

The California Debate

Competing Drug Discount Programs
for Millions of Residents



Public Health Institute
Oakland, California

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Report prepared by Kathryn Saenz Duke, JD, MPH

Director of the Medicine for People in Need (Medpin) program, Public Health Institute

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MEDICINE FOR PEOPLE IN NEED (MEDPIN)

Medpin is a program within the Public Health Institute (www.phi.org). Medpin (www.medpin.org) works with safety net providers in California and across the U.S. to improve access to medicine and pharmaceutical care for people in need. (The National Institute of Medicine describes *safety net providers* as those that maintain an “open door” by offering access to services for patients regardless of their ability to pay, and that have a substantial share of uninsured, Medicaid, and other vulnerable patients.)¹

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1. Institute of Medicine, *America's Health Care Safety Net: Intact but Endangered*. Washington, DC: National Academy Press, 2000.

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EXECUTIVE SUMMARY

Major efforts are under way to create a state government program to help five to ten million California residents benefit from significant drug discounts. California's two prescription drug voter initiatives—Proposition 78 (Cal Rx) and Proposition 79 (Cal Rx Plus)—both offer proposals to use California's state government staff, plus an unspecified amount of state funding, to create a drug discount program for limited-income, uninsured residents of all ages. Both measures would create a system of purchase discounts based on drug manufacturing company rebates, in addition to unspecified pharmacy discounts.

The language of the Cal Rx and Cal Rx Plus voter initiatives was foreshadowed by several key legislative measures and vetoes from 2004, and is directly related to bills introduced and debated in early 2005. Cal Rx and Cal Rx Plus have many similarities. Both measures:

- ▶ create a major new state program based on point of purchase discounts;
- ▶ have been determined by the nonpartisan Legislative Analyst's Office to have potentially large but unknown fiscal and program effects on California;
- ▶ focus on people without prescription drug coverage;
- ▶ cover California residents with income less than 300% of the poverty level;
- ▶ face implementation delays resulting from possible legal challenges, intention to seek federal approval as a program exempt from Medicaid Best Price, or other administrative matters;
- ▶ contain complex language that sets levels of drug discount based on specified rebate calculation methods;
- ▶ would probably result in similar overall discount levels, assuming that drug companies voluntarily offer those discounts initially and on an ongoing basis; and
- ▶ focus on discounts, not on overall medication costs or health effectiveness.

Despite these important similarities, the two ballot initiatives also have key differences.

- ▶ Cal Rx, sponsored by the pharmaceutical companies, is based on drug companies' voluntary offer of specified discounts. Cal Rx Plus, sponsored by a coalition of nonprofits, creates for a non-participating drug manufacturer a possible penalty linked with diminished access for that company to the Medi-Cal market.
- ▶ Cal Rx Plus includes an expanded eligibility group of people with incomes between 300% and 400% federal poverty level, and people with more than 5% unreimbursed medical expenses.
- ▶ Cal Rx is part of a national information and outreach effort launched a year ago by PhRMA's Partnership for Prescription Assistance.
- ▶ Only Cal Rx Plus requires drug companies to report on their patient assistance program activities, and creates anti-profiteering penalties and enforcement provisions.

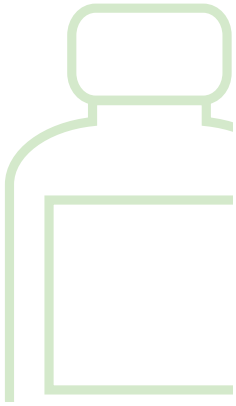
INTRODUCTION

People across the United States are concerned about rising drug prices and their impact on people without insurance coverage or sufficient personal resources to pay for expensive medications. California law has empowered voters to approve or reject two competing initiatives appearing on the November 2005 ballot. Proponents of both measures acknowledge the need to address medication affordability issues for uninsured residents, and proponents of both claim their measure is the better solution to these concerns. Whatever collective decision is expressed by the November election results, the outcome will have major impact on health policy and the pharmaceutical industry actions in this state and across the country.

The two ballot measures' supporters and opponents are expected to spend tens of millions of dollars trying to convince voters of the merits or flaws of complicated new laws and program design elements. Significantly more money has been raised and spent by the pharmaceutical industry supporters of Cal Rx (Proposition 78), who are to date the only group to launch a series of television advertisements.

To effectively assess what approval or rejection of each measure is likely to achieve, here are four key questions to consider:

1. Both ballot measures require the State of California to create, supervise, and help pay for a significant new drug discount program. Which measure represents the better balance between public sector involvement and reliance on drug companies to voluntarily address drug pricing issues?
2. If California is to create and fund a new drug discount program, what are the potential program advantages and risks to the target group (lower-income people with little or no prescription drug coverage) of choosing Cal Rx Plus's approach of linking drug manufacturers' access to the Medi-Cal market with their agreement to significantly discount medications for an additional group of purchasers? What are the advantages and risks of such an approach for other Californians, who are currently covered either by public programs such as Medi-Cal or by private health insurance?
3. If voters approve one or both measures, how likely is it that California would soon see discounts that create real price reductions for the target group? How likely are those prices to continue into the future?
4. If neither ballot measure is approved or fully implemented, how likely is it that California would soon see discounts that create real price reductions for the target group? How likely are those prices to continue into the future?



Recent History of California Drug Discount Program Efforts

PROGRAMS ENACTED

California's only state-operated drug discount program relies on pharmacies, not drug manufacturing companies or state government, to help residents with their prescription drug costs. A more recently enacted discount program was never implemented.

SB 393 program for Medicare recipients (1999)

For five years, California has had a limited drug discount program, sometimes called the "SB 393 program" after the bill that created it.¹ This program allows Medicare beneficiaries to show their Medicare card at a pharmacy and request a drug purchase price not exceeding "the Medi-Cal reimbursement rate" plus a small transaction fee.² The law requires pharmacies to give this price, when requested by a purchaser, as a condition of the pharmacy's participation in the state's Medicaid program. The source of the SB 393 discount is participating pharmacies, without contributions from the state or from drug manufacturing companies.³ As of April of 2002, the SB 393 program was reported to have enabled more than one million Californians to fill approximately 800,000 prescriptions per month and save an average of 20-25% off of the retail price.⁴

1. S.B. 393 (Speier), 1999 Reg. Sess., (Cal. 1999), encoded as CAL. BUS. & PROF. CODE § 4425 et seq. (2005).
2. The fee is 15 cents per prescription filled.
3. The bill also required the state to study "the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services" CAL. BUS. & PROF. CODE § 4426 (2005).
4. Adam Van de Water, DISCOUNT PRESCRIPTION DRUGS FOR LOW-INCOME SENIORS, LEGISLATIVE ANALYST REPORT TO THE SAN FRANCISCO BOARD OF SUPERVISORS, April 18, 2002, available at http://www.sfgov.org/site/bdsupvrs_page.asp?id=5064 (last visited Sept. 13, 2005). See also J.H. Lewis et al., *Pharmacy compliance with California's prescription drug discount program for Medicare beneficiaries*, Vol. 346(11), NEW ENGLAND J. MED., 830 - 835 (2002).

Golden Bear State Pharmacy Assistance Program (2001)

SB 393's author, Senator Jackie Speier, decided to follow that legislation with an effort to add pharmaceutical manufacturer discounts to SB 393's pharmacy-based discounts. In 2001, the Golden Bear Pharmacy Assistance Program was created.⁵ Unlike SB 393, the discounts sought by this legislation were not directly tied to Medi-Cal participation but instead used the Medi-Cal program to negotiate voluntary rebates. The state appropriated \$1 million of its general funds to cover start-up costs.

Golden Bear was never implemented. More than two years after the program was created, the California Department of Health Services (DHS) sent a letter to Senator Speier stating that it had ended its efforts to implement Golden Bear.

DHS gave the following reasons to account in part for the failure of Golden Bear to begin operation:⁶

- ▶ Claims processing organizations, which were needed to process the pharmacy claims for payment from the State, would not participate due to “an inability to make a sufficient profit on activities limited to claims processing.”
- ▶ Only one generic manufacturer agreed to participate in the program, which was problematic because over 54 percent of drugs purchased by Medicare beneficiaries are generic drugs.
- ▶ Only 13 brand manufacturers agreed to participate, out of 500 companies solicited.
 - ▶ Some companies refused because the program did not qualify as a state pharmaceutical assistance program (SPAP) that was exempt from Medicaid Best Price rules.⁷ (CMS did not consider Golden Bear an SPAP because it did not contain a means test.)
 - ▶ Other companies refused because they were unwilling to offer Medicaid Best Price to “a clientele wider than Medicare beneficiaries (i.e., the entire Medi-Cal population).”
- ▶ Proposed cuts in the Medi-Cal reimbursement rate, which would serve as the base upon which pharmacy payments were calculated, could adversely affect a pharmacy participating in the program.⁸

5. S.B. 696 (Speier), 2001 Reg. Sess., (Cal. 2001), encoded as CAL. HEALTH & SAFETY CODE § 130400 et seq. (2005).

6. Letter from California Department of Health Services to Senator Jackie Speier on March 23, 2004.

7. For brand-name drugs, the required Medicaid rebate gives Medicaid a net price of the Average Manufacturers' Price (AMP) minus 15.1% or the manufacturer's “best price” for that drug, whichever is lower. For generic drugs, the required Medicaid rebate gives Medicaid a net price equal to AMP minus 11%; there is no “best price” provision for generic drugs. This Medpin report uses the phrase “Medicaid Best Price” to refer to this federally created pricing formula for all prescription drugs paid for by state Medicaid programs and 340B purchasers, which combines a “flat” discount rate of 15.1% or 11% with a variable one based on actual brand-name drug purchasing activity by non-governmental entities. *Public Law* 101-508, § 603, 104 Stat. 1388 (1990), 42 U.S.C.A. § 13964r-8(c)(1) (2005).

