserting “, or”; and

14 (3) by adding at the end the following new sub-  
15 paragraph:

16 “(D) the medicare program under title  
17 XVIII of the Social Security Act.”.

18 **SEC. 102. REBATES FOR COVERED OUTPATIENT DRUGS.**

19 (a) IN GENERAL.—Part B of title XVIII is amended  
20 by adding at the end the following new section:

21 “REBATES FOR COVERED OUTPATIENT DRUGS  
22 “SEC. 1849. (a) REQUIREMENT FOR REBATE  
23 AGREEMENT.—In order for payment to be available under  
24 this part for a covered outpatient drug of a manufacturer  
25 dispensed on or after January 1, 1995, the manufacturer  
26 must have entered into and have in effect a rebate agree-

1 ment with the Secretary meeting the requirements of sub-  
2 section (b).

3 “(b) TERMS, IMPLEMENTATION, AND ENFORCEMENT  
4 OF REBATE AGREEMENT.—

5 “(1) PERIODIC REBATES.—

6 “(A) IN GENERAL.—A rebate agreement  
7 under this section shall require the manufac-  
8 turer to pay to the Secretary for each calendar  
9 quarter, not later than 30 days after the date  
10 of receipt of the information described in para-  
11 graph (2) for such quarter, a rebate in an  
12 amount determined under subsection (c) for all  
13 covered outpatient drugs of the manufacturer  
14 described in subparagraph (B).

15 “(B) DRUGS INCLUDED IN QUARTERLY  
16 REBATE CALCULATION.—Drugs subject to re-  
17 bate with respect to a calendar quarter are cov-  
18 ered outpatient drugs which are dispensed by a  
19 pharmacy during such quarter to individuals  
20 (other than individuals enrolled with an eligible  
21 organization with a contract under section  
22 1876) eligible for benefits under this part, as  
23 reported by such pharmacies to the Secretary.

24 “(2) INFORMATION FURNISHED TO MANUFAC-  
25 TURERS.—

1           “(A) IN GENERAL.—The Secretary shall  
2 report to each manufacturer, not later than 60  
3 days after the end of each calendar quarter, in-  
4 formation on the total number, for each covered  
5 outpatient drug, of units of each dosage form,  
6 strength, and package size dispensed under the  
7 plan during the quarter, on the basis of the  
8 data described in paragraph (1)(B) reported to  
9 the Secretary.

10           “(B) AUDIT.—The Comptroller General  
11 may audit the records of the Secretary to the  
12 extent necessary to determine the accuracy of  
13 reports by the Secretary pursuant to subpara-  
14 graph (A). Adjustments to rebates shall be  
15 made to the extent determined necessary by the  
16 audit to reflect actual units of drugs dispensed.

17           “(3) PROVISION OF PRICE INFORMATION BY  
18 MANUFACTURER.—

19           “(A) QUARTERLY PRICING INFORMA-  
20 TION.—Each manufacturer with an agreement  
21 in effect under this section shall report to the  
22 Secretary, not later than 30 days after the last  
23 day of each calendar quarter, on the average  
24 manufacturer retail price for each dosage form

1 and strength of each covered outpatient drug  
2 for the quarter.

3 “(B) BASE QUARTER PRICES.—Each man-  
4 ufacturer of a covered outpatient drug with an  
5 agreement under this section shall report to the  
6 Secretary, by not later than 30 days after the  
7 effective date of such agreement (or, if later, 30  
8 days after the end of the base quarter), the av-  
9 erage manufacturer retail price, for such base  
10 quarter, for each dosage form and strength of  
11 each such covered outpatient drug.

12 “(C) VERIFICATION OF AVERAGE MANU-  
13 FACTURER RETAIL PRICE.—The Secretary may  
14 inspect the records of manufacturers, and sur-  
15 vey wholesalers, pharmacies, and institutional  
16 purchasers of drugs, as necessary to verify  
17 prices reported under subparagraph (A).

18 “(D) PENALTIES.—

19 “(i) CIVIL MONEY PENALTIES.—The  
20 Secretary may impose a civil money pen-  
21 alty on a manufacturer with an agreement  
22 under this section—

23 “(I) for failure to provide infor-  
24 mation required under subparagraph

1 (A) on a timely basis, in an amount  
2 up to \$10,000 per day of delay;

3 “(II) for refusal to provide infor-  
4 mation about charges or prices re-  
5 quired by the Secretary for purposes  
6 of verification pursuant to subpara-  
7 graph (C), in an amount up to  
8 \$100,000; and

9 “(III) for provision, pursuant to  
10 subparagraph (A) or (B), of informa-  
11 tion that the manufacturer knows or  
12 should know is false, in an amount up  
13 to \$100,000 per item of information.

14 Such civil money penalties are in addition  
15 to any other penalties prescribed by law.  
16 The provisions of section 1128A (other  
17 than subsections (a) (with respect to  
18 amounts of penalties or additional assess-  
19 ments) and (b)) shall apply to a civil  
20 money penalty under this subparagraph in  
21 the same manner as such provisions apply  
22 to a penalty or proceeding under section  
23 1128A(a).

24 “(ii) SUSPENSION OF AGREEMENT.—  
25 If a manufacturer with an agreement

1 under this section has not provided infor-  
2 mation required under subparagraph (A)  
3 or (B) within 90 days of the deadline im-  
4 posed, the Secretary may suspend the  
5 agreement with respect to covered out-  
6 patient drugs dispensed after the end of  
7 such 90-day period and until the date such  
8 information is reported (but in no case  
9 shall a suspension be for less than 30  
10 days).

11 “(4) LENGTH OF AGREEMENT.—

12 “(A) IN GENERAL.—A rebate agreement  
13 shall be effective for an initial period of not less  
14 than one year and shall be automatically re-  
15 newed for a period of not less than one year un-  
16 less terminated under subparagraph (B).

17 “(B) TERMINATION.—

18 “(i) BY THE SECRETARY.—The Sec-  
19 retary may provide for termination of a re-  
20 bate agreement for violation of the require-  
21 ments of the agreement or other good  
22 cause shown. Such termination shall not be  
23 effective earlier than 60 days after the  
24 date of notice of such termination. The  
25 Secretary shall afford a manufacturer an

1 opportunity for a hearing concerning such  
2 termination, but such hearing shall not  
3 delay the effective date of the termination.

4 “(ii) BY A MANUFACTURER.—A man-  
5 ufacturer may terminate a rebate agree-  
6 ment under this section for any reason.  
7 Any such termination shall not be effective  
8 until the calendar quarter beginning at  
9 least 60 days after the date the manufac-  
10 turer provides notice to the Secretary.

11 “(iii) EFFECTIVE DATE OF TERMI-  
12 NATION.—Any termination under this sub-  
13 paragraph shall not affect rebates due  
14 under the agreement before the effective  
15 date of its termination.

16 “(iv) NOTICE TO PHARMACIES.—In  
17 the case of a termination under this sub-  
18 paragraph, the Secretary shall notify phar-  
19 macies and physician organizations not less  
20 than 30 days before the effective date of  
21 such termination.

22 “(c) AMOUNT OF REBATE.—

23 “(1) BASIC REBATE.—Each manufacturer shall  
24 remit a basic rebate to the Secretary for each cal-  
25 endar quarter in an amount, with respect to each

1 dosage form and strength of a covered outpatient  
2 drug (except as provided under paragraph (5)),  
3 equal to the product of—

4 “(A) the total number of units subject to  
5 rebate for such quarter, as described in sub-  
6 section (b)(1)(B); and

7 “(B) the greater of—

8 “(i)(I) in the case of a single source  
9 and innovator multiple source drugs (as  
10 defined in section 1927(k)(7)), 17 percent  
11 of the average manufacturer retail price  
12 for the calendar quarter;

13 “(II) in the case of a noninnovator  
14 multiple source drug (as defined in section  
15 1927(k)(7)) that has an average manufac-  
16 turer retail price which is greater than 50  
17 percent of the average manufacturer retail  
18 price of the corresponding innovator mul-  
19 tiple source drug, 11 percent of the aver-  
20 age manufacturer retail price for such  
21 noninnovator multiple source drug for the  
22 calendar quarter;

23 “(ii) the amount determined pursuant  
24 to paragraph (2); or

1                   “(iii) the amount determined pursuant  
2                   to paragraph (3).

