

Assembly Bill No. 2911

CHAPTER 619

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to pharmacy assistance.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2911, Nunez. California Discount Prescription Drug Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Discount Prescription Drug Program within the department, applicable only to prescription drugs dispensed to recipients on an outpatient basis. The bill would require the department to negotiate drug discount agreements with drug manufacturers, as specified. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to participate in the program. The bill would authorize the department, on August 1, 2010, to require prior authorization in the Medi-Cal program for any drug of a manufacturer if specified conditions are met. The bill would establish eligibility criteria and application procedures for eligible Californians to participate in the program.

The bill would establish the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would provide that moneys in the fund shall be made available, upon appropriation, to the department for purposes of the program.

The people of the State of California do enact as follows:

SECTION 1. The Legislature hereby finds and declares all of the following:

(a) Affordability is critical in providing access to prescription drugs for California residents, particularly the uninsured and those with inadequate insurance.

(b) The California Discount Prescription Drug Program is enacted to make prescription drugs more affordable for qualified California residents,

thereby increasing the overall health of California residents, promoting healthy communities, and protecting the public health and welfare.

(c) It is not the intent of the state to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified California residents under this program.

SEC. 2. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the California Discount Prescription Drug Program.

130501. For purposes of this division, the following definitions shall apply:

(a) "Average manufacturer's price" has the same meaning as this term is defined in Section 1927(k)(1) of the federal Social Security Act (42 U.S.C. Sec. 1396r-8)(k)(1).

(b) "Department" means the State Department of Health Services.

(c) "Eligible Californian" means a resident of the state who meets any one or more of the following:

(1) Has total unreimbursed medical expenses equal to at least 10 percent of his or her family's income where the family's income does not exceed the state median family income.

(2) To the extent allowed by federal law, is enrolled in the Medicare Program, but whose prescription drugs are not covered by the Medicare Program.

(3) Has a family income that does not exceed 300 percent of the federal poverty guidelines and who does not have outpatient prescription drug coverage paid for by any one of the following:

(A) In whole by the Medi-Cal program.

(B) In whole or in part by the Healthy Families Program or other programs funded by the state.

(C) In whole or in part by another third-party payer, provided that the individual has not reached the annual limit on his or her prescription drug coverage.

(4) For purposes of this subdivision, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(d) "Fund" means the California Discount Prescription Drug Program Fund.

(e) “Manufacturer” means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(f) “Manufacturer’s rebate” means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(g) “Medicaid best price” has the same meaning as this term is defined in Section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. Sec. 1396r-8)(c)(1)(C).

(h) “Multiple-source drug” has the same meaning as this term is defined in Section 1927(k)(7) of the Social Security Act (42 U.S.C. Sec. 1396r-8)(k)(7).

(i) “National drug code” or “NDC” means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(j) “National sales data” means prescription data obtained from a national-level prescription tracking service.

(k) “Participating manufacturer” means a drug manufacturer that has contracted with the department to provide an individual drug or group of drugs for the program.

(l) “Participating pharmacy” means a pharmacy that has executed a pharmacy provider agreement with the department for this program.

(m) “Pharmacy contract rate” means the negotiated per prescription reimbursement rate for drugs dispensed to eligible Californians. The department shall establish a single, basic pharmacy rate, but may contract at different rates with pharmacies in order to provide access throughout the state.

(n) “Prescription drug” means any drug that bears the legend: “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(o) “Private discount drug program” means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

(p) “Program” means the California Discount Prescription Drug Program.

(q) “Single-source drug” has the same meaning as this term, and the term innovator multiple-source drug, are defined in Section 1927(k)(7) of the Social Security Act (42 U.S.C. Sec. 1396r-8)(k)(7).

(r) “Therapeutic category” means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

(s) “Volume weighted average discount” means the aggregated average discount for the drugs of a manufacturer, weighted by each drug’s percentage of the total prescription volume of that manufacturer’s drugs. Drugs excluded from contracting by the department, pursuant to

subdivision (d) of Section 130506 and in a manner consistent with subdivision (c) of Section 130506, shall be excluded from the calculation of the volume weighted average discount. National sales data shall be used to calculate the volume weighted average discount pursuant to Section 130506. Program utilization data shall be used to calculate the volume weighted average discount pursuant to Section 130507.