8. On September 1, 2004, the Medi-Cal reimbursement rate for pharmacies changed from AWP-10%+\$4.05 dispensing fee, to AWP-17%+\$7.25.

The fate of this recent attempt to create a state drug discount program suggests feasibility concerns and implementation lessons for Cal Rx and Cal Rx Plus, both of which resemble Golden Bear in that they are based on a discount card and rely on a third party vendor as the probable administrator. However, Golden Bear's failure seems especially sobering for the prospect of Cal Rx's implementation, because that ballot measure further resembles Golden Bear in its expectation that drug manufacturer discounts will be negotiated on a voluntary basis. By contrast, Cal Rx Plus gives DHS a "Medi-Cal hammer" incentive for drug companies that is smaller but somewhat similar to the incentive for pharmacies participating in California's SB 393 program.⁹

MOST RECENT LEGISLATION

Importation from Canada and other countries

In 2004 the California Legislature approved and sent to the Governor four bills pertaining to importation of prescription drugs from Canada.¹⁰ These bills would have increased information on and access to medications available through Canada or other countries, or expand access to an existing federal discount program that helps safety net providers. On the last day that amendments could be filed, the Governor notified the bills' authors that he would veto their bills unless language creating a proposed "Cal Rx" program was inserted as an amendment. The legislators chose not to include the Cal Rx language, prompting the Governor to issue identical veto messages for all four bills.¹¹

When Governor Schwarzenegger vetoed these bills, he noted that access to affordable prescription drugs is a top priority for his administration but that he did not believe the bills would bring sufficient relief to Californians who required assistance in accessing necessary medicines. He warned against oversimplifying "the complex safety, trade, supply, and pricing issues" in the prescription drug marketplace, and indicated that he was working with the pharmaceutical industry to develop a statewide drug discount program to address, in a different manner, many of the same problems addressed by the legislative measures. He called upon drug companies to support a Cal Rx program by "com[ing] forward and negotiat[ing] in good faith,"

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9. Pharmacies must participate in the SB 393 program as a condition of participating in Medi-Cal. CAL. BUS. & PROF. CODE § 4425(a) (2005).
 10. AB 1957 (Frommer) sought to establish a website to facilitate the safe purchase by California residents of prescription drugs at reduced prices. The website would include prescriptions drug price comparisons, including prices charged by Canadian pharmacies that provide mail order service to the United States that meet certification requirements. Original text *available at* http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_1951-2000/ab_1957_bill_20040827_enrolled.html (last visited Sept. 13, 2005). SB 1333 (Perata) would have authorized DHS reimbursement for pharmacies that dispensed drugs purchased from Canadian pharmacies to Medi-Cal and AIDS Drug Assistance Program beneficiaries. Original text *available at* http://www.leginfo.ca.gov/pub/03-04/bill/sen/sb_1301-1350/sb_1333_bill_20040827_enrolled.html (last visited Sept. 13, 2005). SB 1144 (Burton) would have allowed the General Services Department to purchase drugs from authorized Canadian pharmacies or sources for use within state hospitals, prisons, and other agencies. Original text *available at* http://www.leginfo.ca.gov/pub/03-04/bill/sen/sb_1101-1150/sb_1144_bill_20040827_enrolled.html (last visited Sept. 13, 2005). SB 1149 (Ortiz) would have required the Board of Pharmacy to "collect and publish information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have violated safe shipment, handling, and processing standards." Original text *available at* http://www.leginfo.ca.gov/pub/03-04/bill/sen/sb_1101-1150/sb_1149_bill_20040827_enrolled.html (last visited Sept. 13, 2005).
 11. California Healthline, *Lawmakers Say Schwarzenegger Prescription Drug Discount Plan Intended to Counter Reimportation Legislation*, August 23, 2004, *available at* <http://www.californiahealthline.org/index.cfm?Action=dspItem&itemID=105148&ClassCD=CL112> (last visited Sept. 13, 2005).

while warning them publicly that failure to do so would result in his use of “all the options at my disposal to secure lower-cost prescription drugs for low-income, uninsured Californians.”¹²

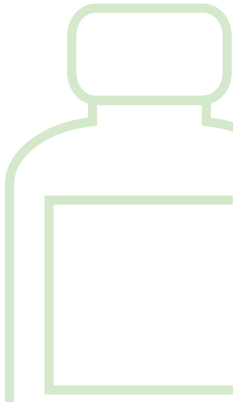
Expansion of an existing program

SB 1563 (Escutia) was also approved by the California Legislature during the 2004 session and vetoed by the Governor. This bill would have required drug manufacturers to offer specified community clinics prices not to exceed 105% of the Medicaid Best Price.¹³ It would also have required manufacturers to disclose a list of prices so those clinics could confirm they were receiving the appropriate price. In his veto message, the Governor stated that the bill would increase drug costs for Medi-Cal and other government purchasers because manufacturers would reduce their rebates as a result of the disclosure of Best Price discounts.¹⁴

12. Veto Messages from Governor Arnold Schwarzenegger for AB 1957, SB 1333, SB 1144, and SB 1149 (September 29, 2004), *available at* http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_1951-2000/ab_1957_vt_20040929.html (last visited Sept. 13, 2005).

13. This requirement would not apply if there is no suitable therapeutic alternative. For a summary of this and the previously mentioned bills, *see* Medpin: Medicine for People in Need, *Selected California Bills*, October 2004 (contact Medpin for article reprint).

14. Veto message from Governor Arnold Schwarzenegger for SB 1563 (September 29, 2004), *available at* http://www.leginfo.ca.gov/pub/03-04/bill/sen/sb_1551-1600/sb_1563_vt_20040929.html (last visited Sept. 13, 2005).



Drug Manufacturers' Voluntary Activities: National and State

NATIONAL EFFORTS BY INDIVIDUAL COMPANIES

Drug manufacturing companies have increased their activities aimed at addressing concerns about lower-income people's ability to afford their medications. Within the past 12-15 months, single companies or groups of companies have launched national drug discount card programs offering voluntary discounts to people with incomes up to limits approximating 300% of the federal poverty level.¹

In addition, individual companies have for a number of years offered drug-specific or company-specific patient assistance programs (PAPs) that fill prescriptions at no charge for individual patients who meet that particular program's eligibility requirements. As more individual patients and safety net providers have discovered the availability of PAPs, usage has rapidly increased. The Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical companies' national trade association, reports that its member companies filled more than 14 million patient assistance program-related prescriptions for 5.4 million patients in 2002, an almost seven-fold increase from the number of patient assistance program prescriptions in 1997.² Last year, PhRMA reported that PAPs had provided a national total of 22 million free or deeply discounted prescriptions, out of the 3.5 billion prescriptions dispensed last year in the United States.³

1. Together Rx Access offers discounts for people with incomes up to 313% federal poverty level for an individual, <http://togetherrxaccess.com> (last visited Sept. 13, 2005); Pfizer U Share does not have an income limit but offers deeper discounts to people with incomes of less than 200% of federal poverty level, <http://www.ussharex.com/> (last visited Sept. 13, 2005); Merck does not have income limits but offers deeper discounts for people with lower incomes, <http://www.merckhelps.com/uninsured/> (last visited Sept. 13, 2005); Pfizer Pfriends does not have an income limit but offers deeper discounts for families earning less than \$45,000, which is approximately 200% of federal poverty level for a family of five, http://www.pfizer.com/pfizer/subsites/corporate_citizenship/Pfizer_CorpCit.pdf (last visited Sept. 13, 2005).
2. K. Duke, K. Raube, & H. Lipton, *Patient assistance programs: Assessment of and use by safety-net clinics*, Vol. 62, AMERICAN JOURNAL OF HEALTH-SYSTEM PHARMACY, 726-731 (April 1, 2005), available at <http://www.ajhp.org/cgi/reprint/62/7/726.pdf> (last visited Sept. 13, 2005).
3. Clea Benson, *Ads tout medical price breaks*, SACRAMENTO BEE, August 1, 2005, at A3, available at <http://www.sacbee.com/content/politics/story/13334918p-14176970c.html> (registration required) (last visited Sept. 13, 2005).

