S 3029 IS

101st CONGRESS

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S. 3029

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

IN THE SENATE OF THE UNITED STATES

September 12 (legislative day, SEPTEMBER 10), 1990

Mr. PRYOR introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XIX of the Social Security Act to provide mechanisms to control medicaid drug prices, to assure that medicaid beneficiaries receive quality medical care, and to protect the physician's right to prescribe.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990'.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS- The Congress finds as follows:

(1) State medicaid programs are under severe and increasing financial pressure as a result of drug price inflation.

(2) States have been forced to respond to this situation with undesirable measures to contain costs, such as excluding categories of drug products from coverage and increasing beneficiary copayments. These actions limit access to needed medications for poor elderly, minority, and other vulnerable low-income populations who rely on the medicaid program.

(3) Drug manufacturers offer, as a matter of business practice, substantial discounts on drug products to many large-volume purchasers.

(4) Medicaid's status as a publicly-funded program for the poor which purchases a large volume of prescription pharmaceuticals entitles it to earn these substantial discounts to the medicaid program.

(5) Drug manufacturers currently discriminate against medicaid recipients by refusing to offer similar discounts to the medicaid program.

(6) Certain drug manufacturers have proposed their own plans for medicaid drug program cost containment that cannot be counted on to achieve cost savings for medicaid and have the potential to create serious access problems to drugs for medicaid beneficiaries.

(b) PURPOSES- The purposes of this Act are--

(1) to assure that State medicaid drug cost control initiatives are focused on drug manufacturer prices and that medicaid beneficiaries and providers do not absorb the cost of such initiatives;

(2) to obtain the best prices for pharmaceuticals dispensed under medicaid programs;

(3) eliminate drug manufacturer discrimination against low-income groups in the United States by requiring discounts on drug products of a manufacturer as a condition of Federal financial participation under the medicaid program for drug products of the manufacturer;

(4) to provide incentives for drug manufacturers to maintain substantial discounts for medicaid programs; and

(5) to enhance physicians' ability to prescribe and the patients' ability to receive needed medications under the medicaid program.

SEC. 3. REIMBURSEMENT FOR PRESCRIBED DRUGS.

(a) IN GENERAL-

(1) DENIAL OF FEDERAL FINANCIAL PARTICIPATION UNLESS REBATE AGREEMENTS AND DRUG USE REVIEW IN EFFECT- Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended--

(A) by striking the period at the end of paragraph (9) and inserting `; or', and

(B) by inserting after paragraph (9) the following new paragraph:

`(10) with respect to covered outpatient drugs of a manufacturer dispensed in any State unless (A) except as provided in section 1927(a)(3), the manufacturer complies with the rebate requirements of section 1927(a) with respect to the drugs so dispensed in all States, and (B) effective January 1, 1993, the State provides for drug use review in accordance with section 1927(g).'.

(2) PROHIBITING STATE PLAN DRUG ACCESS LIMITATIONS FOR DRUGS COVERED UNDER A REBATE AGREEMENT- Section 1902(a) of such Act (42 U.S.C. 1396a(a)) is amended--

(A) by striking `and' at the end of paragraph (52),

(B) by striking the period at the end of paragraph (53) and inserting `; and', and

(C) by inserting after paragraph (53) the following new paragraph:

`(54)(A) provide that, in the case of a manufacturer which has entered into and complies with an agreement under section 1927(a), any formulary or similar restriction (other than a prior authorization program described in section 1927(d)) on the coverage of covered outpatient drugs under the plan shall permit the coverage of covered outpatient drugs of the manufacturer which are prescribed for a medically accepted indication (as defined in section 1927(l)(6)), and

`(B) comply with the reporting requirements of section 1927(b)(2)(A) and the requirements of subsections (d) through (f) and (g)(4) of section 1927. '.

(3) REBATE AGREEMENTS FOR COVERED OUTPATIENT DRUGS, DRUG USE REVIEW, AND RELATED PROVISIONS- Title XIX of the Social Security Act is amended by redesignating section 1927 as section 1928 and by inserting after section 1926 the following new section:

`PAYMENT FOR PRESCRIBED 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 in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of all the States. If a manufacturer has not entered into such an agreement before January 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.