130502. The California Discount Prescription Drug Program is hereby established within the department.

CHAPTER 2. PRESCRIPTION DRUG DISCOUNTS

130505. (a) The amount a participating, eligible Californian pays for a drug through the program shall be equal to the lower of the participating pharmacy's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate for prescription drugs, including multiple-source drugs.

(d) This division shall apply only to prescription drugs dispensed to eligible Californians on an outpatient basis.

130506. (a) The department shall negotiate drug discount agreements with manufacturers to provide discounts for single-source and multiple-source prescription drugs through the program. The department shall attempt to negotiate the maximum possible discount for an eligible Californian. The department shall attempt to negotiate, with each manufacturer, discounts to offer single-source prescription drugs under the program at a volume weighted average discount that is equal to or below any one of the following benchmark prices:

(1) Eighty-five percent of the average manufacturer price for a drug, as published by the Centers for Medicare and Medicaid Services.

(2) The lowest price provided to any nonpublic entity in the state by a manufacturer to the extent that the Medicaid best price exists under federal law.

(3) The Medicaid best price, to the extent that this price exists under federal law.

(b) The department may require the drug manufacturer to provide information that is reasonably necessary for the department to carry out its duties pursuant to this division.

(c) The department shall pursue manufacturer discount agreements to ensure that the number and type of drugs available through the program is sufficient to give an eligible Californian a formulary comparable to the

Medi-Cal list of contract drugs, or if this information is available to the department, a formulary that is comparable to that provided to CalPERS enrollees.

(d) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(e) The drug discount agreements negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by program participants.

(f) All information reported by a manufacturer to, negotiations with, and agreements executed with, the department or its third-party vendor pursuant to this section, shall be considered confidential and corporate proprietary information. This information shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). The Bureau of State Audits and the Controller shall have access to pricing information in a manner that is consistent with their access to this information under the Medi-Cal program and under law. The Bureau of State Audits and the Controller may use this information only to investigate or audit the administration of the program. Neither the Bureau of State Audits, the Controller, nor the department may disclose this information in a form that identifies a specific manufacturer or wholesaler or prices charged for drugs of this manufacturer or wholesaler. Information provided to the department pursuant to subdivision (e) of Section 130530 shall not be affected by the confidentiality protections established by this subdivision.

(g) (1) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(2) Any manufacturer may participate in the program.

130507. (a) On August 1, 2010, the department shall determine whether manufacturer participation in the program has been sufficient to meet both of the following benchmarks:

(1) The number and type of drugs available through the program are sufficient to give eligible Californians a formulary comparable to the Medi-Cal list of contract drugs or, if this information is available to the department, a formulary comparable to that provided to CalPERS enrollees.

(2) The volume weighted average discount of single-source prescription drugs offered pursuant to this program is equal to or below any one of the benchmark prices described in subdivision (a) of Section 130506.

(b) On and after August 10, 2010, the department shall reassess program outcomes, at least once every year, consistent with the benchmarks described in subdivision (a).

130508. To the maximum extent possible, the department shall assure that enrollment and other administrative actions are seamless to all eligible Californians.

130509. (a) The department may require prior authorization in the Medi-Cal program for any drug of a manufacturer if the manufacturer fails to agree to a volume weighted average discount for single-source prescription drugs that is equal to or below any one of the benchmark prices described in subdivision (a) of Section 130506 and only to the extent that this requirement does not increase costs to the Medi-Cal program, as determined pursuant to subdivision (c).

(b) If prior authorization is required for a drug pursuant to this section, a Medi-Cal beneficiary shall not be denied the continued use of a drug that is part of a prescribed therapy until that drug is no longer prescribed for that beneficiary's therapy. The department shall approve or deny requests for prior authorization necessitated by this section as required by state or federal law.

(c) The department, in consultation with the Department of Finance, shall determine the fiscal impact of placing a drug on prior authorization pursuant to this section. In making this determination, the department shall consider all of the following:

(1) The net cost of the drug, including any rebates that would be lost if the drug is placed on prior authorization.