PhRMA's national template offered to individual states

In addition to efforts by single companies or small groups of companies, PhRMA has been operating several state websites as well as a national website for more than a year.⁴ In September 2004, PhRMA created a new Partnership for Prescription Assistance website plus a toll-free call center to help individual patients and prescribers across the United States learn about various private and public programs that can reduce patients' drug costs.⁵ Ken Johnson, a PhRMA vice president, explained PhRMA's financial and organizational commitment to the Partnership for Prescription Assistance and Rx Help for Californians: "If we're going to preserve a free-market health-care system that respects innovation, if we're going to avert health-care rationing and government-run health-care systems, we have to make sure people who fall through the cracks get a helping hand when they need it."⁶

PhRMA's national efforts have been used as the foundation for various state programs in which PhRMA offers its package of services to that state's elected officials, at no charge to the state. This PhRMA program helps a selected state's residents use a state-customized version of the Partnership for Prescription Assistance website, plus the national call center, to learn about the existence of drug company PAPs as well as state and federal health coverage programs that could help lower-income people reduce their medication costs.⁷

CAL RX AS PhRMA'S CALIFORNIA EFFORT

Governor Schwarzenegger's 2005 State of the State address, and later a special newspaper feature, described the Governor's Cal Rx proposal as two different actions taken voluntarily by some or all drug manufacturing companies: (1) voluntary rebates linked to 40% purchase price discounts, and (2) a commitment to "create and publicize a clearinghouse and toll-free number that will bring free and heavily discounted drugs to hundreds of thousands of Californians" by spring 2005.⁸ In mid-March 2005, PhRMA launched *Rx Help for Californians: A Partnership for Prescription Assistance* as the California version of the national Partnership for Prescription Assistance. PhRMA describes this program as "designed to help low-income, uninsured California residents get free or discounted brand-name medicines."⁹

4. See <https://www.pparx.org/ViewCompanies.php> (last visited Sept. 13, 2005) for a complete list.

5. www.pparx.org (last visited Sept. 13, 2005).

6. Clea Benson, *Ads tout medical price breaks*, SACRAMENTO BEE, August 1, 2005, at A3, available at <http://www.sacbee.com/content/politics/story/13334918p-14176970c.html> (registration required) (last visited Sept. 13, 2005).

7. See, e.g., AlohaMeds (<http://alohameds.org> (last visited Sept. 13, 2005)), Rx4DC.org (<http://www.rx4dc.org> (last visited Sept. 13, 2005)), RxIdaho.org (<http://www.rxidaho.org> (last visited Sept. 13, 2005)), Rx for Indiana (<http://rxforindiana.org> (last visited Sept. 13, 2005)), Rx Cares For ME (<http://www.rxcareforme.org> (last visited Sept. 13, 2005)), Rx4NJ.org (<http://rx4nj.org> (last visited Sept. 13, 2005)), Rx for Ohio (<http://www.rxforiohio.org> (last visited Sept. 13, 2005)), and RxforRI.org (<http://www.rxforri.org> (last visited Sept. 13, 2005)). See also *Maryland Connects Patients with PAPs*, Vol. 2, Issue 4, RX FOR ACCESS, p.3 (June 2005).

8. Kim Belshé, *Governor's prescription makes drugs affordable*, SACRAMENTO BEE, February 14, 2005, available at <http://www.sacbee.com/content/opinion/story/12336150p-13202734c.html> (last visited Sept. 13, 2005).

9. See www.rxhelpforca.org (last visited Sept. 13, 2005).

Results to date from Rx Help for Californians

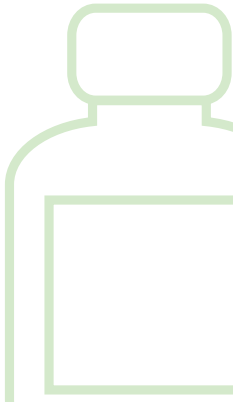
After slightly more than four months of operation, PhRMA's figures show more than 75,000 website searches or calls to Rx Help for Californians.¹⁰ Roughly half of these interactions have been with the Partnership for Prescription Assistance-linked website, and the other half with the call center. Around 53,000, or 71%, of the interactions resulted in Rx Help for Californians providing the searcher or caller with information about a program for which he or she may qualify.¹¹

These are important initial steps within a larger process for a typical patient to apply for a publicly funded program (such as Medi-Cal) or a drug company's patient assistance program (PAP), then receive the medication and understand how to use it. This larger process may sometimes require little additional investment of time and effort. However, a study published earlier this year indicated that safety net providers who assist their patients in the PAP process report that their staff—physicians, pharmacists, and others—spend an average of 111 hours per month helping patients with the PAP application and follow-up process.¹² For this reason, it is unclear how many of the inquiries handled through Rx Help for Californians have brought a patient to receive medication through new enrollment in a drug company PAP, in a national or state discount program, or in publicly financed health care coverage.

10. Personal communication with Merrill Jacobs, PhRMA, July 28, 2005.

11. Personal communication with Merrill Jacobs, PhRMA, July 28, 2005.

12. K. Duke, K. Raube, & H. Lipton, *Patient assistance programs: Assessment of and use by safety-net clinics*, Vol. 62, AMERICAN JOURNAL OF HEALTH-SYSTEM PHARMACY, 726-731 (April 1, 2005), available at <http://www.ajhp.org/cgi/reprint/62/7/726.pdf> (last visited Sept. 13, 2005).



Summary of Both Measures

PROPOSITION 78—CAL RX

Proposition 78 would create a significant new prescription drug discount program in the California Department of Health Services (DHS). It is sponsored by PhRMA and supported by various local business groups, as well as some groups focusing on specific diseases such as epilepsy and Hepatitis C.¹ This ballot measure would seek voluntary rebates from drug manufacturers that could translate into purchase discounts for California residents with family incomes up to 300% of the federal poverty level. The measure calls for rebates that would offer purchase prices “equal to the lowest commercial price for the individual drug or group of drugs.” DHS may terminate the program if there are insufficient discounts offered by companies.

PROPOSITION 79—CAL RX PLUS

Proposition 79 is sponsored by Health Access California, a health care consumer advocacy organization. Other supporters include Consumer’s Union (publisher of Consumer Reports), League of Women Voters, California Labor Federation AFL-CIO, groups focusing on diseases such as AIDS and breast cancer, and a number of nonprofit organizations focusing on seniors or women.² This measure resembles Proposition 78 in its basic concept of a state-operated discount card program, although it would offer discounts to a larger number of residents: those with incomes up to 400% of the poverty level or unreimbursed medical expenses exceeding 5% of their income. It also allows—but does not require—the state health department to require “prior authorization” for prescriptions to fee-for-service Medi-Cal patients

1. <http://www.calrxnow.org> (last visited Sept. 3, 2005).

2. <http://www.voteyesonprop79.com> (last visited Sept. 3, 2005).

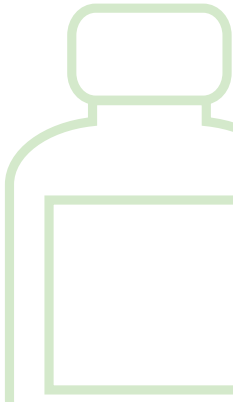
for a drug whose manufacturer declines to offer a rebate making the price comparable or lower than the Medicaid “best price.”³

Provisions only in Cal Rx Plus

In addition to these different approaches to issues specifically addressed by Cal Rx, the Cal Rx Plus measure includes these elements:

- ▶ Creates a Prescription Drug Advisory Board to review and then advise California officials on prescription drug access and pricing. The board would be made up of members of the public representing specified constituencies.
- ▶ Prohibits a drug manufacturer, distributor, or labeler from engaging in “illegal profiteering,” which includes demanding an unconscionable price, earning an unjust or unreasonable profit, and other specified actions.
- ▶ Requires drug manufacturers to report to DHS the total value and number of prescriptions or 30-day supplies of drugs they provided at no or very low cost to California residents through their own patient assistance programs.
- ▶ Allows enforcement of its provisions by the Attorney General upon his or her own initiative, or upon petition of the department by 50 or more California residents.
- ▶ Permits any individual to sue to enforce the initiative if the Attorney General fails to act within 180 days to investigate suspected violations.

3. The measure refers primarily to Medicaid “best price,” but also to “Medi-Cal best price” (proposed Section 130512 (b)), and to “the price for prescription drugs provided to the Federal Government” (130511(b)). It is unclear whether or how these other price benchmark references might be different from the “Medicaid best price” benchmark. However, the measure does clearly state that a drug company’s product whose price does not meet the necessary benchmark shall not be subject to prior authorization, based on that action, if there is no therapeutic equivalent for that drug (proposed Section 130512 (a)).



Comparison and Discussion of the Competing Initiatives

POSSIBLE OUTCOMES OF NOVEMBER ELECTION

There are several potential scenarios of results from the November special election.

- a. Voters may give *both* Cal Rx and Cal Rx Plus a majority of affirmative votes. In such a scenario, the measure receiving the highest affirmative vote prevails.¹ If that is Cal Rx, its “poison pill” provision would probably nullify all Cal Rx Plus provisions, even if some of those do not otherwise appear to conflict with Cal Rx.² Cal Rx Plus does not contain such a “poison pill” provision.
- b. Voters may give both measures a majority of negative votes. If this happens, California’s governor and legislature will presumably return to their earlier attempts to fashion a single bill or bill package, building on the work already done to negotiate revisions to the pending bills related to the Cal Rx and Cal Rx Plus ballot measures. (See Appendix B for a summary of those two bills as they compare with the ballot measures).
- c. Voters may give only one ballot measure a majority of affirmative votes.

The rest of this report focuses on comparing and contrasting the two ballot measures with each other, and does not further address the expected results and implications of outcome (a) or (b).