3                   “(2) NEGOTIATED REBATE AMOUNT FOR NEW  
4                   DRUGS.—

5                   “(A) IN GENERAL.—The Secretary may  
6                   negotiate with the manufacturer a per-unit re-  
7                   bate amount, in accordance with this para-  
8                   graph, for any covered outpatient drug (except  
9                   as provided under paragraph (5)) first mar-  
10                  keted after June 30, 1993, if one of the follow-  
11                  ing criteria apply:

12                  “(i) The medicare program will be a  
13                  primary payer for the drug or biological in  
14                  the outpatient market or will incur signifi-  
15                  cant expenditures for the drug or biologi-  
16                  cal.

17                  “(ii) The Drug Use Review Board (es-  
18                  tablished under section 1850(b)) deter-  
19                  mined that the drug (whether or not a new  
20                  chemical entity) is a significant clinical or  
21                  therapeutic advance over other drugs on  
22                  the market to treat a particular medical  
23                  condition.

24                  “(iii) The manufacturer has provided  
25                  insufficient evidence to the Drug Use Re-

1 view Board that the drug is cost-effective  
2 at the current price charged by the manu-  
3 facturer.

4 “(iv) The price of the drug is higher  
5 in other industrialized nations as compared  
6 with the price in the United States.

7 “(v) The Federal Government had a  
8 substantial role in the research and devel-  
9 opment of the drug.

10 “(B) AGREEMENT TO NEGOTIATE REBATE  
11 FOR SUBSEQUENT NEW DRUGS.—Any manufac-  
12 turer entering into an agreement with the Sec-  
13 retary under this paragraph for any covered  
14 outpatient drug shall agree to enter into good-  
15 faith negotiations for the rebate amount under  
16 this paragraph for any other covered outpatient  
17 drug which is first marketed after such drug.

18 “(C) OPTION TO EXCLUDE OR LIMIT COV-  
19 ERAGE.—If the Secretary is unable to negotiate  
20 with the manufacturer an acceptable rebate  
21 amount with respect to a covered outpatient  
22 drug pursuant to this paragraph, the Secretary  
23 may—

24 “(i) exclude such drug from coverage  
25 under this part; or

1           “(ii) limit the use of the drug based  
2           on treatment or protocol guidelines (as rec-  
3           ommended by the Drug Use Review  
4           Board).

5           “(D) EFFECTIVE DATE OF EXCLUSION OR  
6           LIMITATION FROM COVERAGE.—An exclusion or  
7           limitation of a drug pursuant to subparagraph  
8           (C) shall be effective on and after the earlier  
9           of—

10           “(i) the date 6 months after the effec-  
11           tive date of marketing approval of such  
12           drug by the Food and Drug Administra-  
13           tion (but in no event earlier than July 1,  
14           1996), or

15           “(ii) the date the manufacturer termi-  
16           nates negotiations with the Secretary con-  
17           cerning the rebate amount.

18           “(3) HIGHER NEGOTIATED REBATES.—The  
19           Secretary shall have the authority to negotiate with  
20           a manufacturer a per-unit rebate amount on an an-  
21           nual basis for any covered outpatient drug (except  
22           as provided under paragraph (5)) that is greater  
23           than the per unit rebate amount determined under  
24           clause (I) or (II) of paragraph (1)(B)(i).

1           “(4) ADDITIONAL REBATE.—Each manufac-  
2 turer shall remit to the Secretary, for each calendar  
3 quarter, an additional rebate for each dosage form  
4 and strength of a covered outpatient drug (except as  
5 provided under paragraph (5)), in an amount equal  
6 to—

7           “(A) the total number of units subject to  
8 rebate for such quarter, as described in sub-  
9 section (b)(1)(B), multiplied by

10           “(B) the amount (if any) by which—

11           “(i) the average manufacturer retail  
12 price for the covered drug of the manufac-  
13 turer, exceeds

14           “(ii) the average manufacturer retail  
15 price of the covered drug for the base  
16 quarter, increased by the percentage by  
17 which the Consumer Price Index for all  
18 urban consumers (United States city aver-  
19 age) for the month before the month in  
20 which the calendar quarter begins exceeds  
21 such index for the last month of the base  
22 quarter.

23           “(5) NO REBATE REQUIRED FOR CERTAIN GE-  
24 NERIC DRUGS.—Paragraphs (1) through (4) shall  
25 not apply with respect to a covered outpatient drug

1 that is a noninnovator multiple source drug which is  
2 not described in paragraph (1)(B)(i)(II).

3 “(6) DEPOSIT OF REBATES.—The Secretary  
4 shall deposit rebates under this section in the Fed-  
5 eral Supplementary Medical Insurance Trust Fund  
6 established under section 1841.

7 “(d) CONFIDENTIALITY OF INFORMATION.—Notwith-  
8 standing any other provision of law, information disclosed  
9 by a manufacturer under this section is confidential and  
10 shall not be disclosed by the Secretary, except—

11 “(1) as the Secretary determines to be nec-  
12 essary to carry out this section,

13 “(2) to permit the Comptroller General to re-  
14 view the information provided, and

15 “(3) to permit the Director of the Congres-  
16 sional Budget Office to review the information pro-  
17 vided.

18 “(e) GENERIC DISPENSING INCENTIVES.—

19 “(1) ESTABLISHMENT OF DISPENSING POL-  
20 ICY.—The Secretary shall establish a generic-only  
21 dispensing policy for any drug described in subpara-  
22 graph (A), subject to Federal upper limit for each  
23 such drug described in subparagraph (B), which  
24 shall ensure that expenditures for innovator multiple  
25 source drugs (determined after taking into account

1 any rebates with respect to such drugs under this  
2 section) account for no more than 10 percent of the  
3 total expenditures made under this part for multiple  
4 source drugs (determined after taking into account  
5 any rebates with respect to such drugs under this  
6 section).

7 “(A) GENERIC-ONLY POLICY APPLICA-  
8 BLE.—A drug described in this paragraph is  
9 any covered outpatient drug which is a multiple  
10 source drug (as defined in section 1927(k)(7))  
11 for which there are three or more therapeuti-  
12 cally and pharmaceutically equivalent brands of  
13 the drug sold and marketed in the United  
14 States.

15 “(B) FEDERAL UPPER LIMIT.—The Sec-  
16 retary shall establish a Federal upper limit for  
17 each drug described in subparagraph (A) by  
18 using the prices of each of the therapeutically  
19 and pharmaceutically equivalent brands of such  
20 drug that is sold and marketed in the United  
21 States.

22 “(2) DESCRIPTION OF GENERICS-ONLY POL-  
23 ICY.—The Secretary shall exclude from payment  
24 under section 1862(a)(17) any innovator version of

1 a multiple source drug described in paragraph  
2 (1)(A) unless—

3 “(A) a written prescription for the drug  
4 contains, in the handwriting of the physician or  
5 other person prescribing the drug, the phrase  
6 ‘brand medically necessary’ indicating that the  
7 particular brand of the innovator drug product  
8 must be dispensed; and

9 “(B) at the option of the Secretary, a med-  
10 ical justification is provided for the covered out-  
11 patient drug described in subparagraph (A).

12 The Secretary may require prior authorization for  
13 payment for any innovator version of a multiple  
14 source drug described in paragraph (1)(A) unless  
15 the net cost of the innovator multiple source drug to  
16 the program under this part is less than or equal to  
17 the Federal upper limit (as established by the Sec-  
18 retary under paragraph (1)(B)).

