

**Joint Hearing on Propositions 78 and 79:
Prescription Drug Discount Initiatives**

Prop. 78: Discounts on Prescription Drugs. Initiative Statute

Prop. 79: Prescription Drug Discounts. State Negotiated Rebates. Initiative Statute

**Assembly Committee on Health
Senate Committee on Health**

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State Capitol, Room 4202
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Proposition 78 (which would establish CalRx) and Proposition 79 (which would establish CalRx Plus) are two competing initiatives intended to reduce the cost of prescription drugs for many Californians. Both qualified for the ballot through voter petitions. Proposition 78 is sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association of pharmaceutical manufacturers. Proposition 79 is sponsored by Health Access, a health care consumer advocacy organization.

The Problem: The High Cost of Prescription Drugs in California

Prices for prescription drugs have risen sharply in recent years, causing hardship for Californians. A 2004 study by Families USA found that the prices of the top 30 brand-name drugs dispensed to seniors had increased by nearly 22 percent in just three years. Between 2001 and 2004 the prices of these 30 drugs rose by 3.6 times the rate of inflation, placing increasing stress on the pocketbooks of many Californians dependent on these drugs for good health. A recent AARP study looking back at price increases in 2004 of commonly used brand name drugs found that prices continued to rise at a rate more than three times greater than inflation.

Meanwhile, total spending on prescription drugs grew at a real (inflation-adjusted) average annual rate of 14.5% from 1997 to 2002. That rapid growth raised prescription drug spending's share of total health expenditures to 11% in 2003, compared with 5.8% a decade earlier. In 2003, American consumers paid \$53.2 billion in out-of-pocket costs for prescription drugs, an increase of 26% over 2001.

Californians without drug coverage have been especially hard hit. Some must choose between food, rent, and needed medications. A 2003 Kaiser Family Foundation survey found that 37% of the uninsured, when they finally did see a doctor, did not fill a needed prescription because of cost. Even those with drug coverage, especially through existing Medicare HMOs and Medicare Supplement policies, find the cost of prescription drugs often far exceeds their coverage limits. Other insured Californians are hit with 3-tiered drug benefits, increased cost-sharing and decreased access to needed drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20% and experienced higher rates of emergency room visits and hospital stays. The Medicare Prescription Drug and Modernization Act of 2003 (MMA) will provide some relief to seniors when it takes effect on January 1, 2006. Even then many seniors will be responsible for significant out-of-pocket expenses. For instance, a senior with \$5100 in drug spending will be responsible for \$3600 of that amount in addition to an annual premium of at least \$420.

Responses to the High Cost of Prescription Drugs

Medi-Cal Drug Rebates. In response to increasing Medicaid (Medi-Cal in California) expenses for prescription drugs, Congress enacted a law in 1990 that requires drug companies to pay rebates to states on their Medicaid purchases. That law requires those rebates to result in state Medicaid programs paying no more than the best price offered by drug companies to commercial customers (also known as the "Medicaid best price"). In addition, California negotiates supplemental rebates for its Medi-Cal program. In general, if a drug company does not negotiate a supplemental rebate with the Department of Health Services (DHS), the company's drugs, while available under Medi-Cal, will require prior authorization by DHS before they can be dispensed.

State Pharmacy Assistance Programs. State Pharmacy Assistance Programs (SPAPs) are state-sponsored programs that generally provide selected populations with increased access to prescription drugs. According to the National Conference of State Legislatures, as of August 2005 at least 41 states had established or authorized some type of program, to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Currently, 34 state programs are in operation. Most programs utilize state funds to subsidize a portion of an individual's drug costs, but an increasing number use discounts or bulk purchasing approaches.

Though most SPAPs target low-income individuals who are not eligible for Medicaid, many states have expanded their programs to serve individuals with higher incomes as well. All state SPAPs provide coverage to those aged 65 and older, and half of the programs cover individuals with disabilities under age 65. Eligibility levels range from 100% of the federal poverty level (FPL) (\$9,570 for an individual) in Arkansas and Louisiana to 500% FPL in Massachusetts (\$47,850 for an individual). A few states have moved toward offering the benefits regardless of income, adjusting cost sharing

requirements accordingly. In addition, a few programs have adjusted eligibility limits for individuals who have prescription drug expenses that are considered “catastrophic” (ranging from 3% to 40% of income).