1. CAL. CONST., art. II, § 10 (b).

2. General Provisions of Cal Rx, section 3, states that its provisions “shall prevail in their entirety” if it receives more votes than Cal Rx Plus “*all* [of whose] provisions...shall be null and void.” (emphasis added), full text *available at* http://www.ss.ca.gov/elections/bp_nov05/voter_info_pdf/entire78.pdf (last visited Sept. 13, 2005).

ELIGIBILITY REQUIREMENTS

Income ceilings

Cal Rx proposes to cover an estimated five million California residents with a family income up to 300% of the federal poverty level.³ By contrast, Cal Rx Plus proponents estimate that eight to ten million people will qualify for that program, which proposes to cover California residents with a family income up to 400% of the federal poverty level or unreimbursed medical expenses exceeding 5% of their income.⁴

Cal Rx and Cal Rx Plus both propose income eligibility ceilings within the range of currently operating state pharmaceutical assistance programs. Out of the 29 states with programs in operation, Arkansas and Louisiana have the lowest income eligibility ceilings (100% of federal poverty level),⁵ and Massachusetts has the highest (500%).⁶

Documentation and asset test requirements

Neither initiative requires drug discount program applicants to document the income level stated on their application. Nor do the initiatives include an asset test, which distinguishes them from Medicare Part D's asset test for enrollees receiving a subsidy. Therefore, people eligible for Medicare and possessing assets that disqualify them for the Part D subsidy may be eligible for assistance under both initiatives.⁷

MEDI-CAL "HAMMER"

A key question in evaluating the propositions is whether to link the state's existing Medi-Cal purchasing and negotiating activity to a new state program. Critics of such a link worry about its potential impact on the Medi-Cal program and its low-income, vulnerable patients. Supporters of such a link point to the language of Cal Rx Plus designed to minimize or eliminate negative impact on Medi-Cal patients, and express doubt that a completely voluntary discount program would achieve meaningful and ongoing manufacturer rebates for an additional group of low-income residents.

The U.S. Supreme Court's 2003 decision regarding the State of Maine's drug discount program is relevant to questions regarding legal impediments to a Medi-

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3. Kim Belshé, *Governor's prescription makes drugs affordable*, SACRAMENTO BEE, February 14, 2005, available at <http://www.sacbee.com/content/opinion/story/12336150p-13202734c.html> (last visited Sept. 13, 2005).
 4. See Health Access California and Alliance for a Better California, *Yes on Prop 79*, at <http://www.voteyeson79.com> (last visited Sept. 13, 2005).
 5. 100% FPL equals \$9,570 for an individual and \$12,830 for two people. Annual Update of the HHS Poverty Guidelines, 70 Fed. Reg. 8373-8375 (February 18, 2005).
 6. Jennifer Ryan, *The Basics: State Pharmacy Assistance Programs*, *The George Washington University National Health Policy Forum* (April 26, 2004), available at http://www.nhpf.org/pdfs_basics/Basics%5FSPAPs%2Epdf (last visited Sept. 13, 2005).
 7. An estimated 2.37 million Medicare beneficiaries will have assets that disqualify them for the Part D low-income subsidy, despite incomes below that program's income eligibility ceiling. The study showed that those projected to be ineligible for low-income subsidies because of the asset test are disproportionately widows and persons with relatively modest assets. Thomas Rice and Katherine A. Desmond, *LOW-INCOME SUBSIDIES FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT: THE IMPACT OF THE ASSET TEST, REPORT FOR THE HENRY J. KAISER FAMILY FOUNDATION* (April 2005), available at <http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=52270> (last visited Sept. 13, 2005).

Cal “hammer.” Maine’s program (which was later changed) resembled Cal Rx Plus in its linking of decisions regarding “prior authorization” in that state’s Medicaid program to drug companies’ decisions whether to provide discounts to a new group of that state’s residents. The Court rejected PhRMA’s request for a preliminary injunction that would have prevented Maine from moving forward based on claims regarding impact on interstate commerce and on Maine’s Medicaid program. “The fact that a State’s decision to curtail Medicaid benefits may have been motivated by a state policy unrelated to the Medicaid Act does not limit the scope of its broad discretion to define the package of benefits it will finance.”⁸ What most concerned the Court was whether Maine’s program “severely curtailed Medicaid recipients’ access to prescription drugs.”⁹ The Court declined to prevent Maine from beginning its new program, noting that “the severity of any impediment that Maine’s program may impose on a Medicaid patient’s access to the drug of her choice is a matter of conjecture. To the extent that drug manufacturers agree to participate in the program, there will be no impediment.”¹⁰

Existing programs tied to Medicaid participation

Three discount/rebate programs already in effect in California link that program’s discounts/rebates to participation in Medi-Cal or Medicaid. One is the SB 393 program, which, as indicated earlier, requires a pharmacy to offer specified discounts to all Medicare patients as a condition of that pharmacy’s participation in Medi-Cal. Another is the federal 340B program, which requires that drug manufacturers, as a condition of Medicaid participation, offer specified discounts to many federally funded hospitals and clinics caring for low-income patients who may or may not be covered by Medicaid (Medi-Cal in California). Finally, California’s Medi-Cal program is known for its pioneering success in obtaining “supplemental” drug manufacturer rebates that are a part of the state’s decision whether to place a particular drug on Medi-Cal’s Contract Drug List.¹¹ A physician is usually not required to go through the “prior authorization” process if he or she prescribes pharmaceutical products that appear on this list. Therefore, a drug’s placement on this list “tends to increase the frequency of Medi-Cal prescriptions” for that product.¹² Note that the Medi-Cal linkage in this supplemental rebate program—unlike the other two programs linked to Medi-Cal/Medicaid—involves only a possible restriction on access, not a threat of elimination from all participation.

8. Pharm. Research & Mfrs. of America v. Walsh, 538 U.S. 644, 648 (2003).

9. *Id.* at 665.

10. The Court also noted that “The record does demonstrate that prior authorization may well have a significant adverse impact on the manufacturers of brand name prescription drugs” but this impact “is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program.” *Id.* at 668.

11. CAL. WELF. & INST. CODE §§ 14105.3 et seq. (2005).

12. Legislative Analyst’s Office, LOWERING THE STATE’S COSTS FOR PRESCRIPTION DRUGS, REPORT FOR THE CALIFORNIA LEGISLATURE (February 2005), available at http://www.lao.ca.gov/2005/prscrptn_drugs/prscrptn_drugs_021005.htm (last visited Sept. 13, 2005). The U.S. Supreme Court made a similar observation in its decision concerning the State of Maine’s program linking drug companies’ unwillingness to offer drug discounts for non-Medicaid patients to “prior authorization” of Medicaid drugs. “The record does demonstrate that prior authorization ... will impose some administrative costs on physicians....The impact on doctors may be significant if it produces an administrative burden that affects the quality of their treatment of patients, but no such effect has been proved.” Pharm. Research & Mfrs. of America v. Walsh, 538 U.S. 644, 668 (2003).

Drug companies' willingness to further expand discounts?

In Fiscal Year 2004-5, California paid almost \$5 billion for medications dispensed to people enrolled in Medi-Cal's fee-for-service program, with these expenditures reduced by federally mandated Medicaid rebates of \$1.2 billion plus state-negotiated supplemental rebates of \$510 million.¹³ Medi-Cal's net drug prices are somewhat lower than typical Medicaid prices in other states because of the state-negotiated contracts for supplemental rebates from nearly 100 pharmaceutical manufacturers.¹⁴ Thus, many drug manufacturers appear to be willing offer certain levels of rebates as the price of greater access to the Medi-Cal market.¹⁵

Conversely, it's not clear how likely drug companies are to offer significant discounts under the Cal Rx combination of voluntary discounts and a Medicaid Best Price exemption. Appendix C compares drug prices offered through two different programs that both have prices exempt from Medicaid Best Price requirements; one of these programs uses negotiated, voluntary discounts, the other program uses Medicaid market leverage.¹⁶ Medicare drug discount cards rely on voluntary discounts negotiated between drug manufacturers and card sponsors, while the 340B program uses Medicaid-linked discounts.¹⁷ This chart displays prices for top-selling brand name medications offered through three Medicare-approved drug discount cards.¹⁸ Also displayed are estimates of prices paid by clinics purchasing at federally specified 340B prices, which a recent Congressional Budget Office report found to be on average quite similar to Medicaid Net Manufacturer Price (average 51% of Average Wholesale Price), and somewhat lower than Medicaid Best Price (average 63% of Average Wholesale Price).¹⁹ There is a striking difference between the 340B total of \$361 and the Medicare Drug Discount Card totals ranging from \$623-659 for those same nine top-selling drugs, even if the 340B figures are increased to better approximate Medicaid Best Price. This suggests that popular drugs' prices resulting from voluntary negotiated discounts are significantly higher than prices for those

13. May 2005 Medi-Cal Estimate for FY 2004-05.

14. Legislative Analyst's Office, LOWERING THE STATE'S COSTS FOR PRESCRIPTION DRUGS, REPORT FOR THE CALIFORNIA LEGISLATURE (February 2005), available at http://www.lao.ca.gov/2005/prscrptn_drugs/prscrptn_drugs_021005.htm (last visited Sept. 13, 2005).

15. Note that on January 1, 2006, approximately one million Medi-Cal beneficiaries will be transferred to one of the Medicare Part D prescription drug plans which each have their own formulary restrictions and procedures. See Nancy Weaver Teichert, *Medi-Cal Rx shift hits Jan. 1*, SACRAMENTO BEE, September 4, 2005, at A3, available at <http://www.sacbee.com/content/politics/story/13517790p-14358601c.html> (last visited Sept. 13, 2005).