19 “(3) PUBLICATION OF INFORMATION.—The  
20 Secretary shall publish on no less than a semiannual  
21 basis a prescription resource guide for physicians  
22 and pharmacists for the outpatient prescription  
23 drugs most commonly prescribed for medicare bene-  
24 ficiaries. The guide would indicate when generics are  
25 available for a particular brand name drug and indi-

1       cate the net cost to the medicare program for the  
2       furnishing of each drug in the therapeutic class of  
3       such drug. Such information shall also be available  
4       on any electronic claims prescription processing sys-  
5       tem established by the Secretary.

6       “(f) PRIOR AUTHORIZATION PROGRAM.—The Sec-  
7       retary may establish, as a condition of coverage or pay-  
8       ment for a covered outpatient drug for which payment is  
9       available under this part, a system which requires the ap-  
10      proval of the drug before its dispensing for any medically  
11      accepted indication (as defined in section 1927(k)(6)) but  
12      the system providing for such approval must—

13               “(A) provide a response by telephone or  
14               other telecommunication device within 24 hours  
15               of a request for prior authorization; and

16               “(B) provide for the dispensing of at least  
17               a 72-hour supply of a covered outpatient pre-  
18               scription drug in an emergency situation (as de-  
19               fined by the Secretary).

20      “(g) DEFINITIONS.—For purposes of this section:

21               “(1) AVERAGE MANUFACTURER RETAIL  
22               PRICE.—The term ‘average manufacturer retail  
23               price’ means, with respect to a covered outpatient  
24               drug of a manufacturer for a calendar quarter, the  
25               average price (inclusive of discounts for cash pay-

1       ment, prompt payment, volume purchases, and re-  
2       bates (other than rebates under this section), but ex-  
3       clusive of nominal prices) paid to the manufacturer  
4       for the drug in the United States for drugs distrib-  
5       uted to the retail pharmacy class of trade.

6           “(2) BASE QUARTER.—The term ‘base quarter’  
7       means, with respect to a covered outpatient drug of  
8       a manufacturer, the calendar quarter beginning Oc-  
9       tober 1, 1993, or, if later, the first full calendar  
10      quarter during which the drug was marketed in the  
11      United States.

12          “(3) MANUFACTURER.—The term ‘manufac-  
13      turer’ means, with respect to a covered outpatient  
14      drug, the entity holding legal title to or possession  
15      of the National Drug Code number for such drug.

16          “(4) NOMINAL PRICE.—The term ‘nominal  
17      price’ means any price which is less than 10 percent  
18      of the average manufacturer’s retail price for the  
19      covered outpatient drug of the manufacturer for the  
20      calendar quarter.”.

21      (b) EXCLUSIONS FROM COVERAGE.—Section  
22      1862(a) (42 U.S.C. 1395y(a)) is amended—

23          (1) by striking “or” at the end of paragraph  
24          (15),

1           (2) by striking the period at the end of para-  
2 graph (16) and inserting “; or”, and

3           (3) by inserting after paragraph (16) the fol-  
4 lowing new paragraph:

5           “(17) in the case of a covered outpatient drug  
6 (as described in section 1861(t)) which—

7                   “(A) is furnished during a year for which  
8 the drug’s manufacturer does not have in effect  
9 a rebate agreement with the Secretary that  
10 meets the requirements of section 1849 for the  
11 year,

12                   “(B) is excluded from coverage during the  
13 year by the Secretary pursuant to subpara-  
14 graphs (C) and (D) of section 1849(c)(2) (re-  
15 lating to negotiated rebate amounts for certain  
16 new drugs), or

17                   “(C) is not furnished in accordance with  
18 treatment protocols developed by the Secretary  
19 (based on recommendations from the Drug Use  
20 Review Board)”.

21           (c) CONFORMING AMENDMENTS TO MEDICAID PRO-  
22 GRAM.—Section 1927(a) (42 U.S.C. 1396r-8(a)) is  
23 amended—

24           (1) in the first sentence of paragraph (1), by  
25 striking “and paragraph (6)” and inserting “, para-

1 graph (6), and (for calendar quarters beginning on  
2 or after January 1, 1995) paragraph (7)”; and

3 (2) by adding at the end the following new  
4 paragraph:

5 “(7) REQUIREMENT RELATING TO REBATE  
6 AGREEMENTS FOR COVERED OUTPATIENT DRUGS  
7 UNDER MEDICARE PROGRAM.—A manufacturer  
8 meets the requirements of this paragraph if the  
9 manufacturer has in effect an agreement with the  
10 Secretary under section 1849 for providing rebates  
11 for covered outpatient drugs furnished to individuals  
12 under title XVIII during the year.”.

### 13 **Subtitle B—Drug Use Review**

#### 14 **SEC. 111. MEDICARE DRUG USE REVIEW.**

15 Part B of title XVIII is further amended by adding  
16 at the end the following new section:

17 “MEDICARE DRUG USE REVIEW

18 “SEC. 1850. (a) DRUG USE REVIEW.—

19 “(1) ESTABLISHMENT.—

20 “(A) IN GENERAL.—Except as provided in  
21 subparagraph (C), the Secretary shall provide,  
22 by not later than January 1, 1996, for a drug  
23 use review program for covered outpatient  
24 drugs which—

25 “(i) meets the requirements of para-  
26 graph (2), and

1           “(ii) assures that prescriptions for  
2 covered outpatient drugs are appropriate,  
3 medically necessary, and not likely to re-  
4 sult in adverse medical results.

5           “(B) DRUG USE REVIEW ALLOWANCE.—  
6 Not later than 180 days after the date of the  
7 enactment of the Pharmaceutical Marketplace  
8 Reform Act of 1994, the Secretary shall estab-  
9 lish a methodology to provide payment to phar-  
10 macists for prospective drug review and phar-  
11 maceutical care activities required under sub-  
12 paragraphs (A) through (H) of paragraph (2).

13           “(C) TREATMENT OF NURSING FACILI-  
14 TIES.—The Secretary is not required to provide  
15 for drug use review with respect to drugs dis-  
16 pensed to residents of nursing facilities which  
17 are in compliance with the requirements of sub-  
18 sections (b)(4)(A)(iii) and (c)(1)(D) of section  
19 1819.

20           “(2) REQUIREMENTS OF PROGRAM.—

21           “(A) PROSPECTIVE DRUG USE REVIEW.—

22           “(i) IN GENERAL.—The drug use re-  
23 view program shall provide for a review of  
24 drug therapy before each prescription for a  
25 covered outpatient drug is filled or deliv-

1           ered to an individual receiving a covered  
2           outpatient drug. The review shall be de-  
3           signed to identify potential drug therapy  
4           problems due to therapeutic duplication,  
5           drug-disease contraindications, drug inter-  
6           actions (including serious interactions with  
7           nonprescription or over-the-counter drugs),  
8           incorrect drug dosage or duration of drug  
9           treatment, drug-allergy interactions, and  
10          clinical abuse or misuse.

11           “(ii) STANDARDS FOR COUNSELING  
12          BY PHARMACISTS.—As part of the prospec-  
13          tive drug use review program, the Sec-  
14          retary (in consultation with the Drug Use  
15          Review Board) shall establish standards  
16          for counseling by pharmacists of individ-  
17          uals receiving covered outpatient drugs.  
18          Such standards shall include, at a mini-  
19          mum, the following:

20                   “(I) The pharmacist must offer  
21                   to discuss (in person, face-to-face  
22                   whenever practicable, or through ac-  
23                   cess to a telephone service which is  
24                   toll free for long-distance calls) with  
25                   each individual receiving covered out-

1 patient drugs or caregiver of such in-  
2 dividual who presents a prescription,  
3 matters which in the exercise of the  
4 pharmacist's professional judgment  
5 (consistent with any applicable State  
6 law respecting the provision of such  
7 information), the pharmacist deems  
8 significant, which may include the fol-  
9 lowing:

10 “(aa) The name and de-  
11 scription of the medication.