Federally designated SPAPs. A state SPAP can apply to be a "federally designated SPAP" if it has state funding, receives no federal funds, and has certain limits on eligibility. The exact income limits that must be set are not specified in federal rules. Federally designated SPAPs are exempt from the Medicaid Best Price rule, which allows drug manufacturers to offer those SPAPs lower prices than the Medicaid Best Price without being required to offer that same low price to all state Medicaid programs. Federally designated SPAPs are also permitted to cover out-of-pocket expenses under the MMA. California does not currently have a federally designated SPAP.

Pharmacy Assistance Programs In California. The Legislature has enacted two discount programs to help Medicare beneficiaries cope with high drug costs. SB 393 (Speier), Chapter 946, Statutes of 1999, requires retail pharmacies that participate in Medi-Cal to sell drugs to elderly and disabled persons on Medicare at a discount price that is just above the Medi-Cal price. SB 393 is not a federally designated SPAP. SB 696 (Speier), Chapter 693, Statutes of 2001, established the Golden Bear Pharmacy Assistance Program to provide deeper discounts to Medicare recipients through negotiated voluntary rebates with drug manufacturers. However, in 2004 DHS ended its efforts to implement the program. In a letter to Senator Speier, DHS stated that it had "not been able to successfully conclude negotiations with drug manufacturers for rebates that would generate sufficient revenue to cover the costs of the Golden Bear Pharmacy Assistance Program." Some drug manufacturers have their own patient assistance programs which offer prescription drugs at discounted prices or at no charge to qualifying patients. According to PhRMA, 244,000 Californians received industry sponsored assistance in 2002.

Drug Importation. The ever-increasing cost of prescription drugs has forced growing numbers of Americans, many of them elderly citizens living on fixed incomes, to buy essential medications from beyond U.S. borders. Each year, millions of Americans achieve some level of financial relief by purchasing prescription drugs from Canada, Mexico, and Europe. The recent development of Canadian Internet pharmacies has demonstrated the true demand for inexpensive medication. Researchers estimate that over six million Americans have obtained medicines from online Canadian pharmacies. The federal government estimates that consumer spending on drugs from Canada and other countries totaled \$1.1 billion in 2003.

Legislative Proposals in 2004. In 2004, the Legislature passed a number of bills designed to reduce the cost of prescription drugs for Californians. AB 1957 (Frommer) would have required DHS to establish a Web site to facilitate purchasing prescription drugs at reduced prices with links to Canadian pharmacies. SB 1149 (Ortiz) would have required the Board of Pharmacy to establish a Web site to facilitate purchasing prescription drugs at reduced prices and would also have included links to Canadian pharmacies. SB 1333 (Perata) would have permitted DHS to reimburse pharmacies for

drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that are purchased from a Canadian pharmacy. These bills were all vetoed by the Governor.

Legislative Proposals in 2005. In 2005, bills similar to Propositions 78 and 79 were introduced in the Senate and the Assembly. SB 19 (Ortiz), sponsored by the Schwarzenegger Administration and essentially identical substantively to Proposition 78, failed passage in the Senate Health Committee. AB 75 (Frommer and Chan) with some of the features of Proposition 79 was held by the author in the Senate Health Committee. AB 73 (Frommer and Chan), a bill establishing web links to specified international pharmacies, was vetoed by the Governor.

Other State Programs. Maine and Ohio have legislatively enacted drug discount programs with similarities to Propositions 79 and 78. In 2000, Maine enacted "Maine Rx" in an effort to leverage its market power as a major purchaser of pharmaceuticals through Maine's Medicaid program. Under Maine Rx, Maine would negotiate with drug manufacturers to provide a rebate which would apply every time an uninsured Maine citizen bought a prescription at a pharmacy in Maine. If a manufacturer failed to negotiate this rebate, the manufacturer's name would be released to the public and its drugs would require prior authorization under the state's Medicaid program. Prior to Maine Rx's implementation, PhRMA sued, claiming Maine Rx violated the commerce clause of the Constitution and was preempted by Medicaid federal law. Ultimately, the U.S. Supreme Court, in PhRMA v. Walsh, 538 U.S. 644, ruled in Maine's favor allowing Maine Rx to be implemented. Subsequent to the Court's ruling, Maine substantially revised Maine Rx. The revised program, called "Maine Rx Plus", limited eligibility to individuals with incomes of up to 350% FPL (about \$33,000 annually for an individual and \$68,000 for a family of four), or with high unreimbursed health care costs, and provided that prior authorization would only be imposed to the extent Maine determined it appropriate in order to encourage manufacturer participation in the program and so long as the additional prior authorization requirements remain consistent with the goals of Maine's Medicaid program and the requirements of federal law. Despite these changes, PhRMA continued to bring legal challenges in federal court. On January 27, 2005, PhRMA's case was dismissed by the federal district court. Maine's use of its Medicaid buying power to leverage lower drug prices for other Maine residents is similar to provisions in Proposition 79. According to a study by Prescription Policy Choices, a non-profit public policy organization partially funded by Consumers Union, Maine Rx Plus results in discounts, on average, of 26% for brand name drugs and 51% for generic drugs. Maine Rx Plus has been in operation since January 2004 and has 93,000 enrollees (7.2% of its residents).

