SA2005RF0030

January 13, 2005

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INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

VIA MESSENGER

Office of the Attorney General
1300 "I" Street
Sacramento, CA 95814

Attention: Tricia Knight

Re: *The Safe and Affordable Prescription Drug Act*

Dear Ms. Knight:

Pursuant to Elections Code section 9002, we request that the Attorney General prepare a title and summary of a measure entitled the "The Safe and Affordable Prescription Drug Act." The text of the measure, a check for $200.00, the address at which we are registered to vote and the signed statement certifying that we will not willfully allow initiative signatures to be used for purposes other than qualification of the measure are enclosed.

Please direct all correspondence and inquiries regarding this measure to:

Roberta B. Johansen
James C. Harrison
Remcho, Johansen & Purcell
201 Dolores Avenue
San Leandro, CA 94577
Phone: (510) 346-6200
FAX: (510) 346-6201

Sincerely,

Anthony Wright

SA2005RF0030

The California Rx Plus State Pharmacy Assistance Program or Cal Rx.

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (Cal Rx)

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program or Cal Rx.

130501. The California Rx Plus State Pharmacy Assistance Program, or Cal Rx, is established to reduce prescription drug prices and to improve the quality of health care for residents of the State. The program is administered by the Department of Health Services to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for Californians.

S. 130502. The People of California find that affordability is critical in providing access to prescription drugs for California residents. This program is enacted by the People to enable the State to take steps 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. It is not the intention 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.

130503. CalRx shall be available to Californians facing high prescription drug costs to provide lower prescription drug prices. To the extent permitted by federal law, CalRx shall also be available to small businesses and other entities as defined that provide health coverage for Californians.

130504. For purposes of this division, the following definitions apply:
(a) "Department" means the State Department of Health Services.
(b) "Fund" means the California Rx Plus Program Fund.
(c) "Program" means the California Rx Plus State Pharmacy Assistance Program, or CalRx.
(d) (1) "Qualified Californian" means a resident of California whose total unreimbursed medical expenses equal 5 percent or more of family income.
(2) "Qualified Californian" also means an individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.
(3) "Qualified Californian" also means a resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines and who shall not

have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program.
(4) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.
(e) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

Chapter 2. Prescription Drug Discounts

130510. (a) The amount a CalRx participant pays for a drug through the program shall be equal to the participating provider'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 and the state's share of the discount.
(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130511. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through CalRX.
(b) Upon receipt of a determination from the federal government that the program is a state pharmaceutical assistance program as provided in this division, the department shall seek to contract for drug rebates that result in a net price equal to or lower than the Medicaid best price for drugs covered by the program. The department shall also seek to contract a net price equal to or lower than the price for prescription drugs provided to the Federal Government.
(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.
(d) No less than 95 percent of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.
(e) (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 drug manufacturer may participate in the program.

130512. (a) Subject to this section, the department may not enter into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer will not provide CalRx a rate equal to or lower than the medicaid best price.
(b) The department shall seek the approval of the Centers for Medicaid and Medicare Services by filing a state plan amendment or waiver allowing the department to require prior authorization for any drug if the manufacturer has not agreed to provide the medicaid best price or a lower price to CalRx. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the

program established pursuant to this division complies with any requirements of federal law.

(c) If prior authorization is required for a drug pursuant to this section, in no event shall a Medi-Cal beneficiary 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 of Health Services shall approve or deny requests for prior authorization necessitated by this section as required by state or federal law.

(d) This section shall not be operative until approved by the federal government.

130513. The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130514. (a) 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 (1) dispensed to a participant.

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

(5) Require the manufacturer to provide, upon the request of the department, documentation to validate the rebate.

(6) 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 participant's health information.

(b) The department 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.

(c) (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 state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after the effective date of the act that added this subdivision.

130515. (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) 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.

130516. (a) The department shall provide 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 outlined in federal law.

(b) The department shall pay a participating pharmacy the discount provided to 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 CalRx participants to report problems or complaints regarding Cal Rx.