12 “(bb) The dosage form, dos-  
13 age, route of administration, and  
14 duration of drug therapy.

15 “(cc) Special directions and  
16 precautions for preparation, ad-  
17 ministration, and use by the pa-  
18 tient.

19 “(dd) Common severe side  
20 or adverse effects or interactions  
21 and therapeutic contraindications  
22 that may be encountered, includ-  
23 ing their avoidance, and the ac-  
24 tion required if they occur.

- 1           “(ee) Techniques for self-
- 2           monitoring drug therapy.
- 3           “(ff) Proper storage.
- 4           “(gg) Prescription refill in-
- 5           formation.
- 6           “(hh) Action to be taken in
- 7           the event of a missed dose.
- 8           “(II) A reasonable effort must be
- 9           made by the pharmacist to obtain,
- 10          record, and maintain at least the fol-
- 11          lowing information regarding individ-
- 12          uals receiving benefits under this title:
- 13           “(aa) Name, address, tele-
- 14           phone number, date of birth (or
- 15           age) and gender.
- 16           “(bb) Individual history
- 17           where significant, including dis-
- 18           ease state or states, known aller-
- 19           gies and drug reactions, and a
- 20           comprehensive list of medications
- 21           and relevant devices.
- 22           “(cc) Pharmacist comments
- 23           relevant to the individual’s drug
- 24           therapy.

1           Nothing in this clause shall be construed  
2           as requiring a pharmacist to provide con-  
3           sultation when an individual receiving ben-  
4           efits under this title or caregiver of such  
5           individual refuses such consultation.

6           “(B) RETROSPECTIVE DRUG USE RE-  
7           VIEW.—The program shall provide for the ongo-  
8           ing periodic examination of claims data and  
9           other records in order to identify patterns of  
10          fraud, abuse, gross overuse, or inappropriate or  
11          medically unnecessary care, among physicians,  
12          pharmacists and individuals receiving benefits  
13          under this title, or associated with specific  
14          drugs or groups of drugs.

15          “(C) STANDARDS.—

16                 “(i) IN GENERAL.—The program  
17                 shall, on an ongoing basis, assess data on  
18                 drug use against explicit standards deter-  
19                 mined by the Secretary upon the rec-  
20                 ommendations of the Drug Use Review  
21                 Board (using the sources described in  
22                 clause (ii) as the basis for determining the  
23                 standards for such assessment). Such as-  
24                 sessment shall include monitoring for  
25                 therapeutic appropriateness, overutilization

1 and underutilization, appropriate use of ge-  
2 neric products, therapeutic duplication,  
3 drug-disease contraindications, drug-drug  
4 interactions, incorrect drug dosage or du-  
5 ration of drug treatment, and clinical  
6 abuse or misuse, and introduce remedial  
7 strategies in order to improve the quality  
8 of care and to conserve program funds or  
9 personal expenditures.

10 “(ii) SOURCES.—The sources de-  
11 scribed in this clause are the American  
12 Hospital Formulary Service Drug Informa-  
13 tion, the United States Pharmacopeia-  
14 Drug Information, the American Medical  
15 Association Drug Evaluations, peer-re-  
16 viewed medical literature as approved by  
17 the Secretary, and other sources as deter-  
18 mined by the Secretary in consultation  
19 with the Drug Use Review Board.

20 “(D) EDUCATION AND INTERVENTION.—  
21 The program shall provide for, either directly or  
22 through contracts with accredited health care  
23 educational institutions, medical societies or  
24 pharmacists’ associations or societies, or other  
25 organizations as specified by the Secretary, and

1 using data provided by the Drug Use Review  
2 Board on common drug therapy problems—

3 “(i) ongoing educational outreach pro-  
4 grams to educate practitioners on common  
5 drug therapy problems with the aim of im-  
6 proving prescribing or dispensing practices;  
7 and

8 “(ii) ongoing interventions for physi-  
9 cians and pharmacists targeted toward  
10 common drug therapy problems or individ-  
11 uals identified in the course of retrospec-  
12 tive drug use reviews performed under this  
13 subsection, including, in appropriate in-  
14 stances, at least the following:

15 “(I) Written, oral, or electronic  
16 reminders containing patient-specific  
17 or drug-specific (or both) information  
18 and suggested changes in prescribing  
19 or dispensing practices, communicated  
20 in a manner designed to ensure the  
21 privacy of patient-related information.

22 “(II) Use of face-to-face discus-  
23 sions between health care profes-  
24 sionals who are experts in rational  
25 drug therapy and selected prescribers

1 and pharmacists who have been tar-  
2 geted for educational intervention, in-  
3 cluding discussion of optimal prescrib-  
4 ing, dispensing, or pharmacy care  
5 practices, and follow up face-to-face  
6 discussions.

7 “(III) Intensified review or mon-  
8 itoring of selected prescribers or dis-  
9 pensers.

10 “(E) HIGH RISK INDIVIDUALS.—The pro-  
11 gram shall provide for case management of  
12 drug therapy (under protocols established by  
13 the Secretary) for individuals receiving covered  
14 drugs who are identified as being at high risk  
15 for potential medication-related problems.

16 “(F) INTERCHANGEABLE PHARMA-  
17 CEUTICALS.—The program shall when appro-  
18 priate provide for the interchange of therapeuti-  
19 cally equivalent pharmaceutical products by a  
20 pharmacist after approval of the prescribing  
21 physician.

22 “(G) PATIENT INCENTIVE COMPLIANCE  
23 PROGRAMS.—The program shall provide for the  
24 management of patient incentive compliance  
25 programs.

1           “(H) OTHER SERVICES.—The program  
2 shall contain such other services that the Sec-  
3 retary finds to be standard of pharmacy prac-  
4 tice consistent with the provision of pharma-  
5 ceutical care.

6           “(b) DRUG USE REVIEW BOARD.—

7           “(1) ESTABLISHMENT.—The Secretary shall es-  
8 tablish a Drug Use Review Board (hereafter in this  
9 subsection referred to as the ‘DUR Board’) without  
10 regard to the provisions of title 5, United States  
11 Code, governing appointments in the competitive  
12 service.

13           “(2) MEMBERSHIP.—

14           “(A) COMPOSITION.—The DUR Board  
15 shall consist of 9 members of whom—

16                   “(i) 4 are individuals who are practic-  
17 ing physicians;

18                   “(ii) 4 are individuals who are practic-  
19 ing pharmacists; and

20                   “(iii) 1 is an individual who receives  
21 benefits under this title.

22           “(B) TERMS.—Members of the DUR  
23 Board shall first be appointed by no later than  
24 July 1, 1995, for a term of 3 years, except that  
25 the Director may provide initially for such

1 shorter terms as will ensure that (on a continu-  
2 ing basis) the terms of no more than 4 mem-  
3 bers expire in any 1 year.

4 “(3) CHAIR AND VICE CHAIR.—The DUR  
5 Board shall select a Chair and Vice Chair from  
6 among its members.

7 “(4) MEETINGS.—

8 “(A) IN GENERAL.—The DUR Board shall  
9 meet at the call of the Chair.

10 “(B) INITIAL MEETING.—No later than 30  
11 days after the date on which all members of the  
12 DUR Board have been appointed, the DUR  
13 Board shall hold its first meeting.

14 “(C) QUORUM.—A majority of the mem-  
15 bers of the DUR Board shall constitute a  
16 quorum, but a lesser number of members may  
17 hold hearings.