Ohio is a state in which a program similar to Proposition 78 was implemented earlier this year. "Ohio's Best Rx" is a prescription drug discount card program for Ohio residents without prescription drug insurance who are either aged 60 and over or any age with incomes less than 250% FPL (about \$24,000 annually for an individual and \$48,000 for a family of four). According to its Director, Ohio's Best Rx has offered an average drug discount of 31% from retail prices in its first eight months, which represents about \$1.7 million in savings for the participants, or an average of \$15.50 discount per prescription.

Of the \$1.7 million in savings, \$147,000 was from manufacturer discounts. Of note, 68% of prescriptions filled under the program were for generic drugs. Of the brand name drugs dispensed, 41% had no manufacturer discount. Ohio's Best Rx program has been in operation since January 2005 and has 35,000 enrollees (0.3% of its residents).

Summary of Propositions 78 and 79

What is similar about Props 78 and 79?

Both propositions establish a new prescription drug discount program available to specified Californians and administered by DHS. Both propositions exclude enrollees in Medi-Cal and Healthy Families, two state health care programs available to low-income Californians. Both propositions reduce the price of drugs available to enrollees through negotiated discounts from participating pharmacies and negotiated rebates from participating drug makers.

Under both propositions, people could enroll in the program at any pharmacy, doctor's office, or clinic which chose to participate in the drug discount program. Applications could also be handled through an Internet Web site or through a telephone call center. DHS would review applications and mail the drug discount cards to eligible persons, usually within four days. Both propositions direct DHS to implement agreements with drug discount 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.

Both propositions include a severability clause which states that if any provision of the proposition is held by a court to be invalid, the remaining provisions of the proposition would remain in effect. Both propositions allow amendment by the Legislature by a two-thirds vote, but only to further the purposes of the proposition.

What is different about Props 78 and 79?

Who is eligible for coverage?

Prop 78 includes California residents in families with an income at or below 300% FPL (About \$29,000 annually for an individual and \$58,000 for a family of four.)

Prop 79 includes California residents in families with an income at or below 400% FPL (About \$38,000 annually for an individual and \$77,000 for a family of four.) Prop 79 also includes any California resident in families with medical expenses at or above 5% of their family income.

Who is excluded from coverage?

Prop 78 excludes anyone with outpatient prescription drug coverage through Medi-Cal, Healthy Families, a third-party payer (e.g. private insurance) or a health plan or drug discount program supported with state or federal funds. However, Medicare beneficiaries

who meet the Prop 78 income requirements are eligible for drugs not covered by Medicare. Prop 78 generally imposes a three-month waiting period after a person no longer has any of these private or public coverages before they can apply for the new drug discount program.

Prop 79 excludes anyone with outpatient prescription drug coverage through Medi-Cal or Healthy Families. However, Medicare beneficiaries who meet the Prop 79 income requirements are eligible for drugs not covered by Medicare.

What is the cost for an individual to enroll?

Prop 78 requires a \$15 application fee annually. Prop 79 requires a \$10 application fee annually.

How are rebates obtained from drug makers?

Prop 78 requires DHS to attempt to negotiate rebate agreements with drug makers. Drug makers are not required to sign such agreements and there are no consequences to drug makers who do not sign agreements. The amount of such rebates is not clearly specified.

Prop 79 requires DHS to negotiate rebate agreements with drug makers. Drug makers are not required to sign such agreements. However, if a drug maker does not sell its drugs to the new program at a reduced price that is comparable to or lower than the Medicaid Best Price, DHS may not contract with the drug maker for the Medi-Cal program. Those drugs would still be available to Medi-Cal beneficiaries but they could be subject to an existing requirement that doctors obtain prior approval from the state before such drugs are prescribed for a Medi-Cal patient. In addition, Prop 79 requires that the names of drug makers that have not entered into such contracts be released to the public.