16. Note that the "hammer" for encouraging drug companies to offer specified discounts to the Medicaid and 340B programs is the threat of complete lack of access to the Medicaid market. This is clearly a more significant consequence than Cal Rx Plus' threat of allowing the California Department of Health Services to reduce Medicaid access through prior authorization.

17. Although neither of California's ballot measures refers to 340B pricing, it is used in Appendix C as a rough substitute for Medicaid Best Price data.

18. These cards, whose drug prices are publicly available through the CMS website, have been part of Medicare's "transitional assistance" program to offer some benefits before Medicare's new drug coverage is launched in January 2006. Prices offered through Medicare-approved cards are based on discounts voluntarily offered by drug manufacturers plus whatever markup or professional fee is charged by other parties involved, such as the drug card sponsor and dispensing pharmacy. Medicare law provides drug companies the same exemption from Medicaid Best Price calculations that Cal Rx seeks through designation as a federally approved state pharmaceutical assistance program.

19. A survey of 2003 prices for 130 top-selling brand-name drugs shows that the average Medicaid Best Price is 63% of Average Wholesale Price (AWP), while the average for both the 340B Ceiling Price and the Medicaid Net Manufacturer Price is 51% of AWP. Congressional Budget Office, PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS, Table 1, June 2005.

same drugs available through a less voluntary discount program that is linked to Medicaid Best Price.

Ohio is a state in which a PhRMA-sponsored program similar to Cal Rx was launched earlier this year. Ohio's experience may offer some lessons for California regarding drug company rebates in the absence of a Medicaid link. Ohio's plan, on which Cal Rx was modeled, has offered an average drug discount of 31% from retail prices in its first year, which represents about \$1 million in savings for the participants, or an average of \$15.50 discount per prescription. However, 90% of the discount comes from an across-the-board discount from pharmacies, not from manufacturer rebates; only 8% of the discount can be attributed to manufacturer rebates.²⁰

Specifics of the state's leverage

Cal Rx specifies the level of rebates for drug companies to participate in that program; the measure does not create any consequences for a company declining to provide a rebate at the specified level, or any rebate at all. By contrast, Cal Rx Plus specifies two responses that Medi-Cal may make if a drug manufacturer declines to provide Cal Rx Plus participants with Medicaid Best Price or better rebates. The most serious consequence is that the state health department "may not enter into a new contract or extend an existing [Medi-Cal] contract" with that company, although a refusal to contract would not be permitted for any drug for which there is no therapeutic equivalent.

Cal Rx Plus also creates another, less severe consequence for any drug manufacturer refusing to offer the specified level of rebates, including companies whose Medi-Cal contract has not yet ended and those renewing a contract for a therapeutically unique drug. In these circumstances, Cal Rx Plus states that the health department "may require prior authorization in the Medi-Cal program" for that company's drugs, which would allow access only if the prescriber takes the necessary steps for receiving approval. Note that this language appears to allow the state to decide whether to take this action.

Whether the state health department uses one or both of its leverage points to encourage the required level of manufacturer rebates, Cal Rx Plus specifies that a Medi-Cal patient shall have continued access to a drug that continues to be prescribed for his/her therapy, regardless of the actions of that drug's manufacturer. At the same time, the Medi-Cal prior authorization process is one that physicians and pharmacists prefer to avoid.

DIFFERENT BENCHMARK PRICES

California's two initiatives have somewhat different methods of setting a target for the purchase price available to their program's enrollees. Cal Rx uses a three-part formulation in which manufacturers' rebates are defined to mean individual or

20. Personal communication from Jennifer Lopez, Program Director of Ohio's Best Rx, July 25, 2005.

aggregate rebates “equal to or less than the applicable benchmark price,”²¹ which is defined as the “lowest commercial price,” which is in turn defined as the lowest purchase price for an individual drug in California.²² This set of definitions strongly implies that Cal Rx prices would be no higher than the prices paid by large and pharmaceutically sophisticated California purchasers such as Kaiser Permanente and other large California-based health plans.

By contrast, Cal Rx Plus uses as its target the Medicaid Best Price, but also refers to “a net price comparable to or lower than the price for prescription drugs provided to the Federal Government.”²³ This latter term is not further defined, but could be referring to Federal Supply Schedule (FSS) prices. These are calculated somewhat differently from Medicaid/340B prices, are available to various federal agencies and departments, and are roughly comparable overall to the 340B/Medicaid prices, although individual prices may vary.²⁴ Under either the Best Price or FSS benchmark, large and pharmaceutically sophisticated purchasers in California would probably be less directly affected in their drug price negotiations under Cal Rx Plus than Cal Rx because the former measure’s benchmark relies more on federal government actions (federal negotiations connected with FSS) or statutes (the Medicaid and 340B pricing formula).

STATE PHARMACEUTICAL ASSISTANCE PROGRAM ISSUES

State Pharmaceutical Assistance Programs (SPAPs) are state-sponsored programs that have traditionally provided prescription drug coverage to a portion of senior citizens and individuals who did not qualify for Medicaid drug coverage.²⁵ While many programs take the form of a subsidy to program participants, an increasing number use discounts or bulk purchasing approaches.²⁶ Out of the 41 states that have established or authorized some type of SPAP, half have programs that qualify as federally recognized SPAPs whose drug prices are exempt from the Medicaid Best Price designation.²⁷

Although the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 included some language regarding SPAP issues as they relate to Part D, this

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21. Cal Rx proposed language for CAL. HEALTH & SAFETY CODE § 13061(h); full text of Cal Rx *available at* http://www.ss.ca.gov/elections/bp_nov05/voter_info_pdf/entire78.pdf (last visited Sept. 13, 2005).
 22. The measure would add § 130601(f)(1) to the Health & Safety Code as follows: “*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.” See http://www.ss.ca.gov/elections/bp_nov05/voter_info_pdf/entire78.pdf (last visited Sept. 13, 2005). Government entity purchasing, nominal pricing, and inpatient drugs are excluded from the definition in other provisions.
 23. Cal Rx Plus proposed language for CAL. HEALTH & SAFETY CODE § 130511(b). See http://www.ss.ca.gov/elections/bp_nov05/voter_info_pdf/entire79.pdf (last visited Sept. 13, 2005).
 24. W. von Oehsen, PHARMACEUTICAL DISCOUNTS UNDER FEDERAL LAW: STATE PROGRAM OPPORTUNITIES, REPORT FOR THE PUBLIC HEALTH INSTITUTE (May 2001), *available at* <http://www.medpin.org/pdf/PHI.Pharm.pdf> (last visited Sept. 13, 2005). See also Congressional Budget Office, PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS, JUNE 2005.
 25. Rutgers Center for State Health Policy, *State Pharmaceutical Assistance Programs: A Chartbook*, August 2004. Note that the SPAP acronym can be easily confused with the PAP acronym often used for drug companies’ patient assistance programs, although SPAPs have different sources of financing and control than do PAPs.
 26. National Conference of State Legislatures, *State Pharmaceutical Assistance Programs*, at <http://www.ncsl.org/programs/health/drugaid.htm> (last visited Sept. 13, 2005).
 27. *Id.* Figures given reflect May 2005 information showing 21 federally approved SPAPs.

report does not address those questions except to note that a subsequent Center for Medicare & Medicaid Services (CMS) release on SPAPs did not change any of its previously announced criteria for an SPAP exempt from Medicaid Best Price.²⁸ The criteria for such an SPAP program announced in the April 2005 release are:

- ▶ The [SPAP] is a State developed program specifically for the disabled, indigent, low-income elderly [or] other financially vulnerable persons.
- ▶ The program is funded by the State; that is, no Federal dollars are involved.
- ▶ The program is set up such that payment is provided directly to providers.
- ▶ The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefits or services.
- ▶ The program does not allow for the diversion, resale or transfer of benefits reimbursed under the State pharmacy assistance program to individuals who are not beneficiaries of the State pharmacy assistance program.
- ▶ The program does not violate the non-discrimination provisions of [the Medicare Act relating to states desiring to steer their SPAP members to a certain Part D plan].²⁹

An earlier letter from CMS offers some guidance on federal criteria for other SPAP aspects, including Medicaid prior authorization activities.

- ▶ Contracts with drug manufacturers for rebates must be a “reduction in the amount expended under the State plan in the quarter for medical assistance.”
- ▶ Prior authorization programs are permitted. A prior authorization program need not comply with requirements for restrictive formularies.
- ▶ A Medicaid prior authorization program can be used to secure discounts for non-Medicaid populations if that action furthers the Medicaid program’s goals and objectives. For example, a prior authorization component could increase the Medicaid program’s efficiency and economy, or could “sufficiently benefit the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.”³⁰

Requirements regarding the state’s contribution

It is not clear what amount of state contribution is needed for a state’s drug discount program to be federally approved as an SPAP. An additional unresolved question concerns the type of state contribution. Is it sufficient for SPAP approval for a state’s contribution to be funding for the program’s administrative costs, but not for any

28. MMA §1860D-23(b). The definition requires SPAPs to: 1) provide financial assistance for supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals, 2) provide assistance to Part D eligible individuals in all Part D plans and not discriminate based upon which Part D plan the individual is enrolled, and 3) follow other requirements related to coordination of benefits and relation to other provisions.