18 “(5) DUTIES OF THE DUR BOARD.—The DUR  
19 Board shall—

20 “(A) recommend policies and procedures to  
21 the Secretary for the operation of the out-  
22 patient prescription drug program for the pur-  
23 pose of optimizing therapeutic outcomes in indi-  
24 viduals who receive benefits under this part;

1           “(B) suggest appropriate model criteria  
2 and standards of prescribing and dispensing of  
3 covered outpatient prescription drugs  
4 (prioritized by medical relevance) through an  
5 evaluation of the FDA approved labeling of the  
6 covered outpatient drug, the medical literature,  
7 other clinical data available from pharma-  
8 ceutical manufacturers, and expert advice;

9           “(C) categorize covered outpatient drugs  
10 by therapeutic class, and evaluate the relative  
11 efficacy and cost-effectiveness of new and exist-  
12 ing pharmaceuticals within established and new  
13 therapeutic classes of drugs for the outpatient  
14 drug program under this part;

15           “(D) make recommendations, based on the  
16 clinical literature, of classes of pharmaceuticals  
17 or specific pharmaceuticals that should be  
18 added to or deleted from the list of excludable  
19 drugs for the medicaid program under section  
20 1927(d);

21           “(E) recommend to the Secretary those  
22 covered outpatient drugs which, based on data  
23 collected about the potential for the drug’s clini-  
24 cal misuse, abuse, or economic impact on the  
25 medicare program under this title should be

1 subject to prescribing protocols or treatment  
2 guidelines;

3 “(F) assist in the development of pharma-  
4 ceutical care programs for recipients of out-  
5 patient drugs under this part; and

6 “(G) suggest operational and evaluative  
7 performance standards for the drug use review  
8 program under this section and the State drug  
9 use review programs under title XIX.

10 “(6) REPORTS.—

11 “(A) ANNUAL REPORTS.—Not later than  
12 July 1, 1996, and annually thereafter on July  
13 1, the DUR Board shall deliver an annual re-  
14 port to Congress, the Secretary, the States, and  
15 other interested parties which shall contain rec-  
16 ommendations for appropriate administrative  
17 and legislative action that will—

18 “(i) ensure the cost-effectiveness and  
19 quality of care of drug therapy provided  
20 under this title and title XIX; and

21 “(ii) improve the effectiveness of the  
22 drug use review program under this title  
23 and the State drug use review programs  
24 under title XIX.

1           “(7) SPECIAL REPORTS.—The DUR Board  
2 shall deliver special reports on any of the matters  
3 under paragraph (5) at the request of Congress.

4           “(8) CERTAIN PROVISIONS APPLICABLE.—Sec-  
5 tion 1845(c)(1) shall apply to the DUR Board in the  
6 same manner as it applies to the Physician Payment  
7 Review Commission.

8           “(9) AUTHORIZATION OF APPROPRIATIONS.—  
9 There are authorized to be appropriated such sums  
10 as may be necessary to carry out the provisions of  
11 this subsection.”.

## 12           **Subtitle C—Effective Date**

### 13   **SEC. 121. EFFECTIVE DATE.**

14           Except as otherwise provided, the amendments made  
15 by this title shall apply to items and services furnished  
16 on or after January 1, 1995.

## 17   **TITLE II—MEDICAID PROGRAM**

### 18   **SEC. 201. NO FEDERAL FINANCIAL PARTICIPATION WITH** 19                   **RESPECT TO CERTAIN INNOVATOR MUL-** 20                   **TIPLE SOURCE DRUGS.**

21           (a) IN GENERAL.—Section 1903(i) (42 U.S.C.  
22 1396b(i)) is amended—

23                   (1) in paragraph (14), by striking the period at  
24                   the end and inserting a semicolon; and

1           (2) by adding at the end the following new  
2 paragraphs:

3           “(15) with respect to an innovator multiple  
4 source drug unless—

5                   “(A) a written prescription for the drug  
6 contains, in the handwriting of the physician or  
7 other person prescribing the drug, the phrase  
8 ‘brand medically necessary’ indicating that a  
9 particular brand of the innovator drug product  
10 must be dispensed; and

11                   “(B) the physician or other person pre-  
12 scribing the drug provides a medical justifica-  
13 tion to the State agency for prescribing such  
14 drug; or

15           “(16) with respect to expenditures made by the  
16 State for the dispensing of innovator multiple source  
17 drugs (determined after taking into account any re-  
18 bates with respect to such drugs under section 1927)  
19 that exceed an amount equal to—

20                   “(A) for 1995, 15 percent, and

21                   “(B) for 1996 and succeeding years, 10  
22 percent,

23 of the expenditures made by the State for the dis-  
24 pensing of all multiple source drugs (determined

1 after taking into account any rebates with respect to  
2 such drugs under section 1927).”.

3 (b) EFFECTIVE DATE.—The amendments made by  
4 subsection (a) shall be effective for calendar quarters be-  
5 ginning on or after January 1, 1995.

6 **SEC. 202. REBATE FOR CERTAIN COVERED OUTPATIENT**  
7 **DRUGS.**

8 (a) IN GENERAL.—Section 1927(c)(3)(B) (42 U.S.C.  
9 1396r-8(c)(3)(B)) is amended to read as follows:

10 “(B) APPLICABLE PERCENTAGE.—

11 “(i) IN GENERAL.—Except as pro-  
12 vided in clause (ii), for purposes of sub-  
13 paragraph (A)(i), the ‘applicable percent-  
14 age’ for rebate periods beginning—

15 “(I) before January 1, 1994, is  
16 10 percent, and

17 “(II) after December 31, 1993, is  
18 11 percent.

19 “(ii) SPECIAL RULE.—For purposes of  
20 subparagraph (A)(i), if a covered out-  
21 patient drug is a noninnovator multiple  
22 source drug and the average manufacturer  
23 price of such drug does not exceed 50 per-  
24 cent of the average manufacturer price for  
25 the corresponding innovator multiple

1 source drug, the ‘applicable percentage’ for  
2 rebate periods beginning—

3 “(I) after December 31, 1994,  
4 and before January 1, 1996, is 9 per-  
5 cent,

6 “(II) after December 31, 1995,  
7 and before January 1, 1997, is 7 per-  
8 cent, and

9 “(III) after December 31, 1996,  
10 is 5 percent.”.

11 (b) EFFECTIVE DATE.—The amendments made by  
12 subsection (a) shall be effective for rebate periods begin-  
13 ning after December 31, 1994.

14 **SEC. 203. STATE REGULATION OF OUTPATIENT PRESCRIP-**  
15 **TION DRUG BENEFITS COVERED BY HEALTH**  
16 **CARE PLANS.**

17 (a) IN GENERAL.—Title XIX (42 U.S.C. 1396 et  
18 seq.) is amended—

19 (1) by redesignating section 1931 as section  
20 1932; and

21 (2) by inserting after section 1930 the following  
22 new section:

23 “STATE REGULATION OF OUTPATIENT PRESCRIPTION  
24 DRUG BENEFITS COVERED BY HEALTH CARE PLANS

25 “SEC. 1931. No payment shall be made to a State  
26 under section 1903 for any calendar quarter in which such

1 State fails to have in effect regulations requiring each  
2 health care plan offered in such State that covers out-  
3 patient prescription drugs—

4           “(1) to establish a pharmacy and therapeutics  
5 committee or drug use review board consisting of  
6 physicians and pharmacists which shall make rec-  
7 ommendations to the plan in order to assure that  
8 outpatient prescription drugs used by individuals en-  
9 rolled in the plan are medically appropriate and like-  
10 ly to result in positive medical outcomes;

11           “(2) to establish a therapeutic formulary of out-  
12 patient prescription drugs which are approved by the  
13 pharmacy and therapeutics committee or drug use  
14 review board for use by individuals enrolled in the  
15 plan;

16           “(3) to establish a pharmaceutical care services  
17 program which shall ensure that services provided by  
18 a pharmacist licensed to practice in the State result  
19 in positive medical and therapeutic outcomes and  
20 which shall include—