`(2) EFFECTIVE DATE- Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

`(3) AUTHORIZING PAYMENT, WITH PRIOR AUTHORIZATION, FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS- Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if the physician has obtained approval of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d).

`(4) EFFECT ON EXISTING AGREEMENTS- In the case of a rebate entitlesr in effect between a State and a manufacturer on the date of the enactment of this section, such agreement may remain in effect, and shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State establishes to the satisfaction of the Secretary that the agreement provides for rebates that are at least as large as the rebates otherwise required under this section.

`(b) TERMS OF REBATE AGREEMENT-

`(1) QUARTERLY REBATES-

`(A) IN GENERAL- A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, for a rebate each calendar quarter in the amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed under the plan during the quarter. Such a rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for that quarter.

`(B) OFFSET AGAINST MEDICAL ASSISTANCE- Amounts received by a State as rebates under this section in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1); except that States shall provide, in a manner specified by the Secretary, for payments to the Prescription Drug Policy Review Commission (established under subsection (i)) of such portion of such rebates as may be specified in appropriation Acts.

`(2) STATE PROVISION OF INFORMATION-

`(A) STATE RESPONSIBILITY- Each State agency under this title shall report to each manufacturer, not later than 60 days after the end of each calendar quarter and in a form consistent with any standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter, and shall promptly transmit a copy of such report to the Secretary.

`(B) LIMITATIONS ON AUDIT- A manufacturer has the right to an audit only of the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

`(C) NOTICE TO SECRETARY- Each State agency shall notify the Secretary within 30 days after the date each rebate is received under this section.

`(3) MANUFACTURER PROVISION OF PRICE INFORMATION-

`(A) IN GENERAL- Each manufacturer with an agreement in effect under this section shall report to the Secretary (and make available upon request to each State agency)--

`(i) not later than 30 days after the last day of each quarter (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (l)(1)) and (for single source drugs and innovator multiple source drugs) the manufacturer's best price (as defined in subsection (c)(3)(A)) for covered outpatient drugs for the quarter, and

`(ii) not later than 30 days after the date of entering into an agreement under this section on the best price (as defined in subsection (c)(3)(B)) as of September 1, 1990 for each of the manufacturer's covered outpatient drugs.

`(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE- The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary to verify average manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $10,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(C) PENALTIES-

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

`(ii) FALSE INFORMATION- Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law (including exclusion under section 1128(b)(11)). The provisions of section

1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

`(D) CONFIDENTIALITY OF INFORMATION- Information disclosed by manufacturers or wholesalers under this paragraph is confidential and shall not be disclosed by the Secretary or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

`(4) LENGTH OF AGREEMENT-

`(A) IN GENERAL- A rebate agreement shall be effective for an initial period of 1 year and shall be automatically renewed for an additional 1-year period unless terminated under subparagraph (B).

`(B) TERMINATION-

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

`(ii) BY A MANUFACTURER- A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until such period (of not more than 1 year) after the date of the notice as the Secretary may provide by regulation.

`(iii) EFFECTIVENESS OF TERMINATION- Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

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

`(c) AMOUNT OF REBATE-

`(1) IN GENERAL-

`(A) SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- Except as provided in this subsection and subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to single source drugs and innovator multiple source drugs shall be equal to the product of--

`(i) the amount by which (I) the average manufacturer price during the quarter for each dosage form and strength of a covered outpatient drug (after deducting customary prompt payment discounts), exceeds (II) the manufacturer's best price (as defined in paragraph (3)) for such form and strength; and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2)).

`(B) OTHER DRUGS- Except as provided in subsection (b)(3)(C)(i), the amount of the rebate to a State during a calendar quarter with respect to covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

`(i) 10 percent of the average manufacturer price to wholesalers during the quarter for each dosage form and strength of a covered outpatient drug (after deducting customary prompt payment discounts); and

`(ii) the number of units of such form and dosage dispensed under the plan under this title in the State in the quarter (as reported by the State under subsection (b)(2).

