

February 23, 2005

Hon. Bill Lockyer
Attorney General
1300 I Street, 17th Floor
Sacramento, California 95814

Attention: Ms. Tricia Knight
Initiative Coordinator

Dear Attorney General Lockyer:

Pursuant to Elections Code Section 9005, we have reviewed the proposed initiative (File No. SA2005RF0030), known as The Safe and Affordable Prescription Drug Act.

Background

Pharmacy Assistance Programs. California and a number of other states have established pharmacy assistance programs to help consumers purchase prescription drugs at reduced prices. Current California law, for example, requires retail pharmacies to sell prescription drugs to persons enrolled in the federal Medicare Program at a discount. The program assists elderly and disabled health care consumers.

Medi-Cal and Healthy Families Programs. The Department of Health Services (DHS) administers the Medi-Cal Program, which provides a wide range of health care services for poor children and adults, including coverage for prescription drugs. Federal law mandates that drug makers sell their products to Medicaid programs, such as Medi-Cal, at a relatively low price compared to the prices paid by most private purchasers.

In addition, the state negotiates for supplemental rebates from drug makers in trade for giving the drugs made by those companies preferred status in the Medi-Cal Program. That preferred status means that doctors may prescribe that particular drug without receiving prior authorization from the state, which tends to increase the frequency of Medi-Cal prescriptions. The practical effect of the supplemental rebates is to lower further the net costs for drugs paid by the state for the Medi-Cal Program by an estimated \$280 million General Fund in 2004-05.

Healthy Families. The state Managed Risk Medical Insurance Board administers the Healthy Families Program, which provides health care coverage, including prescription

drug coverage, for children in low-income and moderate-income families who do not qualify for Medi-Cal.

Unfair Competition Law. California's unfair competition law prohibits any person from engaging in any unlawful or fraudulent business act. Proposition 64, enacted by the voters in November 2004, prohibits any person, other than the Attorney General or local public prosecutors, from bringing a lawsuit for unfair competition unless the person has suffered injury and lost money or property. The measure also imposes other restrictions on unfair competition cases.

Initiative Proposal

This initiative proposal would establish a new state program aimed at reducing the costs that certain low- and middle-income residents of the state would pay for prescription drugs purchased at pharmacies. Some major components of the proposal are outlined below.

Discount Card Program. Under the new pharmacy assistance program, which would be administered by DHS, eligible consumers would be able to apply for and subsequently obtain a card which, when presented at a pharmacy, would qualify them for discounts on their drug purchases. Participation in the program would be open to California residents in a family with an income up to 400 percent of the federal poverty level—up to about \$37,000 a year for an individual or \$75,000 for a family of four. The measure specifies that the discount cards would also be available to persons in families with higher incomes with unreimbursed medical expenses that exceed 5 percent of their family's income. Participants could be enrolled in Medicare but not in the Medi-Cal or Healthy Families programs.

Participants would enroll in the program by paying a \$10 annual fee to pharmacies. The DHS would review applications and mail the cards to eligible participants.

Two types of discounts would result in lower prices for eligible consumers. Pharmacies that voluntarily chose to participate in the program would agree to sell prescription drugs at an agreed-upon discount negotiated in advance with the state. In addition, the state would receive rebates from drug makers that would be passed through to the consumers.

Pricing Provisions. This initiative states that DHS may not enter into a new contract or extend an existing contract with a drug maker for the Medi-Cal Program (including the contracts by which the state obtains supplemental rebates in trade for giving those drugs preferred status) if the drug maker did not sell its drugs at a significantly discounted price to the new pharmacy assistance program.

In particular, the measure specifies that DHS shall seek to contract for rebates from drug makers that would result in a net price for the new pharmacy assistance program that is equal to, or less than, the price required under federal law for drugs purchased for federally supported programs, such as Medi-Cal. If a drug maker did not agree to such a contract, its drugs could be subject to prior authorization in the Medi-Cal Program. The initiative directs DHS to seek federal approval for these provisions and specifies that these pricing provisions would not take effect until such federal approval was forthcoming.

Coordination With Private Assistance Programs. The initiative directs DHS to implement agreements with pharmacy assistance programs operated by drug makers and other private groups so that the discount cards would automatically provide consumers with access to the best discount available to them for a particular drug purchase.

New State Advisory Board. The initiative would create a new nine-member Prescription Drug Advisory Board to review access to, and the pricing of, prescription drugs for state residents and to provide advice and regular reports on drug pricing issues to state officials.

Outreach Efforts. The measure directs DHS to conduct an outreach program to inform state residents of their opportunity to participate in the new pharmacy assistance program. The outreach activities are to be coordinated with the California Department of Aging (CDA), other state agencies, local agencies, and nonprofit organizations that serve residents who might be eligible for the program.

Business Assistance. This initiative directs DHS to establish a pharmacy assistance program to assist businesses, small employer purchasing pools, so-called Taft-Hartley health and welfare funds operated under collective bargaining agreements with labor organizations, and certain other entities that purchase health coverage for employees and their dependents. The DHS is directed under this measure to arrange for qualifying businesses and entities to get the same pharmacy discounts and rebates from drug makers to reduce their drug costs.

Anti-Profiteering Law. This initiative would make it a violation of state law for a drug maker to engage in illegal profiteering from the sale of prescription drugs. The definition of profiteering includes demanding "an unconscionable price" for a drug or demanding "prices or terms that lead to any unjust and unreasonable profit." Profiteering on drugs would be deemed a civil violation subject to prosecution by the Attorney General or by any person acting in the interests of itself, its members, or the

general public. Violations could be penalized in the amount of \$100,000 or triple the amount of damages, whichever was greater, plus legal costs.