Prop 79 specifies that the provisions of the proposition linking it to Medi-Cal would be implemented consistent with federal law, that these provisions would not apply to a drug if there were not another equivalent drug available and that a Medi-Cal beneficiary who has already been prescribed a drug would be allowed to continue to receive it without prior approval.

What are some of the other differences between these two initiatives?

Assistance to Business and Labor Organizations

Proposition 79 permits, but does not require, DHS to establish a drug discount program to assist certain businesses and labor organizations that purchase health coverage for employees and their dependents.

State Advisory Board

Proposition 79 creates a new nine-member Prescription Drug Advisory Board to review the access that state residents have to prescription drugs as well as the pricing of those drugs, and to provide advice and regular reports on drug pricing issues to state officials.

Profiteering from Drug Sales

Proposition 79 makes it a civil violation for drug makers and certain other specified parties to engage in 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 subject to prosecution by the Attorney General or through a lawsuit filed by any person acting in the interests of itself, its members, or the general public. Violators could be penalized in the amount of \$100,000 or triple the amount of damages, whichever was greater, plus legal costs.

Conflict Clause

Proposition 78 includes a clause that if both Propositions 78 and 79 receive a majority of the votes, and Proposition 78 receives more votes than Proposition 79, then Proposition 78 will go into effect and none of the provisions of Proposition 79 will go into effect.

Termination Clause

Proposition 78 includes a clause that permits DHS to terminate the drug discount program created by the proposition if discounts are insufficient, there are not enough applicants or DHS is unable to find a responsible vendor to administer the program.

Summary of Fiscal Effects as Reported by the Legislative Analyst's Office (LAO)

Fiscal Effects that Apply to Both Propositions 78 and 79

State Costs for Administration and Outreach. Under both propositions, state agencies would incur significant startup costs, as well as ongoing costs, for administrative and outreach activities to implement the new drug discount programs enacted by the propositions. In the aggregate these administrative and outreach costs would probably range in the low tens of millions of dollars annually. The exact fiscal effect would depend primarily on the extent of outreach efforts and the number of consumers who chose to participate in the drug discount program. These state costs could be offset by a variety of sources of revenue, including a portion of the enrollment fees collected for the program. However, the amount of these potential sources of revenue is unknown and it appears likely that a significant share of the cost of this program would be borne by the General Fund.

Costs for "Float". Both mechanics of both propositions generally require the state to reimburse pharmacies before the state has received rebates from drug makers. This recurring gap in funding between when the rebate money is collected by the state and when the state must pay pharmacies is commonly referred to as "float." The cost of the float is unknown but could amount to the low tens of millions of dollars, depending on the level of participation in the new drug discount program. Float costs would occur mainly in the early years of implementing this new program. Both propositions permit the state to enter into agreements with drug makers to collect rebates in advance. Float costs that exceed advance rebate payments would be borne by the state General Fund.

Potential Savings for State and County Health Programs. Both propositions could reduce costs to the state and counties for health programs. By making drugs more affordable, individuals are more likely to take their medications and less likely to become ill and require hospitalization, which often triggers eligibility for Medi-Cal, the state's health care program for low income individuals. More affordable drugs also reduce the chance that individuals will "spend down" their financial assets on expensive drug purchases and become eligible for Medi-Cal. Reductions of costs from these effects could also be seen by other state health programs and county indigent care programs. The extent of these potential savings is unknown, but could be significant if the new drug program enrolled a large number of consumers.

Other Fiscal Effects. Both propositions would affect both the prices and quantities of prescription drugs sold in California. In turn, this could affect taxable profits of drug makers and businesses that provide health care for their employees, as well as consumers' disposable income. These changes could affect state revenues. Changes in the prices and quantities of drugs sold could affect state expenditures as well. The net impact of these factors on state revenues and expenditures is unknown.

Fiscal Effects that Apply Only to Proposition 79

State Costs or Savings from Linking Drug Discount Programs to Medi-Cal.