`(2) MINIMUM AND MAXIMUM REBATE RATES FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS- In no case shall the amount of the rebate described in paragraph (1)(A) for a manufacturer for a calendar quarter with respect to single source drugs and innovator multiple source drugs be less than 10 percent, or more than 25 percent of the product of the price described in paragraph (1)(A)(i)(I) and the number of units described in paragraph (1)(A)(ii) for the quarter.

`(3) BEST PRICE DEFINED-

`(A) IN GENERAL- In this subsection, the term `best price' means, for a covered outpatient drug of a manufacturer dispensed in a calendar quarter--

`(i) the lowest price available for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States during the quarter, or

`(ii) the lowest price in effect for the drug from the manufacturer to any wholesaler, retailer, provider, nonprofit entity, or governmental entity within the United States in effect on September 1, 1990, increased (for calendar quarters beginning on or after January 1, 1991) by the percentage increase in the Consumer Price Index for All Urban Consumers (all items; U.S. city average) from September 1990 to the month before the beginning of the calendar quarter involved,

whichever is lower.

`(B) TREATMENT OF NEW DRUGS- In the case of a covered outpatient drug approved for marketing after September 1, 1990, any reference in subparagraph (A)(ii) to `September 1, 1990' or `September 1990' shall be a reference to the first day of the first month, and the first month, respectively, during which the drug was marketed and any reference in subsection (b)(3)(A)(ii) to `30 days after the date of entering into an agreement under this section on the best price described in paragraph (3)(B) as of September 1, 1990' shall be a reference to `30 days after the date the drug is first marketed in the United States'.

`(C) COMPUTATION OF LOWEST PRICE- The lowest price described in this paragraph shall be inclusive of cash discounts, free goods, volume discounts, and rebates, 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.

`(d) LIMITATIONS ON PRIOR AUTHORIZATION PROGRAMS-

`(1) CONDITIONS- A State plan under this title may not require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (l)(6)) unless the system providing for such approval--

`(A) is available to physicians 24 hours a day, 7 days a week, and

`(B) provides an immediate response by telephone or other telecommunication device to an inquiry.

`(2) DELAYED EFFECTIVE DATE- Paragraph (1) shall only apply to prior authorization programs for drugs dispensed on or after April 1, 1991.

`(e) PARTIAL RESTORATION OF PAYMENTS TO PHARMACISTS-

`(1) IN GENERAL- Beginning fiscal year 1991 and ending September 30, 1993, each State plan under this title shall provide, after the end of each fiscal year and in a lump-sum payment, for a payment to pharmacies dispensing covered outpatient drugs under this title during the fiscal year.

`(2) AMOUNT OF PAYMENT- The amount of the payment under this subsection for any fiscal year to a pharmacist shall bear the same ratio to 10 percent of the total amount of rebates received under this section by the State in the fiscal year involved, as the ratio of the number of prescriptions filled by the pharmacy under this title in the fiscal year bears to the total of such number for entpharmacies in the State in the fiscal year, and will be made within 60 days after the end of each fiscal year.

`(f) CHANGES IN REIMBURSEMENT SYSTEM FOR PRESCRIBED DRUGS-

`(1) DISPENSING FEES-

`(A) ANNUAL STUDY- Each State plan shall have conducted, by not later than March 1 of each year (beginning with 1993), a study to determine the cost of dispensing prescriptions for covered outpatient drugs under this title. The study shall include a statistically valid sample of retail pharmacies in the State and shall use a generally accepted method to calculate the cost of dispensing a prescription.

`(B) UPDATING DISPENSING FEES- Beginning on March 1, 1993, and yearly thereafter, each State shall update the payment amounts provided under the State plan for dispensing prescriptions to reflect a reasonable reimbursement fee which is based on the study of costs of dispensing prescriptions most recently conducted under subparagraph (A).

`(2) NO REDUCTIONS IN REIMBURSEMENT LIMITS- Prior to March 1, 1993, no changes may be made by the Secretary or a State to the formula used to determine the reimbursement limits in effect under this title as of August 1, 1990, which would result in a reduction in the limit relative to either the ingredient cost portion or the dispensing fee portion of the formula, for covered outpatient drugs.