21           “(A) drug use review including—

22           “(i) prospective review consisting of  
23 counseling provided by pharmacists to indi-  
24 viduals enrolled in the plan on the appro-  
25 priate use of outpatient prescription drugs

1 and identification and avoidance of poten-  
2 tial adverse medication-related outcomes  
3 before an outpatient prescription drug is  
4 dispensed to an individual enrolled in the  
5 plan;

6 “(ii) retrospective review consisting of  
7 an organized process to collect and analyze  
8 data concerning the drug use patterns of  
9 individuals enrolled in the plan and pro-  
10 vider prescribing and dispensing patterns  
11 under the plan; and

12 “(iii) education of, and interventions  
13 for, health care professionals to provide for  
14 optimal use of outpatient prescription  
15 drugs among individuals enrolled in the  
16 plan;

17 “(B) management of drug therapy and  
18 case management of patients that are identified  
19 as at high risk for potential medication-related  
20 problems;

21 “(C) preapproved or protocol-approved  
22 interchange of pharmaceutical products;

23 “(D) management of patient compliance  
24 incentive programs; and

1           “(E) other services that are consistent with  
2           standard pharmacy practice and consistent with  
3           providing pharmaceutical care; and

4           “(4) to establish a system under which any  
5           pharmacist who provides outpatient prescription  
6           drugs to individuals enrolled in the plan is provided  
7           payment for services required to comply with any re-  
8           quirements imposed on such pharmacist by this sec-  
9           tion.”.

10          (b) EFFECTIVE DATE.—

11           (1) IN GENERAL.—Except as provided in para-  
12           graph (2), the amendments made by subsection (a)  
13           shall be effective for calendar quarters beginning on  
14           or after January 1, 1996.

15           (2) DELAY IF STATE LEGISLATION RE-  
16           QUIRED.—In the case of a State which the Secretary  
17           determines requires State legislation (other than leg-  
18           islation authorizing or appropriating funds) in order  
19           to comply with the amendments made by subsection  
20           (a), the State shall not be regarded as failing to  
21           comply with such amendments solely on the basis of  
22           its failure to meet the requirements of such amend-  
23           ments before the first day of the first calendar quar-  
24           ter beginning after the close of the first regular ses-  
25           sion of the State legislature that begins after the

1 date of the enactment of this Act. For purposes of  
 2 the preceding sentence, in the case of a State that  
 3 has a 2-year legislative session, each year of such  
 4 session shall be deemed to be a separate regular ses-  
 5 sion of the State legislature.

## 6 **TITLE III—COMMISSIONS**

### 7 **SEC. 301. PHARMACEUTICAL MARKETPLACE INFORMATION**

#### 8 **COMMISSION.**

9 Part A of title XI (42 U.S.C. 1301 et seq.), as  
 10 amended by section 13581(a) of the Omnibus Budget Rec-  
 11 onciliation Act of 1993, is amended by adding at the end  
 12 the following new section:

13 “PHARMACEUTICAL MARKETPLACE INFORMATION

14 COMMISSION

15 “SEC. 1145. (a) IN GENERAL.—

16 “(1) ESTABLISHMENT.—The Secretary shall  
 17 provide for the appointment of the Pharmaceutical  
 18 Marketplace Information Commission (in this sec-  
 19 tion referred to as the ‘Commission’), without regard  
 20 to the provisions of title 5, United States Code, gov-  
 21 erning appointments in the competitive service.

22 “(2) MEMBERSHIP.—The Commission shall  
 23 consist of 9 individuals. The membership of the  
 24 Commission shall include recognized experts in the  
 25 fields of pharmacoeconomics, industrial cost account-

1 ing, medicine, pharmacy, and science, a consumer, a  
2 representative of a patient advocacy group.

3 “(3) TERMS.—Members of the Commission  
4 shall first be appointed by no later than July 1,  
5 1995, for a term of 3 years, except that the Director  
6 may provide initially for such shorter terms as will  
7 ensure that (on a continuing basis) the terms of no  
8 more than 4 members expire in any 1 year.

9 “(4) CHAIR AND VICE CHAIR.—The Commis-  
10 sion shall select a Chair and Vice Chair from among  
11 its members.

12 “(5) MEETINGS.—

13 “(A) IN GENERAL.—The Commission shall  
14 meet at the call of the Chair.

15 “(B) INITIAL MEETING.—No later than 30  
16 days after the date on which all members of the  
17 Commission have been appointed, the Commis-  
18 sion shall hold its first meeting.

19 “(C) QUORUM.—A majority of the mem-  
20 bers of the Commission shall constitute a  
21 quorum, but a lesser number of members may  
22 hold hearings.

23 “(b) DUTIES OF THE COMMISSION.—The Commis-  
24 sion shall have the following duties:

25 “(1) DOMESTIC PHARMACEUTICAL PRICES.—

1           “(A) PUBLICATION OF PRICING INFORMA-  
2           TION.—The Commission shall annually publish  
3           the weighted average price of each dosage form  
4           and strength of each single source drug and in-  
5           novator multiple source drug sold to all pur-  
6           chasers of such drug in the United States and  
7           the average manufacturer’s price for each such  
8           drug distributed to the retail class of trade.

9           “(B) INFORMATION SOURCE ON PRICE  
10          CONCESSIONS.—The Commission shall—

11                 “(i) serve as a source of information  
12                 for purchasers on the policies and proce-  
13                 dures of drug manufacturers concerning  
14                 the terms under which manufacturers pro-  
15                 vide rebates, discounts and other price con-  
16                 cessions to pharmaceutical purchasers; and

17                 “(ii) receive and investigate informa-  
18                 tion (provided by purchasers) relating to  
19                 instances in which manufacturers are not  
20                 offering and providing products on similar  
21                 terms and conditions to all purchasers.

22          “(2) INTERNATIONAL PHARMACEUTICAL  
23          PRICES.—The Commission shall monitor, analyze,  
24          and publish price information relating to currently  
25          marketed and new pharmaceutical prices for drugs,

1 biologicals, and vaccines in other industrialized na-  
2 tions, including those nations described in section  
3 802(b)(4)(A) of the Federal Food, Drug, and Cos-  
4 metic Act. Such information shall include the aver-  
5 age price in all classes of trade, and the average  
6 price sold to the retail class of trade in each country.  
7 The Commission shall also monitor mechanisms  
8 used by other industrialized nations to contain phar-  
9 maceutical expenditures.

10 “(3) PRICES OF CERTAIN PHARMACEUTICALS.—

11 “(A) IN GENERAL.—The Commission shall  
12 review the price of drugs and biologicals and  
13 provide information to purchasers to determine  
14 whether the price of the drug or biological is  
15 reasonable if such drug or biological product—

16 “(i)(I) is a new drug or biological  
17 which is a significant clinical advance or  
18 breakthrough over pharmaceutical products  
19 currently available to treat a particular  
20 condition, whether or not the product is a  
21 new chemical or biological entity;

22 “(II) a new drug or biological which  
23 has received a designation of 1-AA or 1-  
24 P by the Food and Drug Administration;

25 “(III) is an orphan drug product;

1           “(IV) is a currently marketed drug  
2           for which there are no other therapeutic al-  
3           ternatives on the market; or

4           “(V) the Federal Government had a  
5           substantial role in the development of the  
6           drug or biological, and such support was  
7           essential to the approval of the drug by the  
8           Food and Drug Administration; and

9           “(ii) a request is made to review the  
10          price of such drug or biological by—

11                   “(I) the Secretary;

12                   “(II) a member of the Commis-  
13                   sion;

14                   “(III) not less than 3 groups rep-  
15                   resenting consumers or patient advo-  
16                   cates, or

17                   “(IV) not less than three health  
18                   plans providing such drug or biologi-  
19                   cal, where such plans present evidence  
20                   that the price is excessive.