Fiscal Effect

State Costs for Administration and Outreach Activities. The DHS, CDA, and the newly created Prescription Drug Advisory Board would, in combination, incur significant startup costs as well as ongoing costs to implement the new pharmacy assistance program authorized under this initiative.

This would include administrative costs associated with establishing the new program, including any necessary new information technology systems that would be needed for its operation, operation of an Internet Web site and a call center to receive applications; processing of applications for drug discount cards; negotiation and collection of rebates from drug manufacturers; processing of prescription drug claims and payments of rebates; and monthly reporting of data related to the program. Additional administrative costs would result from the companion programs established under this measure to assist small businesses in obtaining drug discounts and to coordinate the state's drug pharmacy assistance program with other private programs. To the extent that additional prior authorizations of drugs are required as a result of this measure, DHS would incur additional administrative costs to process these prior authorization requests. The state would also incur costs for the proposed outreach program.

In the aggregate, these administrative and outreach costs would probably amount to the millions to low tens of millions of dollars annually. The exact fiscal effect would depend primarily on the extent of the outreach and enforcement activities that were undertaken under this measure and the number of consumers who chose to participate in the pharmacy assistance program.

These state costs could be partly offset, under the terms of the measure, by (1) up to a 5 percent share of the rebates collected from drug makers, (2) any private donations received by the state for the support of outreach efforts, and (3) any civil penalties recovered by the state from enforcement of the anti-profiteering provisions. Our analysis indicates that the rebate funding alone is unlikely to offset these state costs. The amount of donations that the state would receive for outreach or that it would recover from anti-profiteering prosecutions is unknown. However, it appears likely at this time that a significant share of program costs would be borne by the state General Fund.

One-Time Costs for "Float." This initiative would require that drug manufacturers pay rebates to the state on at least a quarterly basis. However, the initiative also requires that the state reimburse pharmacies for rebates within two weeks after a claim has been filed by a pharmacy because of a consumer's drug purchase. In other words, the state

will, in many cases, be obligated to pay out rebates to pharmacies before it actually collects the rebate funds from a drug maker. Moreover, any disputes that will likely arise over the actual amounts owed for rebates could further slow payments of rebate funds from drug makers to the state.

This funding gap between the time the rebate money comes to the state and when the state has to pay pharmacies is referred to as float costs. The amount of the largely one-time cost of the float are unknown, but could amount to the low tens of millions of dollars, depending on the level of participation in the new state pharmacy assistance program. These costs could be partly offset, under the terms of the measure, by any rebate funds that were collected in advance through agreements for this purpose with drug manufacturers. The amount of funding that the state would receive through such advance payments is unknown. Any float costs that were incurred in excess of these advance rebate payments would be borne by the state General Fund.

Unknown Costs and Savings From Pricing Provisions. The provisions in this measure that link the prices of drugs sold for the new pharmacy assistance program to the Medi-Cal Program, and thus potentially affect the state's receipt of supplemental rebates, could have several fiscal effects that would depend primarily upon whether the federal government approves of this linkage and upon how drug makers and prescribing doctors responded to these provisions. The net fiscal effect on the Medi-Cal Program is unknown but could be significant.

Potential Savings on State and County Health Program Costs. The pharmacy assistance program established under this initiative could provide some fiscal benefits to the state and to counties by reducing costs for health programs.

Absent the discounts available under such a pharmacy assistance program, some poorer uninsured individuals might forego the purchase of their prescribed drugs. Such individuals might eventually become disabled or require hospitalization as a result of their untreated medical conditions and thus add to Medi-Cal Program costs. Other individuals might "spend down" their financial assets on expensive drug purchases absent such discounts and become eligible for Medi-Cal. The exact fiscal benefit to the Medi-Cal Program from a pharmacy assistance program is unknown, but could be significant if the program enrolled a large number of consumers.

Similarly, the availability of such a pharmacy assistance program could also reduce costs for county indigent care by decreasing out-of-pocket drug expenses for poor persons who require medications, thereby making them less likely to rely on county hospitals or clinics for assistance. The extent of these potential savings are unknown.

Fiscal Effects of Anti-Profiteering Provision. This measure would have an unknown fiscal impact on state support for local trial courts, depending primarily on whether the measure increases the overall level of court workload. The number of civil cases that would result from this measure is unknown. The measure could result in some additional costs for the Attorney General to prosecute profiteering cases. However, these costs are estimated by the Department of Justice to be less than \$1 million annually. However, these costs could be offset to the extent that the state collected civil penalties in cases where civil prosecutions were successful.

Summary

- One-time and ongoing state costs, potentially in the millions to low tens of millions of dollars annually, for administration and outreach activities for a new drug discount program. A significant share of these costs would probably be borne by the state General Fund.
- A largely one-time state cost, potentially in the low tens of millions of dollars, to cover the funding gap between the time when drug rebates are collected by the state and when the state pays funds to pharmacies for drug discounts provided to consumers. Any such costs not covered through advance rebate payments from drug makers would be borne by the state General Fund.
- Unknown costs and savings as a result of provisions linking drug prices for the new drug discount program to Medi-Cal prices, including the potential effect on the state's receipt of supplemental rebates; unknown savings on state and county health program costs due to the availability of drug discounts; and unknown costs and offsetting revenues from the anti-profiteering provisions.

Sincerely,

Elizabeth G. Hill
Legislative Analyst

Tom Campbell
Director of Finance