29. Center for Medicare & Medicaid Services, STATE PHARMACY ASSISTANCE PROGRAMS—REVISED CRITERIA, Release #68, April 1, 2005.

30. Letter from Dennis G. Smith, Director of the Center for Medicaid and State Operations, to State Medicaid Directors, September 18, 2002.

portion of the discounts offered to eligible purchasers?

Only one federal court ruling speaks directly to the state contribution issue. In 2001, a Court of Appeals ruling struck down a Vermont program that required pharmaceutical manufacturers to give rebates to non-Medicaid beneficiaries.³¹ The court struck down the program because rather than contributing its own funds, the state was acting merely as a ‘pass-through’ for drug manufacturer rebates. Because Congress created the rebates in order to reduce the cost of the Medicaid program, only state rebate programs that create savings for Medicaid will be allowed. Additionally, rebates can only be elicited from manufacturers for drugs on which “payment was made under the State plan.”

The court discussed what would qualify as an acceptable “payment” under the statute:

- ▶ *Payment* means “only payments with state or federal funds appropriated for Medicaid expenditures.”
- ▶ The amount of funds expended by a state must be determined independently of the amount of any manufacturer rebates.

In 2002, the same court considered a Maine program that was identical to the Vermont program except that it included a 2% state contribution along with the manufacturer rebates.³² However, the court’s ruling did not address the question of whether Maine’s 2% contribution was sufficient for SPAP purposes.

Why wait for “Best Price” exemption?

The ability of a California discount program to gain federal SPAP designation is a central tenet of Cal Rx, which also calls itself the California State Pharmacy Assistance Program.³³ Federal SPAP designation leading to an exemption from Medicaid Best Price was also one of the factors cited in some drug companies’ decisions about participation in California’s Golden Bear program. However, such federal approval is worth pursuing only if Cal Rx discounts take drug prices below the Medicaid Best Price, in which case the federal SPAP approval protects drug companies from being required to extend these same prices to all states’ Medicaid programs and 340B purchasers. As discussed earlier, experience from the Medicaid Best Price–exempt Medicare drug discount cards suggests uncertainty about whether drug companies would voluntarily offer discounts below Medicaid Best Price, even when permitted to do so without being required to extend those prices to other groups of purchasers.³⁴

Another approach could allow more immediate, and potentially substantial, discounts without the waiting and uncertainty of federal SPAP approval. Drug companies could avoid Medicaid Best Price implications by offering prices just above or at the

31. *Pharm. Research & Mfrs. of America v. Thompson*, 251 F.3d 219 (2001). This ruling was from the U.S. Court of Appeals for the District of Columbia Circuit, which is not binding on California.

32. *Pharm. Research & Mfrs. of Am. v. Thompson*, 313 F.3d 600, 602 (2002).

33. Cal Rx, section 2.

34. Note that these prices then become the new Medicaid Best Price.

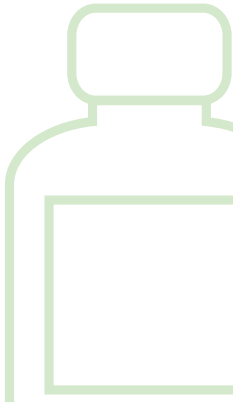
existing Medicaid Best Price benchmark.³⁵ If companies were willing to do this, and if a state drug discount program—similar to those outlined by either of the two ballot measures—could negotiate these discounts without violating price confidentiality laws, such a program could begin operating more quickly and with more certainty than if state officials must await federal SPAP approval before beginning.³⁶ These discounted prices could be available while SPAP designation was pending, or if no SPAP designation was sought or achieved.³⁷

FISCAL IMPACT ON STATE OF CALIFORNIA

The Legislative Analyst estimates that both the Cal Rx and Cal Rx Plus programs will have “significant” startup and ongoing costs to the state for administrative and outreach activities, ranging from the millions to low tens of millions of dollars annually. The Analyst also reports that the state General Fund would likely bear “a significant share” of total costs for either program, although these would be partly offset by an unknown amount of private donations and individual enrollment fees, and by potential savings for state and county health programs due to some low-income people no longer needing public assistance programs.³⁸

For Cal Rx Plus, there are potential state costs and cost offsets connected with its provisions regarding Attorney General prosecution of profiteering cases and possible collection of revenues from civil penalties. In addition, Cal Rx Plus allows the state to retain up to 5 percent of the rebates it collects from drug companies, which would partially offset state program costs. Cal Rx Plus is also estimated to have an unknown positive or negative, but potentially significant, net fiscal impact on Medi-Cal as a result of its linkage of the new program with Medi-Cal’s list of “prior authorization” drugs.

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35. SB 1563 (Escutia) (2004) attempted to create this kind of pricing program, setting prices at 105% of the Medicaid best price. Under Cal Rx Plus, drug companies could offer prices “comparable to... Medicaid best price” that would not trigger a new Medicaid best price and therefore and not need federal SPAP designation exempting these prices from that federal calculation.
36. This line of thought is also explored in the Legislative Analyst’s report on Governor Schwarzenegger’s Cal Rx proposal, as carried in Senate Bill 19 (Ortiz). Legislative Analyst’s Office, *EVALUATING THE ADMINISTRATION’S CALIFORNIA RX PROPOSAL* (February 2005), *available at* http://www.lao.ca.gov/analysis_2005/2005_pandi/pandi_05.pdf at 243 (last visited Sept. 13, 2005).
37. Even if substantial discounts could be achieved for most Cal Rx or Cal Rx Plus enrollees without SPAP designation, a small portion of enrollees in Medicare Part D might receive a different kind of benefit from SPAP designation. This involves a different, complex question of the ability of the state to help Part D beneficiaries move through the coverage gap “doughnut hole” by counting SPAP expenditures as True Out of Pocket costs. However, many Part D enrollees with incomes qualifying them for Cal Rx or Cal Rx Plus are likely to also be eligible for a Part D Limited Income Subsidy and therefore exempt from the “doughnut hole.”
38. California Legislative Analyst’s Office, *INITIATIVES QUALIFIED FOR THE NOVEMBER 8, 2005, SPECIAL STATEWIDE ELECTION BALLOT*, July 21, 2005, *at* http://www.ss.ca.gov/elections/elections_j.htm#2005Special (last visited Sept. 13, 2005). Specific components of the total state costs would include funding for any new information technology systems needed, operation of the internet website and call center to received discount card applications, processing of discount card applications and renewals, negotiating with and collecting rebates from drug companies, making advance payments to pharmacies providing the purchase discounts, and coordinating the state’s program with other private drug discount programs.



Related Issues

NATIONAL ATTENTION TO CALIFORNIA'S CHOICES

There is little question that both Cal Rx and Cal Rx Plus supporters see their efforts in this state as having major impact on the rest of the United States. Part of the Cal Rx Plus campaign frames California's initiative campaigns as a chance for voters to "stand up to the drug companies."¹ For Cal Rx, both the public statements from PhRMA officials and the level of campaign contributions from its member companies convey the importance they attach to the outcome of California's initiative campaigns.

Following its public launch of the Partnership for Prescription Assistance in spring 2005, PhRMA has increased its efforts to use Partnership for Prescription Assistance for outreach to the individual states' governors, including California. In this state, PhRMA reportedly spent \$10 million getting Cal Rx on the ballot, which is assumed to have also financed its legal challenges to signatures on the petitions to put Cal Rx Plus on the November ballot.² This \$10 million pre-qualification expenditure amount appears to be in addition to PhRMA's previously announced \$10 million commitment toward implementing its California version of Partnership for Prescription Assistance, which provides general support for the voluntary approach contained in both the Cal Rx ballot initiative and the Cal Rx program contained in legislation supported by California's Governor.³

Why this notable amount of funding to put a ballot measure before voters, followed by additional tens of millions of dollars toward campaign expenses? PhRMA Vice President Jan Faiks explains:

We take it [Cal Rx Plus] as such a serious threat to the health and welfare of the pharmaceutical industry that we have to make a stand [in California]. It's a very

1. <http://www.voteyesonprop79.com/index.htm> (last visited Sept. 13, 2005).

2. The same action was taken in Ohio, where the industry filed lawsuits in 41 counties to "challenge voter petition signatures." Jordan Rau, *Industry Aims to Defeat Discount Drug Initiatives*, LOS ANGELES TIMES, March 28, 2005, available at <http://www.prometheus6.org/node/9292> (last visited Sept. 13, 2005).

3. <http://www.calrxnow.org> (last visited Sept. 13, 2005).

bad precedent. You're the leader in the country, and there are 26 states that allow ballot initiatives.... [The industry will spend] whatever it takes [to defeat the Cal Rx Plus initiative]. We are (1) trying to get out of harm's way and (2) trying to help people.⁴

The Cal Rx and Cal Rx Plus initiatives come at a time when PhRMA is making a national effort to avoid government-imposed discounts by demonstrating the benefits of voluntary programs. PhRMA CEO Billy Tauzin, speaking of PhRMA's Partnership for Prescription Assistance, notes:

This is serious business. This is going to be very expensive for the companies, but they're willing to make this commitment to save the free-market system in America. The reason why PhRMA supports the free-market system is that it's the last bastion that rewards innovation. But we realize that if we're going to retain that system, we can't leave people out simply because they're impoverished.⁵

Bob Stern, president of California's Center for Governmental Studies (www.cgs.org), agrees with PhRMA's Faiks about the wider implications of approval or defeat of Cal Rx Plus. "How California votes on these propositions will affect the national debate and efforts in other states. If California passes Proposition 79, the pharmacy companies will be on the defensive throughout the country."⁶

FOCUS ON DISCOUNTS INSTEAD OF LOW PRICES?

