

SA2005RF0065

ASHLEE N. BROWN

February 4, 2005

Ms. Tricia Knight
Initiative Coordinator
Office of the Attorney General
State of California
PO Box 994255
Sacramento, CA 94244-25550

RECEIVED
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INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

Re: Request for Title and Summary for Proposed Initiative

Dear Ms. Knight:

Pursuant to Article II, Section 10(d) of the California Constitution, I am submitting the attached proposed statewide ballot measure to your office and request that you prepare a title and summary of the measure as provided by law. Included with this submission is the required proponent affidavit signed by the proponent of this measure pursuant to section 9608 of the California Elections Code. I have also included a check to cover the \$200 filing fee.

Thank you for your time and attention to this important matter. If you require additional information or have any questions, please feel free to contact me at (916) 442-7757.

Very truly yours,

Ashlee N. Brown

Enclosure

INITIATIVE MEASURE TO BE SUBMITTED DIRECTLY TO VOTERS

SECTION 1. FINDINGS AND DECLARATION OF PURPOSE

The People of the State of California do hereby find and declare that:

- (a) Prescription drugs are an integral part to managing acute and chronic illness improving quality of life; and
- (b) Prescription drugs are a convenient, cost-effective alternative to more costly medical interventions; and
- (c) Increasing the affordability and access of prescription medicines will significantly improve healthcare quality and lower overall healthcare costs.

SECTION 2. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read as follows:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

Chapter 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

- (a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.
- (b) "Cal Rx" means the California State Pharmacy Assistance Program.
- (c) "Department" means the State Department of Health Services.
- (d) "Fund" means the California State Pharmacy Assistance Program Fund.
- (e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) “Lowest commercial price” means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

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

(h) “Manufacturers 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.

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

(j) “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.

(k) “Recipient” means a resident that has completed an application and has been determined eligible for Cal Rx.

(l) “Resident” means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

(m) “Third-party vendor” means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, 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.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer.

(B) The Medi-Cal program.

(C) The children's health insurance program.

(D) The disability medical assistance program.

(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third-party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi-Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. 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.

130606. (a) The department or third-party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall 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) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars (\$15).

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

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third-party vendor. A pharmacy, physician office, clinic, or third-party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

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

(f) During normal hours, the department or third-party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third-party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department or third-party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

130607. (a) The department or third-party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department or third-party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.

(c) The department or third-party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third-party vendor.

(d) The department or third-party vendor shall provide a claims processing system that complies with all of the following requirements:

- (1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8(g)).

(e) The department or third-party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third-party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third-party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third-party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.

(b) Each drug rebate 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 in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

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

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

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

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(e) The department or third-party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(f) Drug rebate contracts negotiated by the third-party vendor 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 Cal Rx recipients.

(g) The third-party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third-party vendor.

130619. (a) The department or third-party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

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

130620. (a) The department or third-party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. 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.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

- (1) The competitive bidding requirements of State Administrative Manual Management Memo 03-10.
- (2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.
- (3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

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

130624. The department may terminate Cal Rx if the department makes any one of the following determinations:

- (a) That there are insufficient discounts to participants to make Cal Rx viable.
- (b) That there are an insufficient number of applicants for Cal Rx.
- (c) That the department is unable to find a responsible third-party vendor to administer Cal Rx.

130625. 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.

SECTION 3: GENERAL PROVISIONS

(a) Conflicting Measures.

(1) This measure is intended to be comprehensive. It is the intent of the People that in the event that this measure and another initiative measure or measures relating to the same subject shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed to be in conflict with this measure. In the event that this measure shall receive a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and all provisions of the other measure or measures shall be null and void.

(2) If this measure is approved by voters but superseded by law by any other conflicting ballot measure approved by the voters at the same election, and the conflicting ballot measure is later held invalid, this measure shall be self-executing and given full force of law.

(b) Severability: The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(c) Amendment: The provisions of this Act may be amended by a statute that is passed by a vote of two-thirds of the membership of each house of the Legislature and signed by the Governor. All amendments to this Act shall be to further the Act and shall be consistent with its purposes.