AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 4, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 72

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

An act to add Chapter 9 (commencing with Section 119500) to Part 15 of Division 104 of the Health and Safety Code, relating to prescription drug trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as amended, Frommer. Prescription drugs: clinical trials.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would establish the Patient Safety and Drug Review Transparency Act in order to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. The bill would prohibit an institutional review board with responsibility for ensuring the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it (1) will register the clinical trial, no later than 21 days after ~~it begins~~ *its approval by the institutional review board*, with a government sponsored and public clinical trial registry, (2) will publish the results of the study, and (3) has complied with the registry and publication

requirements for any prior ~~study~~ *clinical trial* that was approved by the board.

~~This bill would prohibit the board from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board to comply with the above requirements. Prior to approval, the bill would require the board to review whether the sponsor, in prior approved studies, actually complied with those requirements.~~

The bill would provide that any sponsor who does not comply with the requirements it certified in writing is liable for a civil penalty of $1,000 per violation. The bill would authorize the Attorney General, a district attorney, or city attorney to bring an action against a sponsor to ~~recover civil penalties~~ *enforce compliance with its requirements*.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Chapter 9 (commencing with Section 119500)
2 is added to Part 15 of Division 104 of the Health and Safety
3 Code, to read:
4
5 CHAPTER 9. ~~INFORMATION REQUIRED FOR DRUG STUDIES~~
6 *PATIENT SAFETY AND DRUG REVIEW TRANSPARENCY*
7
8 119500. (a) This chapter may be referred to as the "Patient
9 Safety and Drug Review Transparency Act."
10 (b) The purpose of this act is to ~~assure~~ *ensure* that information
11 regarding clinical trials of prescription drugs is available to the
12 public, physicians, and researchers. Making information about
13 drug trials and their results available in a national, publicly
14 accessible database will improve the safety of human subjects
15 and provide all citizens of this state with complete safety
16 information about the prescription drugs they take.
17 (c) For purposes of this chapter, the following terms have the
18 following meanings:
19 (1) "Clinical trial" means a *Phase 2, 3, or 4* clinical
20 investigation as defined by the federal Food and Drug
21 Administration ~~that involves any experiment~~ to test the safety or
22 efficacy of a drug or biological product with one or more human

subjects and is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

(2) "Clinical trial registry" means a publicly available ~~databank~~ *database* established by the National Library of Medicine pursuant to 42 U.S.C. Section 282 (j).

(3) "Institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs by, among other things, reviewing, approving, and providing continuing review of trial protocol and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *The institutional review board is constituted under Subtitle A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations, to review and monitor research involving human subjects.*

(4) "Sponsor" means the manufacturer, or if the manufacturer provides no monetary support for the trial, the person who provides the majority of monetary support, or, where the majority funder is a state or federal agency, the principal investigator.

~~(d) An institutional review board shall not approve any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done or will do all of the following:~~

(d) A sponsor of a clinical investigation shall certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:

(1) Register the clinical trial, no later than 21 days after ~~it begins, by providing information necessary for publication in a government-sponsored~~ *approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored* and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

(2) Publish the ~~results of the study by providing the results of the study for publication~~ *summary results of the trial, whether positive or negative,* in a government sponsored and public clinical trial registry, in a manner required by regulations or other

guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services, *in a peer-reviewed medical journal,* or in another publicly accessible database.

(3) Complied with the provisions of paragraphs (1) and (2) for any prior ~~study~~ *clinical trial* that was approved by the board pursuant to this chapter.

~~(c) An institutional review board shall not approve any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board pursuant to this chapter to comply with the requirements it certified in writing under subdivision (d). Prior to approval, the board shall review whether the sponsor, in prior studies approved pursuant to this chapter, actually complied with those requirements.~~

~~(f) Any sponsor who does not comply with the requirements it certified in writing under subdivision (d) shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor is in violation shall be considered a separate violation. The Attorney General, a district attorney, or city attorney may bring an action against a sponsor to recover civil penalties for not complying with the requirements the sponsor certified in writing under subdivision (d).~~

(e) Any sponsor who does not comply with the requirements of this chapter within 30 days after receipt of written notice from the Attorney General, a district attorney, or a city attorney shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor remains in violation of this chapter after the conclusion of the 30-day period shall be considered a separate violation. The Attorney General, a district attorney, or a city attorney may bring an action against a sponsor to enforce compliance with the requirements of this chapter.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 72 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: CLINICAL TRIALS

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

This Bill:

1) Establishes the Patient Safety and Drug Review Transparency Act.

2) Defines the terms: "Clinical trial", "Clinical trial registry", "Institutional review board", and "Sponsor."