`(3) DENIAL OF FEDERAL FINANCIAL PARTICIPATION IN CERTAIN CASES- The Secretary shall provide that no payment shall be made to a State under section 1903(a) for an innovator multiple-source drug dispensed on or after April 1, 1991, if, under applicable state law, a noninnovator multiple source drug (other than the innovator multiple-source drug) could have been dispensed consistent with such law.

`(g) DRUG USE REVIEW-

`(1) IN GENERAL- In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs and for prescription drugs (other than psychopharmacologic drugs described in section 1919(c)(2)(D)) dispensed to residents of nursing facilities in order to assure that prescriptions (A) are appropriate, (B) are medically necessary, and (C) are not likely to result in adverse medical results.

`(2) DESCRIPTION OF PROGRAM- Each drug use review program shall meet the following requirements for covered outpatient drugs and other prescription drugs:

`(A) PROSPECTIVE DRUG REVIEW- (i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to the patient, typically at the point-of-sale or point of distribution. Each pharmacist shall use the compendia referred to in subsection (l)(6)) as its source of standards for such review.

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

`(I) The pharmacist must offer to discuss with each patient or caregiver (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a new prescription all matters, which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, including at least the following:

`(a) The name and description of the medication.

`(b) The route, dosage, administration, and continuity of drug therapy.

`(c) Special directions for use by the patient as deemed necessary by the pharmacist.

`(d) Common severe adverse effects or interactions that may be encountered, and the action required if they occur.

`(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following patient information:

`(a) Patient name, address, telephone number, date of birth (or age), and gender.

`(b) Patient history where significant, including chronic disease state or states, known allergies and drug reactions, and as current of a comprehensive list of medications and relevant devices as possible.

`(c) Pharmacist comments.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when a patient or caregiver refuses such consultation.

`(B) RETROSPECTIVE DRUG USE REVIEW- The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs.

`(C) APPLICATION OF STANDARDS- The program shall assess data on drug use against explicit predetermined standards and, as necessary, introduce remedial strategies, in order to improve the quality of care, to conserve program funds or personal expenditures, and to control fraud and benefit abuse.

`(D) EDUCATIONAL PROGRAM- The program shall, through its State drug use review board established under paragraph (4), educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacies, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs, including such reactions due to--

`(i) interaction of two or more drugs being taken concurrently;

`(ii) concurrent use of two or more drugs from within the same drug use class;

`(iii) excessive or subtherapeutic daily dose;

`(iv) allergies to drugs;

`(v) interaction of prescribed drugs with drugs available without a prescription (commonly referred to as `over-the-counter' drugs);

`(vi) incorrect drug dosage or duration of drug treatment; and

`(vii) interaction between a drug and an existing disease State.

`(3) USE OF INFORMATION BY SECRETARY- At the earliest possible date after the date of the enactment of this section, the Secretary shall use the information on individual prescription claims which is available in the mechanized claims processing and information retrieval system provided for in section 1903(r) in order to perform retrospective drug use reviews described in paragraph (2)(B); except that information which comes to the Secretary's attention through a State's mechanized claims processing and information retrieval system and which suggests a pattern of inappropriate or medically unnecessary prescribing or dispensing of covered outpatient drugs shall be referred to the drug use review board of the concerned State, which shall use the information as the basis for targeting educational outreach and intervention under paragraph (4). This authority of the State board is not to be construed to limit any existing authority of the Secretary or the State to respond to problems identified in the course of the prospective drug use reviews performed under this subsection.

`(4) STATE DRUG USE REVIEW BOARD-

`(A) ESTABLISHMENT AND MEMBERSHIP- Each State shall provide for the establishment of a drug use review board. The chairman of the board and a majority of the membership shall be practicing physicians. The remaining membership shall include clinical pharmacologists and pharmacists. All members shall have recognized knowledge and expertise in one or more of the following:

`(i) The appropriate prescribing the dispensing of covered outpatient drugs.

`(ii) Drug prescribing and dispensing.

`(iii) Drug use review.