21           “(B) GUIDELINES FOR DETERMINATION.—

22           The Commission shall use the following infor-  
23           mation to determine whether the price of the  
24           drug or biological is reasonable:

1           “(i) DOMESTIC COMPARISON.—The  
2 Commission shall compare the price of the  
3 drug or biological with the price of drugs  
4 or biologicals in the same therapeutic class  
5 used to treat similar therapeutic conditions  
6 in the United States.

7           “(ii) INTERNATIONAL COMPARISON.—  
8 The Commission shall compare the price of  
9 the drug or biological with the price of the  
10 drug or biological in section 802(b)(4)(A)  
11 of the Federal Food, Drug, and Cosmetic  
12 Act.

13           “(iii) MANUFACTURER INFORMA-  
14 TION.—The Commission shall consider the  
15 following information provided by the man-  
16 ufacturer of the drug or biological:

17           “(I) The manufacturer’s costs of  
18 manufacturing, researching, and de-  
19 veloping the product.

20           “(II) The anticipated revenue  
21 from the sales of the product in the  
22 United States and international mar-  
23 kets.

1           “(III) The manufacturer’s antici-  
2           pated costs of marketing and advertis-  
3           ing for the product.

4           “(IV) Anticipated revenue from  
5           off-label uses of the product.

6           “(V) Extraordinary circum-  
7           stances that justify the price charged  
8           in the United States market.

9           “(VI) the expected period of pat-  
10          ent life or market exclusivity for the  
11          product.

12          “(VII) Profit expected by the  
13          manufacturer as a result of the sales  
14          of the product in the United States  
15          and other industrialized nations.

16          “(VIII) Other relevant factors  
17          that the manufacturer would like the  
18          Commission to consider.

19          “(iv) INVESTIGATIONS PAID FOR BY  
20          FEDERAL GOVERNMENT.—Funds expended  
21          by the Federal Government either directly  
22          or indirectly to support investigations that  
23          were significant to the application made to  
24          the Food and Drug Administration to ap-  
25          prove the drug or biological.

1           “(v) COST-EFFECTIVENESS.—The  
2 cost-effectiveness of the pharmaceutical  
3 relative to other medical treatment alter-  
4 natives, including nonpharmaceutical treat-  
5 ments, such as devices.

6           “(vi) QUALITY OF LIFE IMPROVE-  
7 MENT.—The improvements in the quality  
8 of life offered by the product, including the  
9 ability to return to work and other appro-  
10 priate measures of improvement in the  
11 quality of life.

12           “(C) DETERMINATION.—

13           “(i) HEARING.—The Commission  
14 shall hold a public hearing to collect infor-  
15 mation and data from groups interested in  
16 the price of the drug or biological before  
17 making a report described in subparagraph  
18 (B).

19           “(ii) REPORT.—The Commission shall  
20 publish a report on the reasonableness of a  
21 drug or biological as determined under this  
22 paragraph, with all available information  
23 and justification for its findings.

1           “(iii) APPEAL.—The Commission shall  
2           develop a process for an interested party to  
3           appeal the report of the Commission.

4           “(iv) NO BINDING EFFECT.—No re-  
5           port of the Commission issued under this  
6           subparagraph shall have binding effect  
7           upon any manufacturer or purchaser.

8           “(D) CONFIDENTIALITY OF PROPRIETARY  
9           INFORMATION PROVIDED TO THE COMMIS-  
10          SION.—Any proprietary information provided by  
11          a manufacturer to the Commission under this  
12          subsection shall be held confidential.

13          “(4) UTILIZATION OF GENERIC PHARMA-  
14          CEUTICALS.—The Commission shall—

15               “(A) monitor the rate of dispensing generic  
16               drugs in the United States;

17               “(B) publish (at least semiannually) and  
18               make available to health care providers infor-  
19               mation about the availability and relative costs  
20               of generic drugs compared to the costs for the  
21               equivalent innovator versions of these drugs;  
22               and

23               “(C) monitor the pricing patterns of ge-  
24               neric drugs, and the extent to which domestic  
25               and international trade policies affect the ability

1 of generic pharmaceutical manufacturers to ob-  
2 tain materials for the purpose of manufacturing  
3 and selling generic drugs in the United States.

4 “(5) PHARMACEUTICAL PATENT EXTEN-  
5 SIONS.—Not less than 90 days before the expiration  
6 of a pharmaceutical patent for which the holder of  
7 the patent has sought an extension of that patent,  
8 the Commission shall provide to the Congress and  
9 the Office of Patents and Trademarks an analysis of  
10 the feasibility and desirability of extending the pat-  
11 ent as provided in the terms of the Drug Price Com-  
12 petition and Patent Term Restoration Act of 1984.

13 “(6) PHARMACOECONOMIC AND COST-EFFEC-  
14 TIVENESS ANALYSIS.—The Commission shall—

15 “(A) develop a standard methodology for  
16 the purpose of conducting pharmacoeconomic  
17 and cost-effectiveness analyses of pharma-  
18 ceutical and biological products; and

19 “(B) collect and disseminate information  
20 to purchasers about the relative cost-effective-  
21 ness and cost-benefit of various pharmaceutical  
22 products as compared to other pharmaceutical  
23 products and other medical technologies, includ-  
24 ing making evaluations of the new savings to

1           the health care system as a result of new phar-  
2           maceutical and biological products.

3           “(c) CERTAIN PROVISIONS APPLICABLE.—Section  
4 1845(c)(1) shall apply to the Commission in the same  
5 manner as it applies to the Physician Payment Review  
6 Commission.

7           “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
8 are authorized to be appropriated such sums as may be  
9 necessary to carry out the provisions of this section.”.

10 **SEC. 302. PRESCRIPTION DRUG PAYMENT REVIEW COMMIS-**  
11 **SION.**

12           Part A of title XI (42 U.S.C. 1301 et seq.), as  
13 amended by section 301, is amended by adding at the end  
14 the following new section:

15           “PRESCRIPTION DRUG PAYMENT REVIEW COMMISSION

16           “SEC. 1146. (a) ESTABLISHMENT.—The Director of  
17 the Congressional Office of Technology Assessment (in  
18 this section referred to as the ‘Director’ and the ‘Office’,  
19 respectively) shall provide for the appointment of a Pre-  
20 scription Drug Payment Review Commission (in this sec-  
21 tion referred to as the ‘Commission’) without regard to  
22 the provisions of title 5, United States Code, governing  
23 appointments in the competitive service.

24           “(b) MEMBERSHIP.—

25           “(1) COMPOSITION.—The Commission shall  
26 consist of 11 individuals with expertise in the provi-

1 sion and financing of prescription drugs under feder-  
2 ally funded health care programs.

3 “(2) TERMS.—Members of the Commission  
4 shall first be appointed by no later than July 1,  
5 1995 for a term of 3 years, except that the Director  
6 may provide initially for such shorter terms as will  
7 ensure that (on a continuing basis) the terms of no  
8 more than 4 members expire in any 1 year.

9 “(3) CHAIR AND VICE CHAIR.—The Commis-  
10 sion shall select a Chair and Vice Chair from among  
11 its members.

12 “(c) MEETINGS.—

13 “(1) IN GENERAL.—The Commission shall meet  
14 at the call of the Chair.

15 “(2) INITIAL MEETING.—No later than 30 days  
16 after the date on which all members of the Commis-  
17 sion have been appointed, the Commission shall hold  
18 its first meeting.

19 “(3) QUORUM.—A majority of the members of  
20 the Commission shall constitute a quorum, but a  
21 lesser number of members may hold hearings.