Both ballot measures focus on discount levels for patient purchases, not on actual value to that patient of his or her total drug expenditures. However, a person whose condition can be effectively and safely treated by more than one medication may get better health value by looking at the actual purchase price of several drugs, not their level of discount. Such a perspective would shift attention to generic drugs, whose lower research and development costs and lower marketing expenditures allow their manufacturers to price them at about a third of the price of brand name products.⁷ In 2004, the average price of a generic prescription drug was approximately \$29, compared with \$96 for a brand name prescription drug.⁸ An AARP Public Policy Institute report shows that wholesale prices charged by manufacturers of brand-name drugs increased an average of 6.6% over a 12-month period ending March 2005, compared to a 0.7% average increase for generic drugs.⁹

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4. Jan Faiks, PhRMA Vice President as quoted in Jordan Rau, *Industry Aims to Defeat Discount Drug Initiatives*, LOS ANGELES TIMES, March 28, 2005. *available at* <http://www.prometheus6.org/node/9292> (last visited Sept. 13, 2005).
 5. Kevin Freking, *Drug firms launch \$10 million ad campaign*, THE ASSOCIATED PRESS, April 5, 2005, *available at* http://archive.mail-list.com/hbv_research/msg07894.html (last visited Sept. 13, 2005).
 6. Personal communication, Robert Stern, September 9, 2005.
 7. C. Peters, FUNDAMENTALS OF THE PRESCRIPTION DRUG MARKET, NATIONAL HEALTH POLICY FORUM BACKGROUND PAPER (August 24, 2004), *at* http://www.nhpf.org/pdfs_bp/BP_RxIndustry_08-24-04.pdf (last visited Sept. 13, 2005).
 8. Generic Pharmaceutical Association, *About Generic Pharmaceuticals*, *at* <http://www.gphaonline.com/aboutgenerics/index.html> (last visited Sept. 13, 2005).
 9. D. Gross, S. Schondelmeyer, and S. Raetzman, TRENDS IN MANUFACTURER PRICES OF PRESCRIPTION DRUGS USED BY OLDER AMERICANS, AARP PUBLIC POLICY INSTITUTE (August 2005), *available at* <http://www.aarp.org/research/health/drugs/aresearch-import-869-2004-06-IB69.html>. *See also* U.S. Government Accountability Office, PRESCRIPTION DRUGS: PRICE TRENDS FOR FREQUENTLY USED BRAND AND GENERIC DRUGS FROM 2000 THROUGH 2004, August 2005.

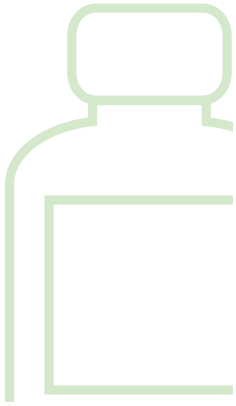
One reading of the recent history of California's attempts to address drug costs is that the two ballot initiatives take a new approach to issues previously discussed in terms of purchasing drugs through Canada. However, whatever comparative price advantage exists for Canadian prices over U.S. prices is largely limited to brand-name drugs. A study shows that Canadian prices for 100 top-selling generic drugs average 78% higher than U.S. prices.¹⁰ It would be ironic if all the attention now being given to discount levels on higher priced, brand-name drugs were to distract physicians and other prescribers, as well as policy officials and the general public, from cost savings often immediately available through use of generic drugs readily available in the United States.

The uninsured, limited-income people who are targeted by both Cal Rx and Cal Rx Plus can benefit greatly if they and their health care providers can make cost-effective medication choices without being inappropriately influenced by promotion of expensive, brand-name drugs. There is growing evidence that a number of older generic drugs used in treatment and management of chronic diseases may be as medically effective as newer, costlier, brand name drugs.¹¹ However, it can be challenging to get this message out to patients and their physicians—especially in a safety net setting that often relies heavily on free drug samples or patient assistance programs, both of which are usually limited to brand-name drugs. “I see physicians prescribe expensive medications when a much less expensive medication could be used,” comments a pharmacist with many years of experience in a California clinic serving thousands of uninsured patients. “A big issue not addressed by either [Cal Rx or Cal Rx Plus] measure is trying to educate physicians to recommend using much less expensive generics when that is a choice.”¹²

10. B.J. Skinner, CANADA'S DRUG PRICE PARADOX: THE UNEXPECTED LOSSES CAUSED BY GOVERNMENT INTERFERENCE IN PHARMACEUTICAL MARKETS, FRASER INSTITUTE (February 2005), *available at* <http://www.fraserinstitute.ca/admin/books/files/CanDrugPriceParadox1-2.pdf> (last visited Sept. 13, 2005). *See also* FDA, GENERIC DRUG PRICES IN THE U.S. ARE LOWER THAN DRUG PRICES IN CANADA, OFFICE OF PLANNING (November 2003), *available at* <http://www.fda.gov/oc/whitepapers/drugprices.html> (last visited Sept. 13, 2005).

11. The multi-state Drug Effectiveness Review Project, whose two California participating organizations are University of California at Davis/ Medicine for People in Need (financed by the California HealthCare Foundation) and Medi-Cal, conducts “unbiased systematic reviews” that make “effectiveness and safety comparisons between drugs in the same class.” Some of these medications may have significantly lower prices than others. For general information on this project, *see* Oregon Health Sciences University Drug Effectiveness Review Project, *at* <http://www.ohsu.edu/drugeffectiveness/> (last visited Sept. 13, 2005).

12. Personal communication, Ruth Smarinsky, August 7, 2005.



Conclusion

Public officials and affected stakeholder groups have engaged in much discussion on whether to implement a legislative or private market solution to address public concern about rising prescription drug costs. Now Californians are poised to decide more directly on proposals for a major new state drug discount program. Voters' decision in the November special elections will have major implications for this state and for the rest of the country.

California's two drug discount voter initiatives both propose a new, state-operated program to help people who are likely to have problems affording their medications but are not covered by Medicare. PhRMA-sponsored Proposition 78 (Cal Rx) and Health Access-sponsored Proposition 79 (Cal Rx Plus) are also similar in that both measures have significant unknowns regarding their impact on individual residents, on drug manufacturers, and on state government costs and ability to operate them as expected.

Despite many similarities, the two proposals also reflect major differences. Cal Rx Plus proposes to cover a much larger number of Californians (up to ten million), and has a broader scope of provisions than Cal Rx's more modest and more voluntary approach. Cal Rx's pharmaceutical industry supporters claim that their program discounts' reliance on voluntary actions is the most realistic and appropriate. The coalition supporting Cal Rx Plus prefers to increase the state's bargaining power by tying the new program's discounts to Medi-Cal purchasing power.

It is difficult to predict the final outcome of the November elections and possible litigation or implementation barriers connected with the prescription drug ballot measures. However, Californians' high-visibility deliberations on competing approaches to medication affordability, added to major preparations for new Medicare drug coverage, will keep medication access and affordability issues at the forefront of health policy discussions across the United States.

Appendix A

SUMMARY OF KEY PROVISIONS OF CAL RX AND CAL RX PLUS

	Proposition 78—Cal Rx	Identical or Highly Similar Provisions	Proposition 79—Cal Rx Plus
Program Name	California State Pharmacy Assistance Program (Cal Rx)		Cheaper Prescription Drugs for California Program (Cal Rx Plus)
Income Eligibility	Includes CA residents in a family with an income up to 300% of FPL (\$28,000 individual; \$56,500 family of four)	CA Department of Health Services (DHS) uses applicant's reported (under penalty of perjury) income information without requiring additional documentation	Includes CA residents in a family with an income up to 400% of FPL (\$37,000 individual; \$75,000 family of four) Includes CA residents whose unreimbursed medical expenses exceed 5% of their family's income
No Other Drug Coverage	Participants may not be enrolled in third party payer, or a health plan or drug discount program supported with state or federal funds Participants cannot have had outpatient prescription drug coverage in the three months prior to applying, with specified exceptions	Medicare enrollees may participate for drugs not covered by Medicare Participants may not be enrolled in Medi-Cal or Healthy Families	
Application	\$15 annual fee paid to the pharmacy, physician office, clinic, or third-party vendor completing the application	May also apply through a website or a call center	\$10 annual fee paid to the pharmacy, physician office, clinic or non-profit community organization completing the application
Outreach	DHS shall conduct outreach re Cal Rx and private drug discount programs as funds are available DHS may also accept outreach advertisements Outreach gifts and ads accepted by DHS are subject to specified rules re name of sponsoring organization appearing in outreach material, and are exempted from specified California law governing gifts and ads for state programs or officials	DHS may accept outreach gifts, donations, services, and materials	DHS shall conduct outreach re Cal Rx Plus Name of organization sponsoring any DHS outreach materials shall not appear on material but shall be reported to public and Legislature