Proposition 79 states that DHS may not enter into a Medi-Cal contract with a drug maker that did not agree to provide discounts on the price of their drugs for the new drug discount program. This provision could result in additional costs and savings to the Medi-Cal Program depending upon future actions by the federal government, drug makers, or doctors. For example, this provision could result in the state receiving fewer drug rebates from drug makers for the Medi-Cal Program, thus resulting in costs. On the other hand, this provision could result in savings in cases in which the removal of a drug from preferred status resulted in fewer prescriptions of the drug and its replacement by a less costly medication. The net fiscal effect of this provision on the Medi-Cal Program is unknown but could be significant.

State Costs and Revenues from Provision on Profiteering From Drug Sales.

Proposition 79 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 might result from this measure is unknown. Also, the measure could result in some additional costs for the Attorney General to prosecute profiteering cases. 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 revenues from civil penalties in cases where civil prosecutions were successful.

Arguments from Supporters and Opponents of Proposition 78

Yes on Prop 78

According to proponents, including pharmaceutical manufacturers, the California Arthritis Foundation Council, California Association for Nurse Practitioners, California Senior Advocates League and local NAACP chapters, Prop 78 (“Cal Rx”) is a workable program that can immediately deliver prescription drug discounts to an estimated 8 million eligible seniors and low-income, uninsured Californians. Eligibility extends to those with annual incomes of less than \$58,000 (for a family of four) and seniors regardless of income. According to the Health and Human Services Agency based on SB 19, discounts would average at least 40% off retail prices, with the potential for deeper discounts if the program becomes a federally designated SPAP. Prop 78 is identical to SB 19 (Ortiz/Poochigian), which was supported by more than three dozen health, senior and business organizations. Prop 78 is based on a successful program launched earlier this year in Ohio, in which all major drug manufacturers participate and consumers save an average of 30% per prescription.

No on Prop 78

According to opponents, such as AARP, League of Women Voters, Consumers Union, publisher of *Consumer Reports*, and Health Access, Proposition 78 would create a voluntary drug discount program controlled entirely by the drug industry. Proposition 78 can be ended at any time if drug companies decide not to participate. The companies have no incentive to participate and they suffer no consequences if they do not participate. Proposition 78 allows the drug companies to determine the amount of the discount, as well as which drugs will be covered. California tried a voluntary approach before, the Golden Bear program, which failed because drug companies refused to participate. Proposition 78 offers inadequate eligibility, covering only about half as many Californians as Proposition 79. It does not cover the under-insured. Discounts under Proposition 78 will not be as great as under Proposition 79 because it uses a higher benchmark price than Proposition 79.

Arguments from Supporters and Opponents of Proposition 79

Yes on Prop 79

According to the supporters, including AARP, League of Women Voters, Consumers Union, publisher of *Consumer Reports*, and Health Access, Proposition 79 will create an enforceable prescription drug discount program for millions of California residents. Proposition 79 will allow uninsured and under-insured Californians to reduce their costs by 50% when purchasing prescription drugs from their pharmacies. Eligible persons (persons under 400% FPL or who spend five percent or more of income on health care expenses or Medicare recipients with drug expenses not covered by Medicare) would qualify for the discount card. The program builds on the state’s success in securing significant discounts for drugs purchased for those on Medi-Cal. Under Proposition 79, the state would use Medi-Cal’s bargaining power to negotiate drug discounts for 8-10 million additional Californians. By making prescription drugs more affordable,

Proposition 79 will create savings for state and county health programs by keeping people out of hospital emergency rooms.

No on Prop 79

According to opponents, including pharmaceutical manufacturers, the Down Syndrome Information Alliance, Epilepsy Foundation of San Diego and Civil Justice Association of California, Prop 79 is unlikely to deliver drug discounts because the federal government is unlikely to approve it. The federal government, which pays for 52 percent of Medi-Cal drug costs, has never approved a state drug discount program that could restrict access to drugs by Medicaid patients as leverage to force manufacturers to provide discounts to non-Medicaid patients with incomes over 200% FPL. Prop 79's income threshold is 400% FPL. If Prop 79 did take effect, new state programs would be needed to review requests for drugs made by manufacturers that do not participate in the discount program, as well as to set up a state purchasing pool to provide drugs to an unknown number of small business employees and union members. Opponents also believe that Prop 79's prohibition on future Medi-Cal contracts with non-participating manufacturers threatens \$481 million in supplemental rebates paid by drug manufacturers to the state. Opponents argue that the new private right of action established by Prop 79 will negatively impact investment in medical research and development of new cures, encourage frivolous lawsuits and thwart the will of voters who passed Proposition 64 last November.