22 “(d) DUTIES OF THE COMMISSION.—

23 “(1) IN GENERAL.—The Commission shall—

24 “(A) monitor the scope of coverage, reim-  
25 bursement, expenditure levels, and financing of

1 prescription drugs under Federal health care  
2 programs;

3 “(B) monitor the prices for prescription  
4 and nonprescription drugs (on the retail level  
5 and manufacturer level) used in Federal health  
6 care programs;

7 “(C) recommend modifications and  
8 changes in cost containment measures and pay-  
9 ment and reimbursement rates under Federal  
10 health care programs;

11 “(D) monitor and analyze the extent to  
12 which pharmaceuticals and pharmacy services  
13 are available to specific populations, including  
14 citizens in rural areas of the United States;

15 “(E) evaluate technologies available for ef-  
16 ficient administration of Federal health care  
17 programs and other third party prescription  
18 drug programs; and

19 “(F) determine the annual cost of dispens-  
20 ing a prescription for various classes of phar-  
21 macies to assist in the development of  
22 reimbursement and payment rates to providers.

23 “(2) REPORTS.—

24 “(A) ANNUAL REPORTS.—Not later than  
25 July 1, 1996, and annually thereafter on July

1           1, the Commission shall deliver an annual re-  
2           port to Congress which shall contain the find-  
3           ings and conclusions of the Commission, on  
4           each of the matters under paragraph (1).

5           “(B) SPECIAL REPORTS.—The Commission  
6           shall deliver special reports on any of the mat-  
7           ters under paragraph (1) at the request of Con-  
8           gress.

9           “(e) CERTAIN PROVISIONS APPLICABLE.—Section  
10          1845(c)(1) shall apply to the Commission in the same  
11          manner as it applies to the Physician Payment Review  
12          Commission.

13          “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
14          are authorized to be appropriated such sums as may be  
15          necessary to carry out the provisions of this section.”.

## 16           **TITLE IV—ADDITIONS TO THE** 17           **MASTER AGREEMENT**

### 18          **SEC. 401. EQUAL ACCESS TO DISCOUNTS.**

19           (a) IN GENERAL.—Section 8126(a) of title 38, Unit-  
20          ed States Code, as amended by section 101(b), is amend-  
21          ed—

22                   (1) by striking “and” at the end of paragraph  
23                   (3);

24                   (2) by redesignating paragraph (4) as para-  
25                   graph (5); and

1           (3) by inserting after paragraph (3) the follow-  
2           ing new paragraph:

3           “(4)(A) each manufacturer of single source and  
4           innovator multiple source drugs (as described in sec-  
5           tion 1927(k) of the Social Security Act) shall offer  
6           such pharmaceuticals for sale to every purchaser on  
7           equal terms and conditions including any rebates,  
8           free merchandise, discounts, and other similar ad-  
9           justments (excluding any terms offered to the De-  
10          partment of Veterans Affairs, the Department of  
11          Defense, entities that receive funding under the  
12          Public Health Service, any other entity receiving dis-  
13          counts under section 340(b) of the Public Health  
14          Service Act, and any other Federal or State govern-  
15          ment agency that directly procures pharmaceuticals);

16          “(B) each manufacturer of single source and in-  
17          novator multiple source drugs may only offer re-  
18          bates, free merchandise, discounts, and other similar  
19          adjustments, if the manufacturer experiences savings  
20          as a result of efficiencies in purchasing, such as vol-  
21          ume buying (including programs to increase volume  
22          buying through influencing physician prescribing  
23          practices or by making an agreement to place drugs  
24          on a formulary), prompt delivery, single-site delivery,  
25          and prompt payment;

1           “(C) each manufacturer of single source and in-  
2           novator multiple source drugs shall make informa-  
3           tion describing the terms and conditions described in  
4           subparagraph (A) available to the public and the  
5           Pharmaceutical Marketplace Information Commis-  
6           sion (established under section 1145 of the Social  
7           Security Act); and

8           “(D) each manufacturer that knowingly violates  
9           the requirement under the preceding subparagraphs  
10          shall be subject to a civil fine of not more than  
11          \$100,000 per violation; and”.

12 **SEC. 402. PROVISION OF INFORMATION TO THE PHARMA-**  
13                   **CEUTICAL MARKETPLACE INFORMATION**  
14                   **COMMISSION.**

15          (a) IN GENERAL.—Section 8126(a) of title 38, Unit-  
16          ed States Code, as amended by sections 101(b) and 401,  
17          is amended—

18               (1) by striking “and” at the end of paragraph

19               (4);

20               (2) by redesignating paragraph (5) as para-  
21               graph (6); and

22               (3) by inserting after paragraph (4) the follow-  
23               ing new paragraph:

24               “(5)(A) each manufacturer of a single source  
25               and innovator multiple source drug (as defined in

1 section 1927(k) of the Social Security Act) shall re-  
2 port to the Pharmaceutical Marketplace Information  
3 Commission (established under section 1145 of the  
4 Social Security Act) such information as the Com-  
5 mission may require to compile the data necessary  
6 to publish the domestic pricing information de-  
7 scribed in section 1145(b)(1)(A) of the Social Secu-  
8 rity Act and the international pricing information  
9 described in section 1145(b)(2) of such Act no later  
10 than 30 days after the end of each calendar quarter,  
11 and

12 “(B) each manufacturer shall make available to  
13 the Pharmaceutical Marketplace Information Com-  
14 mission any additional information required by the  
15 Commission; and”.

16 **SEC. 403. CONFORMING AMENDMENTS.**

17 (a) **ADDITIONAL REQUIREMENTS FOR PARTICIPA-**  
18 **TION.**—Section 8126(a)(6) of title 38, United States  
19 Code, as redesignated in section 402(a)(2), is amended by  
20 striking “, and (3)” and inserting “(3), (4), and (5)”.

21 (b) **AMENDMENTS TO EFFECTIVE DATE PROVI-**  
22 **SIONS.**—

23 (1) **MEDICAID.**—Section 1927(a) is amended—  
24 (A) in paragraph (5)—

1 (i) in subparagraph (D), by striking  
2 “title VI of the Veterans Health Care Act  
3 of 1992” and inserting “the Pharma-  
4 ceutical Marketplace Reform Act of 1994”;  
5 and

6 (ii) in subparagraph (E), by striking  
7 “immediately after the enactment of this  
8 paragraph)” and inserting “immediately  
9 after the enactment of the Pharmaceutical  
10 Marketplace Reform Act of 1994)”; and

11 (B) in paragraph (6)—

12 (i) in subparagraph (B), by striking  
13 “title VI of the Veterans Health Care Act  
14 of 1992” and inserting “the Pharma-  
15 ceutical Marketplace Reform Act of 1994”;  
16 and

17 (ii) in subparagraph (C), by striking  
18 “immediately after the enactment of this  
19 paragraph)” and inserting “immediately  
20 after the enactment of the Pharmaceutical  
21 Marketplace Reform Act of 1994)”.

22 (2) PUBLIC HEALTH SERVICE.—Section  
23 340B(d) of the Public Health Service Act is amend-  
24 ed by striking “the Veterans Health Care Act of

1 1992” and inserting “the Pharmaceutical Market-  
2 place Reform Act of 1994”.

3 (3) VETERANS’ AFFAIRS.—Section 8126(g) of  
4 title 38, United States Code, is amended—

5 (A) in paragraph (1), by inserting “, ex-  
6 cept that such reference shall include any  
7 amendments to the Social Security Act made by  
8 the Pharmaceutical Marketplace Reform Act of  
9 1994” before the period at the end; and

10 (B) in paragraph (2)—

11 (i) by striking “this section)” and in-  
12 serting “the Pharmaceutical Marketplace  
13 Reform Act of 1994)””; and

14 (ii) by striking “date of the enactment  
15 of this section” and inserting “date of the  
16 enactment of the the Pharmaceutical Mar-  
17 ketplace Reform Act of 1994”.

18 **SEC. 404. EFFECTIVE DATE.**

19 Except as otherwise provided, the amendments made  
20 by this title shall apply on and after December 31, 1994.

○

21 S 2239 IS—2

22 S 2239 IS—3

23 S 2239 IS—4

24 S 2239 IS—5

1 S 2239 IS—6