

March 2, 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. SA2005RF0052), known as the Affordable and Safe Prescription Drugs for All Californians 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, which is administered by the state Department of Health Services, assists elderly and disabled health care consumers.

Public Employees' Retirement System (PERS). California's PERS provides retirement and health benefits for more than 1.4 million state and local public employees, retirees, and their families. The health benefits offered by PERS includes coverage for prescription drugs. The PERS is administered by a 13-member Board of Administration (the PERS board).

Board of Pharmacy. The 13-member Board of Pharmacy regulates the individuals and firms that ship, store, and dispense prescription drugs—including pharmacies—to the state's patients and health care providers.

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 new state programs aimed at reducing the costs that individuals pay for prescription drugs purchased at pharmacies and regulating drug makers and drug marketers. Major components of the proposal are outlined below.

Discount Card Program. Under the new pharmacy assistance program, which would be administered by the PERS board, any individual would be able to apply for and subsequently obtain a card which, when presented at a pharmacy, would qualify him or her for discounts on drug purchases. The drug discount card is to provide cardholders access to the same pharmacies that are available to state workers, including mail-order pharmacies. Participants would enroll in the program by paying what initially would be an annual fee of up to \$10. The fee amount could subsequently be adjusted to reflect the rate of inflation, but could be reduced or eliminated to the extent that certain other revenues are available to support the drug discount program. Individuals would be able to enroll in the program at a Web site, at pharmacies, in doctor's offices, and other locations determined by the PERS board.

The PERS board is authorized under the measure to enter into contracts with entities that administer pharmacy benefits (such as so-called pharmacy benefit managers, also known as PBMs) to arrange for price discounts, rebates, or other forms of savings on drugs from drug makers, wholesalers, or pharmacies.

Pharmacies typically charge a dispensing fee to consumers who purchase prescription drugs in addition to a charge to reimburse them for the drug ingredients that are purchased. This measure limits the dispensing fee that pharmacies could charge to a person enrolled in the new pharmacy assistance program to \$3.50 per prescription. No limit is placed by the measure on the additional cost of the drug ingredients costs charged by a pharmacy.

Outreach Efforts. The measure directs the PERS board to conduct an outreach program to inform the public of its eligibility to participate in the new pharmacy assistance program through various means, including press releases and television or radio advertising. The measure generally limits the cost of these outreach activities to \$1 million annually, but specifies a process by which additional funding for outreach

activities could be provided from a new special fund created by this measure, which we discuss below.

Licensing of Drug Makers and Drug Marketers. This initiative would require that specified drug makers and drug marketers—those that market their products in the state to physicians who prescribe drugs—secure a license from the state Board of Pharmacy. This requirement would commence six months after the measure was enacted. Licensees would be subject to various state requirements, including that they disclose to prescribing physicians the health risk results of any clinical trials of their drugs. The measure also requires disclosure on a quarterly basis to the Board of Pharmacy of any gifts exceeding \$10 made by licensees to prescribing doctors.

The measure also imposes annual licensing charges of \$25,000 on each drug maker and \$750 on each person who is a drug marketer, and specifies that these revenues be deposited in a newly created state special fund, called the Prescription Drug Discount Fund. Also, the Board of Pharmacy could impose specified fines on drug makers or drug marketers who operated without a license, which would also be deposited into the special fund. With some limitations specified in the initiative, the PERS board would generally be able to spend monies from the fund without an annual budget act appropriation by the Legislature, including some funds that would be allocated to the Board of Pharmacy.

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 excessive price” for a drug or demanding “a price or terms that lead to any unjust and unreasonable profit.” The PERS board would be required to adopt regulations determining what would constitute an excessive price and unjust or 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. Each violation could be penalized in the amount of \$100,000 plus legal costs.

Fiscal Effect

Licensing and Fine Revenues. The exact number of drug makers and drug marketers that would obtain licenses and pay licensing charges into the Prescription Drug Discount Fund is not known, and would depend in part upon the regulations to implement the measure adopted by the Board of Pharmacy. The amount of fine revenues that would be collected by the Board of Pharmacy for violations of the licensing provisions is also unknown. Given the available data on the number of entities

subject to licensure in California, however, we estimate that these licensing and fine revenues in the aggregate are likely to exceed \$10 million annually. These funds would not begin to be collected until six months after the measure was enacted, once the licensing provisions went into effect.

Administration and Outreach Costs. The PERS board would incur significant one-time startup costs as well as ongoing costs to implement the new pharmacy assistance program authorized under this initiative. These costs, which could be incurred either directly or also through a contract with a PBM or similar pharmacy administrator, would include any necessary new information technology systems for operation of the new program; operation of a Web site or other locations to receive applications; processing of applications for drug discount cards; negotiation and collection of any rebates from drug manufacturers; processing of prescription drug claims and payments of any rebates; adoption of regulations related to the anti-profiteering law; and the conduct of outreach activities.

The Board of Pharmacy would incur one-time start-up costs and ongoing administrative costs for issuing licenses and collecting licensing charges; adopting regulations to implement the measure; and enforcing the licensing requirements.

The measure provides that up to \$2 million from the Prescription Drug Discount Fund would be used to offset Board of Pharmacy costs for its new licensing functions, and that the remaining funds would be available to PERS to defray its costs for the new pharmacy assistance program. In the aggregate, on an ongoing basis, the PERS board and Board of Pharmacy costs would probably amount to less than \$10 million annually so long as outreach was limited, as the initiative provides, to \$1 million per year. Thus, the ongoing new revenues generated under this measure would probably be sufficient to pay ongoing program costs. To the extent that excess funds were ever available, the PERS board could use the funds to reduce or eliminate enrollment fees for discount cards, and additional legislative appropriations could be requested to increase program outreach activities or increase the resources for Board of Pharmacy regulatory activities.

In any event, for an initial six-month period, none of these new revenues would be available to either the PERS board or the Board of Pharmacy for start up of the pharmacy assistance and licensing programs. Under the terms of the initiative, the PERS board could request the Legislature to provide a loan of as much as \$5 million from the General Fund for PERS' start-up costs that are to be repaid from the Prescription Drug Discount Fund. To the extent that any start-up or ongoing costs

exceeded the monies available from the Prescription Drug Discount Fund and from the General Fund loan, these costs would likely be borne by the General Fund.

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 is unknown and would depend primarily upon the level of drug discounts obtained by PERS and the level of participation in the program by Californians who are poor.

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

- Ongoing state costs, probably less than \$10 million annually, for administration and outreach activities by PERS and the Board of Pharmacy for new pharmacy assistance and licensing programs established by this initiative. These ongoing costs would probably be offset by licensing revenues and fines.

- 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