`(iv) Medical quality assurance.

`(B) ANNUAL REPORT- Each State drug use review board shall prepare and submit to the Secretary on an annual basis a report of the activities of the Board to identify the nature and the scope of the retrospective drug use review program, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's retrospective program.

`(C) EDUCATIONAL OUTREACH AND INTERVENTION- Each State drug use review board shall, either directly or through contracts with utilization and quality control peer review organizations, as defined in section 1152, or with State medical societies, conduct ongoing educational outreach and intervention programs for physicians and pharmacists, targeted toward problems or individuals identified in the course of retrospective drug use reviews performed under this subsection, and evaluate the success of the interventions and make modifications as necessary. These educational outreach and intervention programs shall include at least--

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

`(ii) use of face-to-face interventions by health professionals with prescribers and dispensers, including follow up visits and discussion of optimal prescribing or dispensing practices; and

`(iii) enhanced review or monitoring of prescribers or dispensers exhibiting a pattern of suspected substandard care.

`(h) ELECTRONIC CLAIMS MANAGEMENT-

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

`(2) ENCOURAGEMENT- In order to carry out paragraph (1)--

`(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development and operation of a system described in shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through the applicable competitive procurement process in the State, the most efficient and cost-effective telecommunications network and automatic data processing services and equipment; and

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

`(i) PRESCRIPTION DRUG POLICY REVIEW COMMISSION-

`(1) IN GENERAL- The Director of the Congressional Office of Technology Assessment (in this subsection referred to as the `Director' and the `Office', respectively) shall provide for the appointment of a Prescription Drug Policy Review Commission (in this subsection referred to as the `Commission'), to be composed of individuals with expertise in the provision and financing of inpatient and outpatient drugs and biologicals. The provisions of title 5, United States Code, governing appointments in the competitive service shall not apply to the appoint of members of the Commission.

`(2) COMPOSITION-

`(A) IN GENERAL- The Commission shall consist of 11 individuals. Members of the Commission shall first be appointed by no later than January 1, 1991, for a term of 3 years, except that the Director may provide initially for such shorter terms as will insure that (on a continuing basis) the terms of no more than 4 members expire in any one year.

`(B) MEMBERSHIP- The membership of the Commission shall include recognized experts in the fields of health care economics and quality assurance, medicine, pharmacology, pharmacy, and prescription drug reimbursement, as well as at least one individual who is a medicaid recipient.

`(3) ANNUAL REPORTS- The Comission shall submit to the Congress an annual report (by not later than June 1 of each year beginning with 1992) which shall include information and recommendations regarding drug policy issues, such as--

`(A) the scope of coverage and reimbursement for prescribed drugs under this title, including accessibility of drugs to medical assistance recipients;

`(B) the availability and affordability of private insurance for prescription drug costs, the advisability of providing Federal funding to encourage the development of State pharmaceutical assistance plans for the elderly;

`(C) changes in manufacturers' prices for prescribed drugs and pharmacists' charges for covered outpatient drugs; and

`(D) changes in the level and nature of use of covered outpatient drugs by medical assistance recipients, taking into account the impact of such changes on aggregate expenditures under this title.

`(4) SPECIAL REPORT- The Commission shall submit to Congress a report, by not later than December 1, 1993, including information and recommendations concerning--

`(A) methods of payment for drug products, including evaluation of methods of negotiating prices with drug manufacturers, of reimbursing pharmacists for cognitive services and prescription drug products, and other approaches to payment policy;

`(B) methods for assessing the relative therapeutic contribution of new drugs approved for marketing in the United States, including recommendations for expedited coverage under this title for products making a significant contribution to existing drug therapies;

`(C) requirements necessary for efficient program administration, such as uniform drug nomenclature, electronic claims management and payment technologies, and uniform reporting of claims; and

`(D) forms of cost-containment now used by private entities, including an assessment of the documented potential for significant expenditure reductions under this title resulting from price negotiations between manufacturers of drug products which are therapeutic alternates.

`(5) ADMINISTRATIVE PROVISIONS- Section 1845(c)(1) shall apply to the Commission in the same manner as it applies to the Physician Payment Review Commission.