	Proposition 78—Cal Rx	Identical or Highly Similar Provisions	Proposition 79—Cal Rx Plus
Coordination and Single Point of Entry	DHS 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 private discount drug programs, which may require additional eligibility information	Shall coordinate with other drug discount programs to provide the best available drug discounts	DHS shall execute agreements with drug manufacturer and private patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs, which may require additional eligibility information
Discounts		Any drug company may participate by offering rebates Pharmacies that choose to participate may be paid a rate other than their usual and customary rate	
Amount of Potential Discounts	DHS should attempt to negotiate rebates with drug manufacturers that make the price of the drug ingredients equal to or less than 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 Entire rebate shall go to reducing program enrollees' purchase price		DHS should seek rebates that result in the net price of drugs to be comparable to or lower than the Medicaid Best Price and the price provided to the federal government At least 95% of the rebate shall go to reducing program enrollees' purchase price
Program Operations	DHS shall seek and obtain confirmation from CMS that Cal Rx is a federally recognized SPAP and that discounts provided under it are exempt from Medicaid Best Price requirements	DHS shall generate monthly information at the NDC level that includes program drug utilization, payments to pharmacies, and manufacturer rebates	Requires rebates to be consistent with federal law

	Proposition 78—Cal Rx	Identical or Highly Similar Provisions	Proposition 79—Cal Rx Plus
Manufacturer Participation	Voluntary		<p>A manufacturer that fails to provide Cal Rx Plus a rate comparable to or lower than the Medicaid Best Price may not participate or extend participation in Medi-Cal, except for drugs for which there is no therapeutic equivalent</p> <p>DHS may require prior authorization in Medi-Cal for any drug of a manufacturer that fails to agree to a price comparable to or lower than the Medi-Cal Best Price</p> <p>A Medi-Cal beneficiary shall not be denied the continued use of a drug that is part of a prescribed therapy</p> <p>Names of manufacturers that do and do not enter into rebate agreements with DHS shall be released to the public</p>
Information Reporting			<p>Manufacturers must annually submit to DHS the following information regarding drugs provided at no or very low cost to CA residents during the previous year:</p> <ul style="list-style-type: none"> a) total value of the manufacturer's drugs b) total number of prescriptions or 30-day supplies of the manufacturer's drugs
Business Assistance			<p>DHS must establish a program to assist small business and labor entities in getting the same pharmacy discounts and rebates from drug makers</p>
Anti-Profitteering			<p>Makes profiteering by a drug manufacturer, distributor, or labeler a civil violation, subject to the greater of \$100k fines or treble damages</p>

	Proposition 78—Cal Rx	Identical or Highly Similar Provisions	Proposition 79—Cal Rx Plus
Administration and Enforcement	DHS shall develop a program to prevent the occurrence of fraud	DHS may delegate much of its negotiation and administration responsibilities to a third-party vendor	<p>The Attorney General, upon his or her own initiative or upon petition of DHS or of 50 or more residents of the State, shall investigate suspected violations of the provisions</p> <p>If the Attorney General fails to act within 180 days, any person may sue for injunctive relief and a civil penalty of up to \$100k or three times the amount of the damages</p> <p>Creates new Prescription Drug Advisory Board to review access to and pricing of prescription drugs</p>
Program Termination or Modification	DHS may terminate Cal Rx if (a) there are insufficient discounts to make Cal Rx viable, (b) there are insufficient applicants, or (c) a responsible third-party vendor cannot be found		
Estimated Fiscal Impact on State		<p>Annual administrative and outreach costs between millions and low tens of millions of dollars</p> <p>Onetime tens of millions of \$ cost to state for “float” involved in pharmacy payments</p> <p>Potential savings on state and county health programs</p>	

Appendix B

DIFFERENCES BETWEEN EACH DRUG DISCOUNT PROGRAM BALLOT MEASURE AND RELATED PENDING LEGISLATION

A Senate bill currently before the California Legislature is highly similar to Proposition 78; a pending Assembly bill shares a number of similarities with Proposition 79.¹

Senate Bill 19 (Ortiz)

The 2005 legislative vehicle for the Governor's Cal Rx proposal is Senate Bill (SB) 19, authored by the Chair of the Senate Health Committee, Senator Deborah Ortiz.² Proposition 78 strongly resembles SB 19 as it existed in its January 6, 2005, version. However, SB 19 has been amended since January and now contains some differences from Proposition 78.³ The Senate bill:

- ▶ Clarifies that individuals are eligible for Cal Rx if they are in the Medicare coverage gap ("doughnut hole"), have reached their annual limit on private coverage, or lose drug coverage due to loss of employment.
- ▶ Defines participating manufacturer as one that provides the target rebate necessary to allow the Department of Health Services (DHS) to reach lowest commercial price.
- ▶ Requires DHS to encourage participating manufacturers to maintain the level of private discount drug programs provided at a level comparable to what was provided previously, and to simplify the application and eligibility processes for those private discount drug programs.
- ▶ Allows DHS to contract with private or public purchasing groups in order to obtain the most favorable discounts on multiple-source drugs.
- ▶ Does not include the Proposition 78 language allowing DHS to terminate the program due to insufficient discounts or inability to find a responsible third-party vendor to administer the program.

1. Comparisons are based on the versions of SB 19 and AB 75 in effect on August 15, 2005.

2. The ballot initiative (Proposition 78) and legislative vehicle for the Governor's program (Senate Bill 19), have almost the same language and the use the same name—"Cal Rx"—for the program each would create. Governor Schwarzenegger and his administration have publicly stated strong support for SB 19, but to date taken no public position on either ballot initiative.

3. For information on the current version and all previous versions of SB 19 and AB 75, see <http://www.leginfo.ca.gov/bilinfo.html>.

Assembly Bill 75 (Frommer)

The Cal Rx Plus voter initiative has important similarities to—but also notable differences from—the pending version of Assembly Bill (AB) 75.

- ▶ Only AB 75 clarifies that Cal Rx Plus eligibility is limited to people not enrolled in any program, except Medicare, that uses federal funds to pay part or all of their outpatient prescription drugs.
- ▶ AB 75 requires DHS to initially seek rebates equal to the Medi-Cal rebate amount; once DHS receives approval from CMS that Cal Rx Plus is an SPAP, DHS must seek rebates that result in a price lower than the Medicaid Best Price for drugs covered by the program. Proposition 79 requires DHS to seek rebates comparable to or lower than those made available by federal law to Medicaid programs and 340B purchasers through the Best Price mechanism.
- ▶ Only Proposition 79 prohibits Medi-Cal contracts with manufacturers that do not provide adequate discounts. Both Proposition 79 and AB 75 permit DHS to require prior authorization for any drug of a manufacturer that does not agree to rebates; AB 75 is silent about the level of rebates sufficient to avoid prior authorization, whereas Proposition 79 makes vulnerable all manufacturers that do not provide rebates comparable to or lower than Medi-Cal Best Price. Under both measures, a Medi-Cal beneficiary would be allowed continued use of a currently prescribed drug regardless of prior authorization requirements.
- ▶ Only Proposition 79 requires DHS to seek rebates for small businesses comparable to the Cal Rx Plus rebates.
- ▶ Only Proposition 79 creates a Prescription Drug Advisory Board to review drug pricing for California residents.
- ▶ Only Proposition 79 contains anti-profiteering provisions with the possibility of treble damages. Such action may be brought by the Attorney General or members of the public against drug manufacturers, distributors, and labelers.

Appendix C

COMPARATIVE PRICE INFORMATION

TOP SELLING PRESCRIPTION DRUGS ¹	AVERAGE WHOLESALE PRICE (AWP) ²	MEDICARE DRUG DISCOUNT CARDS ³			"MEDICAID BEST PRICE" APPROXIMATION 340B ⁴
		MedCo	Advanced PCS	Argus Rx	
Lipitor 40 mg, 30 tabs	\$118	\$102	\$106	\$102	\$77
Synthroid .1 mg, 30 tabs	17	13	14	12	8
Norvasc 5 mg, 30 tabs	52	46	48	46	28
Toprol XL 50 mg, 30 tabs	28	24	26	24	11
Zoloft 50 mg, 30 tabs	91	78	81	78	48
Zocor 20 mg, 30 tabs	151	85	89	88	58
Ambien 10 mg, 30 tabs	101	87	95	95	36
Lexapro 20 mg, 30 tabs	81	69	73	69	46
Prevacid 30 mg, 30 caps	154	119	127	120	49
Total	\$793	\$623	\$659	\$634	\$361

All figures based on September 12, 2005, information.

1. These are nine of the ten brand-name drugs with highest retail sales in 2004. Zithromax Z-PAK not included here due to package comparability issues.
2. Average Wholesale Price (AWP) is the suggested list price for sales by a wholesaler to a pharmacy or other provider. Although it reflects more of a "sticker price" than an actual price, it is often used as a reference point.
3. The Medicare Modernization Act of 2003 created a transitional assistance program of discount cards available June 2004 through December 2005. Discount card sponsors' negotiations with drug companies benefit from an exemption from the Medicaid Best Price calculation.
4. Only federally designated clinics and hospitals may purchase drugs for outpatient use through the 340B program. They may dispense these drugs only to their own patients. See text accompanying footnote 19 on page 15 for information comparing 340B, Medicaid Best Price, and Medicaid Net Manufacturer Price with AWP.

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