(2) The projected volume of purchases of the drug, before and after the drug is placed on prior authorization, considering the continuity of care provisions set forth in subdivision (b).

(3) The net cost of comparable drugs to which volume would be shifted if a drug is placed on prior authorization, including any additional rebates that would be received.

(4) The projected volume of purchases of comparable drugs, before and after the drug is placed on prior authorization.

(5) Any other factors determined by the department to be relevant to a determination of the fiscal impact of placing a drug on prior authorization.

(d) This section shall be implemented only to the extent permitted under federal law, and in a manner consistent with state and federal laws.

(e) This section may apply to any manufacturer that has not negotiated with the department.

(f) The department shall notify the Speaker of the Assembly and the President pro Tempore of the Senate that the department is requiring prior authorization no later than five days after making this requirement.

(g) (1) Subject to paragraph (2), this section shall become operative on August 1, 2010.

(2) This section shall become operative only if the department determines that participation by manufacturers has been insufficient to meet both of the benchmarks identified in Section 130507.

130510. The names of manufacturers of single-source drugs that do or do not enter into discount agreements with the department pursuant to this division shall be public information and shall be posted on the department's Internet Web site when the discount agreements are reached or the manufacturer ends negotiations, commencing within six months

after the initial implementation date of this division and updated on the first of each month thereafter.

130511. (a) Each drug discount agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement if there is a dispute over the drug's utilization.

(3) Permit a manufacturer to audit claims for the drugs the manufacturer provides under the program. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a program participant's health information.

(b) In addition to the requirements of subdivision (a), each drug discount agreement with a single-source manufacturer shall do all of the following:

(1) Require the manufacturer to make a rebate payment to the department for each drug described in paragraph (1) of subdivision (a) dispensed to a program participant.

(2) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(3) Require the manufacturer to provide, upon request, documentation to validate the rebate.

(c) The department may collect prospective rebates from single-source manufacturers for payment to pharmacies. The amount of the prospective discount shall be specified in the drug rebate agreements.

(d) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For rebate payments to the program, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after January 1, 2007.

(e) Interest required by subdivision (d) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment. Interest rates and calculations for purposes of this section shall be at 10 percent.

(f) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for the program, in a manner designated by the department.

130512. (a) The department shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Program discounts compared to the usual customary price.

(4) Aggregate amounts of rebates collected from manufacturers.

(5) A summary of the problems or complaints reported regarding the program.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

(c) The department shall generate an annual report that, in addition to the information described in subdivision (a), reports on the number of all of the following:

- (1) Individuals enrolled.
- (2) Individuals receiving a prescription under the program.
- (3) Participating pharmacies.
- (4) Participating manufacturers.

(d) All reports shall be made available on the department's Internet Web site.

130513. (a) The department shall establish and maintain a claims processing system that complies with all of the following requirements:

- (1) Charges a price that meets the requirements of this division.
- (2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.
- (3) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards provided in federal law.

(b) The department shall pay a participating pharmacy the discount provided to program participants pursuant to this division by a date that is not later than two weeks after the claim is received.

(c) The department shall develop a mechanism for the program participants to report problems or complaints.

CHAPTER 3. APPLICATION, ENROLLMENT, AND OUTREACH

130520. (a) The department shall develop an application and reapplication form for the determination of a resident's eligibility for the program. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

(b) The application shall, at a minimum, do all of the following:

- (1) Specify the information that an applicant or the applicant's representative must include in the application.
- (2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Specify that the application fee due upon submission of the applicable form is ten dollars (\$10) annually.

(c) In assessing the income requirement for eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) An application may be completed at any pharmacy, physician office, or clinic participating in the program through an Internet Web site or call center staffed by trained operators approved by the department. A

pharmacy, physician's office, clinic, or nonprofit community organization that completes the application may keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in the program, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a program participant.

(e) The department shall utilize a secure electronic application process that can be used by a pharmacy, physician's office, or clinic, by an Internet Web site, by a call center staffed by trained operators, by a nonprofit community organization, or through the third-party vendor to enroll applicants in the program.