`(6) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this subsection. Rebates provided under agreements under this section shall be available, in the manner specified in subsection (b)(1)(B) to carry out this subsection.

`(j) ANNUAL REPORT AND DATABASE-

`(1) IN GENERAL- Not later than May 1 of each year (beginning with 1992), the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

`(2) DETAILS- Each report shall include information on--

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

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

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

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

`(E) trends in prices paid under this title for covered outpatient drugs.

`(3) Medicaid prescription drug data base-

`(A) DEVELOPMENT- Not later than October 1, 1991, the Secretary shall develop and make available for research purposes a medicaid prescription drug data base, which contains information (in a form that protects the confidentiality of information that identifies individual patients or confidential manufacturer information) on each State's program for covered outpatient drugs under this title.

`(B) TRANSMITTAL OF INFORMATION- Each State agency shall transmit to the Secretary such data as may be necessary to carry out this paragraph.

`(C) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this paragraph. Rebates provided under agreements under this section shall be available, in the same manner specified in subsection (b)(1)(B) as such rebates are available to carry out subsection (i), to carry out this subsection.

`(C) EXPENSES- Expenses required to carry out this paragraph in any quarter shall be considered to be amounts expended during such quarter as medical assistance under section 1903(a)(1) and shall be offset against rebates received by States under this section in a manner proportional to the rebates received by each such State.

`(k) MISCELLANEOUS-

`(1) EXCLUSION OF CERTAIN DRUG ASSOCIATED WITH EXCLUSIVE PATIENT MONITORING SERVICES- Nothing in this title shall be construed as requiring a State to provide medical assistance for covered outpatient drugs of a manufacturer which requires, as a condition for the purchase of the drugs, that the manufacturer be paid for associated services or tests (such as patient monitoring systems) provided only by the manfacturer or its designee.

`(2) APPLICATION OF REBATE- If a State elects to provide medical assistance for drugs described in paragraph (1), such drugs shall be subject to the rebate schedule described in subsection (c).

`(l) DEFINITIONS- In this section:

`(1) AVERAGE MANUFACTURER PRICE- The term `average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug by retail pharmacies or by wholesalers for drugs distributed to the retail pharmacy class of trade.

`(2) COVERED OUTPATIENT DRUG- Subject to the exceptions in paragraph (3), the term `covered outpatient drug' means--

`(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

`(i) which is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

`(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a `new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of such Act to enforce sections 502(f) or 505(a) of such Act; or

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

`(B) a biological product which--

`(i) may only be dispensed upon prescription,

`(ii) is licensed under section 351 of the Public Health Service Act, and

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

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

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

`(A) Inpatient hospital services.

`(B) Hospice services.

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

`(D) Physician office visits.

`(E) Outpatient hospital emergency room visits.

`(F) Outpatient surgical procedures.

Such term also does not include any such drug or product which is used for a medical indication which is not a medically accepted indication.

`(4) NONPRESCRIPTION DRUGS- If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as `over-the-counter' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug may be regarded as a covered outpatient drug.

`(5) MANUFACTURER- The term `manufacturer' means any entity which is engaged in--

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

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

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

`(6) MEDICALLY ACCEPTED INDICATION- The term `medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

`(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG-

`(A) DEFINITIONS-

`(i) MULTIPLE SOURCE DRUG- The term `multiple source drug' means, with respect to a calendar quarter, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

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

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

`(III) are sold or marketed in the State during the period.

`(ii) INNOVATOR MULTIPLE SOURCE DRUG- The term `innovator multiple source drug' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

`(iii) NONINNOVATOR MULTIPLE SOURCE DRUG- The term `noninnovator multiple source drug' means a multiple source drug that is not an innovator multiple source drug.

`(iv) SINGLE SOURCE DRUG- The term `single source drug' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers operating under the new drug application.

`(B) EXCEPTION- Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

`(C) DEFINITIONS- For purposes of this paragraph--

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

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

`(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

`(8) STATE AGENCY- The term `State agency' means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.'.