Chapter 3. CalRx Application, Enrollment and Outreach

130520. (a) The department shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx. 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, 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) Specify that the application and annual reapplication fee due upon submission of the applicable form is ten dollars ($10).

(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. A pharmacy, physician office, clinic or non-profit community organization 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 participant.

(e) The department 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, non-profit community organization or through the third-party vendor to enroll applicants in Cal Rx.

(f) During normal hours, the department shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department shall mail the participant an identification card no later than four 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 Cal Rx.
(h) A CalRx participant who has been determined to be eligible shall be enrolled for 12 months or until the participant notifies the department of a desire to end enrollment.
(i) The department shall notify a participant 30 days prior to the termination of enrollment. A CalRx participant shall remain enrolled until the participant notifies the department that the participant no longer meets the enrollment criteria.

130521. (a) The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify 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 Cal Rx. The name of the organization sponsoring the material pursuant to subdivision (b) shall in no way appear on the material but shall be reported to the public and the Legislature as otherwise provided by law.

130522. (a) A drug dispensed pursuant to prescription, including a drug dispensed without charge to the consumer, must be accompanied by CalRx participation information in a manner approved by the department and as permitted by law.

(b) The information shall include advice to consult a health care provider or pharmacist about access to drugs at lower prices.

(c)The requirements of this section may be met by the distribution of a separate writing that is approved by or produced and distributed by the department.

Chapter 4. Pharmaceutical Manufacturer Patient Assistance Programs

130530. (a) The department shall execute agreements with drug manufacturer 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.
(b) The department shall develop a system to provide a 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.
(c) (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 program established pursuant to this division.

(d) 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.

(e) The Cal Rx 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. Employer-Paid Health Insurance Prescription Drug Discounts

S. 130540. The department may establish a prescription drug purchasing program to assist small businesses, small employer purchasing pools, Taft-Hartley trust funds and other entities that purchase health coverage for employees of those employers and their dependents.

S. 130541. No employer or other entity that purchases coverage for employees and dependents shall be eligible to participate unless the employer pays more than 50% of the cost of health coverage for their employees and their dependents.

S.130542. The department shall seek to obtain the department shall seek to contract for drug rebates that result in a net price comparable to the CalRx program.

S. 130543. (a) The amount a participant pays for a drug through the program shall be equal to the participating provider'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 and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

S.150544. The department shall work with employers, the California Chamber of Commerce, and other associations of employers as well as the California Labor Federation AFL-CIO and consumer organizations to develop and implement this chapter.

Chapter 6. Administration.

S. 130550. The Prescription Drug Advisory Board ("Board") is established to review access to and the pricing of prescription drugs for residents of the State, to advise the Secretary on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

(a) No board member shall have a financial interest in pharmaceutical companies or have worked for pharmaceutical companies or their agents or served within 5 years

before being appointed to the Board. No board member shall be employed for a pharmaceutical company for 5 years after serving on the board.
(b) The board shall consist of nine representatives of the public from the state at large. The Governor, the Senate President pro Tempore, and the Speaker of the Assembly shall each appoint three of these members. Legislative appointees shall serve staggered terms.
(c) (1) Of the three appointees by the Governor, one shall be a person over 65 enrolled in Medicare, one shall be from a school of pharmacy at the University of California, and one shall be an economist.
(2) Of the three appointees by the Speaker of the Assembly, one shall be a consumer or a representative of a recognized organization representing consumers eligible under this division, one shall be a retail pharmacist, and one shall be an employer or a representative a recognized organization representing employers eligible for Business Discount Drug Purchasing program.
(3) Of the three appointees by the Speaker Pro Tempore of the Senate, one shall be a labor trustee of a Taft-Hartley trust fund, one shall be a physician or nurse with expertise in drug benefits, and one shall be a member of the board of CalPERS.
(d) The term of office of board members shall be as follows:

(i) (1) A member appointed by the Governor shall serve for two years at the pleasure of the Governor, and may be reappointed for succeeding two-year periods, provided that the member may continue to serve beyond the two-year term until the Governor has acted and the appointee is authorized to sit and serve on the board.
(2) A member appointed by the Senate President pro Temp or the Speaker of the Assembly shall serve for four years, and may be reappointed for succeeding four-year periods, provided that the member may continue to serve beyond the four-year term until his or her appointing authority has acted and the appointee is authorized to sit and serve on the board. If the Senate President pro Temp or the Speaker of the Assembly has not acted within 60 days after the expiration of a member's term, the position shall become vacant until a person is appointed to a four-year term, calculated from the expiration date of the preceding term.
(ii) If a vacancy occurs prior to the expiration of the term for the vacated seat, the appointing authority shall appoint a member for the remainder of the unexpired term pursuant to this chapter.
(iii) On the effective date of the act, the Senate President pro Temp shall appoint three members to serve to two-year terms and the Speaker of the Assembly shall each appoint three members to serve four-year terms. All subsequent terms shall be for four years.

(d) Vacancies that occur shall be filled within 30 days after the occurrence of the vacancy, and shall be filled in the same manner in which the vacating member was selected or appointed.
(e) The Board members shall select one of their members to serve as chairperson and one of their members to serve as vice chairperson on an annual basis. The chairman shall have the authority to call meetings of the Prescription Drug Advisory Board.

130552. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130553. 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. Drug rebate contracts 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 Cal Rx participants.

130554. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.
(b) The fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to this division and for defraying the costs of administering this division. 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.

130555. (a) (1) The director may adopt regulations as are necessary for the initial implementation of this division. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the department is hereby exempted from the requirement that it describe specific facts showing the need for immediate action.

(b) As an alternative to the adoption of regulations pursuant to subdivision (a), and 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 article, in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action, provided that no such bulletin or other similar instructions shall remain in effect after July 31, 2007. It is the intent that regulations adopted pursuant to subdivision (b) shall be in place on or before July 31, 2007.

Chapter 7. Enforcement.

S. 130570. The Attorney General, upon the Attorney General's own initiative or upon petition of the department or of 50 or more residents of the State, shall investigate suspected violations of this division.

S. 130571. The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served

in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside.

S.130572. A court of competent jurisdiction may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

S.130574. If the Attorney General fails to act within 180 days to investigate suspected violations of this division, any person acting for the interests of itself, its members or the general public may seek to obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount of up to $100,000 or three times the amount of the damages, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

Division 112.5. Profiteering in prescription drugs

S. 130600 Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs. A manufacturer or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:
(a) Exacts or demands an unconscionable price;
(b) Exacts or demands prices or terms that lead to any unjust or unreasonable profit;
(c) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or
(d) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

S. 130601. Each violation of this division is a civil violation for which the Attorney General or any person acting for the interests of itself, its members or the general public may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount of $100,000 or three times the amount of the damages, whichever is greater, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

Section 2. This act shall be broadly construed and applied in order to fully promote its underlying purposes. If any provision of this initiative conflicts directly or indirectly with any other provisions of law, or any other statute previously enacted by the Legislature, it is the intent of the voters that such provisions shall be null and void to the extent that they are inconsistent with this initiative and are hereby repealed.

(b) No provision of this Act may be amended by the legislature except to further the purposes of that provision by a statute passed in each house by roll call vote entered in the journal, two-third of the membership concurring, or by a statute that becomes effective only when approved by the electorate. No amendment by the legislature shall be deemed to further the purposes of this Act unless it furthers the purpose of the specific provision of this Act that is being amended. In any judicial action with respect to any legislative amendment, the court shall exercise its independent judgment as to whether or not the amendment satisfies the requirements of this subsection.

(c) If any provision of this act or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect other provisions or applications of the act that can be given effect in the absence of the invalid provision or application. To this end, the provisions of this act are severable.