(f) During the department's normal working hours, the department shall make a determination of eligibility within 24 hours of receipt by the program of a completed application. The department shall mail the program participant an identification card no later than seven days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a participant identification number for eligible applicants to the pharmacy for immediate access to the California Discount Prescription Drug Program.

(h) Any program participant that has been determined to be eligible shall be enrolled for 12 months or until the program participant notifies the department of an intent to end enrollment.

(i) The department shall notify a program participant of termination of enrollment 30 days prior to the termination.

(j) A person shall be required to apply pursuant to this section for each 12-month period of eligibility.

130521. (a) The department may conduct an outreach program to inform California residents of their opportunity to participate in the program. The department shall coordinate outreach activities with the California Department of Aging, the Employment Development Department, and other state and local agencies, and nonprofit organizations that serve residents who may be eligible for the program. No outreach material shall contain the name or likeness of a drug.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about the program. The name of the organization sponsoring the materials shall in no way appear on the material but shall be reported to the public and the Legislature as otherwise provided by law.

CHAPTER 4. PHARMACEUTICAL MANUFACTURER PATIENT ASSISTANCE PROGRAMS

130530. (a) The department shall encourage a participating manufacturer to maintain those private discount drug programs that are comparable to or more extensive than those provided prior to the

enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.

(b) The department may execute agreements with drug manufacturers and other private patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs to the extent permitted by state and federal law.

(c) The department shall develop a system to provide a program participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer or other private patient assistance program.

(d) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the California Discount Prescription Drug Program.

(e) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(f) The California Discount Prescription Drug Program card issued pursuant to this division shall serve as a single point of entry for drugs available pursuant to subdivision (a), and shall meet all legal requirements for a health benefit card.

CHAPTER 5. ADMINISTRATION

130540. (a) Contracts, contract amendments, change orders, change requests, and any project or systems development notices, entered into for purposes of this division, shall be subject to the same exemptions provided for in the Medi-Cal drug program and those provided to the department in paragraph (4) of subdivision (c) of Section 124977. In addition, contracts, contract amendments, change orders, change requests, and any project or systems development notices, entered into for purposes of this division, are specifically exempt from:

(1) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(2) The competitive bidding requirements of State Administrative Manual Management Memo 03-10.

(3) The project authority requirements of State Administrative Manual, Section 4800 et seq.

(4) Section 11.00 and Provision 6 of Item 4260-001-0001 of Section 2 of the Budget Act of 2006 and related Budget letters.

(b) Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

(c) Change orders entered into pursuant to this division shall not require a contract amendment.

(d) To the extent that any exemption set forth in this section conflicts with exemptions set forth in paragraph (4) of subdivision (c) of Section 124977, the exemption in this section shall govern over the conflicting provision in Section 124977.

130541. To implement the program, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. Drug discount agreements negotiated by a third party shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or program participants. Participating pharmacy contracts entered into pursuant to Section 130505 shall be considered contracts between the participating pharmacy and the department and shall not be associated with, or leveraged against, other third-party agreements.

130542. (a) The department shall deposit all payments the department receives pursuant to this division into the California Discount Prescription Drug Program Fund, which is hereby established in the State Treasury.

(b) Moneys in the fund shall be made available to the department, upon appropriation by the Legislature, for purposes of the program. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund. The fund shall also contain any interest accrued on moneys in the fund.

130543. (a) The director may adopt regulations as are necessary to implement and administer this division.

(b) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division, in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action, provided that no bulletin or other similar instructions shall remain in effect after August 1, 2011. It is the intent that regulations adopted pursuant to this section shall be adopted on or before August 1, 2011.

130544. If any provision of this division, or the application thereof, is for any reason, held invalid, ineffective, or unconstitutional by a court of competent jurisdiction, the remainder of this division, or the application of this provision, shall not be affected thereby, and to this end the provisions of this division are severable.

SEC. 3. The Legislature finds and declares the following: Section 2 of this act, which adds Section 130506 to the Health and Safety Code, imposes a limitation on the public's rights of access to the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to facilitate manufacturer participation and deliver affordable prescription drugs to low-income Californians, it is necessary to protect the confidentiality trade secrets and pricing information.