(c) FUNDING-

(1) DRUG USE REVIEW PROGRAMS- Section 1903(a)(3) of such Act (42 U.S.C. 1936b(a)(3)) is amended--

(A) by striking `plus' at the end of subparagraph (C) and inserting `and', and

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

`(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g); plus'.

(2) TEMPORARY INCREASE IN FEDERAL MATCH FOR ADMINISTRATIVE COSTS- The per centum to be applied under section 1903(a)(7) of the Social Security Act for amounts expended during calendar quarters in fiscal year 1991 which are attributable to administrative activities necessary to carry out section 1927 (other than subsection (g)) of such Act shall be 75 percent, rather than 50 per centum.

(d) DEMONSTRATION PROJECTS-

(1) PROSPECTIVE DRUG UTILIZATION REVIEW-

(A) The Secretary of Health and Human Services shall provide, through competitive procurement by not later than January 1, 1992, for the establishment of at least 10 statewide demonstration projects to evaluate the efficiency and cost-effectiveness of prospective drug utilization review (as a component of on-line, real-time electronic point-of-sales claims management) in fulfilling patient counseling and in reducing costs for prescription drugs.

(B) Each of such projects shall establish a central electronic repository for capturing, storing, and updating prospective drug utilization review data and for providing access to such data by participating pharmacists (and other authorized participants).

(C) Under each project, the pharmacist or other authorized participant shall assess the active drug regimens of recipients in terms of duplicate drug therapy, therapeutic overlap, allergy and cross-sensitivity reactions, drug interactions, age precautions, drug regiment compliance, prescribing limits, and other appropriate elements.

(D) Not later than January 1, 1994, the Secretary shall submit to Congress a report on the demonstration projects conducted under this paragraph.

(2) DEMONSTRATION PROJECT ON COST-EFFECTIVENESS OF REIMBURSEMENT FOR PHARMACISTS' COGNITIVE SERVICES-

(A) The Secretary of Health and Human Services shall conduct a demonstration project to evaluate the impact on quality of care and cost-effectiveness of paying pharmacists under title XIX of the Social Security Act, whether or not a drug is dispensed, for drug use review services. For this purpose, the Secretary shall provide for no fewer than 5 demonstration sites and the participation of a significant number of pharmacists.

(B) Not later than January 1, 1995, the Secretary shall submit a report to the Congress on the results of the demonstration project conducted under subparagraph (A).

(e) STUDIES-

(1) STUDY OF THERAPEUTIC INTERCHANGE- ABILITY-

(A) The Secretary of Health and Human Services shall undertake a study of therapeutic interchangeability among pharmaceutical products and biologicals.

(B) The study shall include a review of--

(i) the scientific and clinical foundation for the concept of therapeutic interchangeability among drug products;

(ii) the use of therapeutic interchangeability by health care institutions, including Federally funded hospitals and health care programs, in managing drug therapy and containing costs;

(iii) current outpatient prescription drug systems which employ therapeutic interchangeability for the purpose of developing a therapeutic formulary and the patient safeguards incorporated into such a system;

(iv) how the concept of therapeutic interchangeability can be used by Federally-funded programs and other third-party insurers for the purpose of managing drug therapy and containing costs; and

(v) mechanisms that might be developed on the national and State level to make determinations of therapeutic interchangeability of drug products.

(C) By not later than June 1, 1992, the Secretary shall submit a report to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives concerning the study conducted under this paragraph.

(2) STUDY OF DRUG PURCHASING AND BILLING ACTIVITIES OF VARIOUS HEALTH CARE SYSTEMS-

(A) The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the medicaid program. The study shall compare the ingredient costs of drugs for medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies.

(B) By not later than May 1, 1991, the Comptroller General shall report to the Secretary of Health and Human Services, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives on the study conducted under subparagraph (A).

(3) REPORT ON DRUG PRICING- By not later than May 1 of each year, the Comptroller General shall submit to the Secretary of Health and Human Services, the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and House of Representatives an annual report on changes in prices charged by manufacturers for prescription drugs to the Department of Veterans' Affairs, other Federal programs, retail and hospital pharmacies, and other purchasing groups and managed care plans.

END

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