3) Requires a sponsor of a clinical investigation to certify to the relevant institutional review board and the Attorney General that the sponsor has done or will do all of the following:

a. Register the clinical trial, no later than 21 days after approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

b. Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, or other publicly accessible database.

c. Complied with the provisions of the measure for any prior clinical trial that was approved by the board.

5) Establishes a civil penalty of $1,000 per violation for any sponsor who does not comply with provisions of the bill. Each day a sponsor is in violation would be considered a separate violation.

(H&S 119500 Added)

Comment:

1) Author's Intent. The author's intent is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

2) History.

2005

June 2	Action rescinded and record expunged whereby the bill was read third time and whereby a final roll call vote was taken. To inactive file on motion of Assembly Member Frommer
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 13	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 10. Noes 3.) (April 12).
Apr. 5	Re-referred to Com. on HEALTH.
Apr. 4	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and JUD.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 72

As Amended May 26, 2005

ASSEMBLY THIRD READING

Majority vote

HEALTH 10-3 APPROPRIATIONS 11-5

Ayes:	Chan, Berg, Cohn, Dymally, Frommer, De La Torre, Jones, Montanez, Negrete McLeod, Ridley-Thomas	Ayes:	Chu, Bass, Berg, Karnette, Klehs, Leno, Nation, Oropeza, Ridley-Thomas, Saldana, Yee
Nays:	Aghazarian, Nakanishi, Strickland	Nays:	Sharon Runner, Emmerson, Haynes, Nakanishi, Walters

SUMMARY : Requires sponsors of clinical trials to certify that they have registered the clinical trials and that they will publish the results of the trial, whether positive or negative, as specified. Specifically, this bill :

1)Requires a sponsor of a clinical investigation to certify to the relevant institutional review board (IRB) and to the Attorney General (AG) that the sponsor has done or will do all of the following:

a) Register the clinical trial, no later than 21 days after approval of the clinical trial by IRB by providing information necessary for publication in a government sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Department of Health and Human Services (USHHS);

b) Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, in a manner required by regulations or other guidance established by the National Library of Medicine or the USHHS, in a peer-reviewed medical journal or in another publicly accessible database; and,

c) Comply with the provisions of a) and b), above, for any prior clinical trial that was approved by IRB pursuant to

this bill.

2)Makes a sponsor who does not comply with the requirements of this bill within 30 days receipt of written notice, as specified, liable for a civil penalty of $1,000 per violation. Makes each day a sponsor remains in violation of this bill after the conclusion of the 30-day period a separate violation. Permits the AG, a city attorney, or a district attorney to enforce compliance with the provisions of this bill.

3)Defines, for the purpose of this bill, the following terms: clinical trial, clinical trial registry, institutional review board, and sponsor.

FISCAL EFFECT : According to the Assembly Appropriations Committee, General Fund costs of approximately $150,000 to the Department of Justice (DOJ) to administer and enforce the provisions of this bill.

COMMENTS : According to the author, this bill would improve the safety of prescription drugs by ensuring that patients, physicians, and researchers could access information about the clinical trials that test the safety and effectiveness of those drugs. The author states that federal law dealing with clinical trials fails to require registration of all trials, does not penalize companies that fail to register their trials and does not mandate the publication of the results of these trials. The author believes that this bill will not only improve patient care, but could also reduce health care costs. According to the author, research has shown that publication bias (that is, that studies showing positive results are more likely to be published than studies showing negative results) leads to a bias toward new and more expensive treatment options. A clinical trial registry can help patients and doctors understand that in some cases less expensive treatment may be just as effective. Although federal legislation has been introduced to address some of these shortcomings, the author states that Congress shows little willingness to ensure that the public gets the information it needs about clinical trials. As a result, states must step in with legislation such as this bill.

Current state law does not require the registration of a clinical trial or the publication of the results of a trial. Congress, in the Food and Drug Administration Modernization Act (FDAMA) of 1997, required USHHS to establish a publicly accessible data bank of information about clinical trials for serious or life threatening diseases and conditions. FDAMA also requires the sponsors of investigational new drug applications to submit to the data bank a description of the purpose of each experimental drug, eligibility criteria for participation in the

trial, the location of clinical trial sites and a point of contact for people interested in enrolling in the trial.

To implement this law, the National Institutes of Health, through its National Library of Medicine, and the Food and Drug Administration (FDA) developed the ClinicalTrials.gov Web site in 2000 to serve as the data bank for clinical trial information. Despite the best efforts by FDA to inform drug manufacturers and drug trial sponsors of the FDAMA registration requirements, an FDA review published in 2004 found that:

1)Some pharmaceutical companies are not providing adequate information about their trials, for example, some trials are listed without identifying the sponsoring company or the drug being tested.
2)Some companies listed no trials and some listed only a few that follow FDA guidelines,
3)Only 48% of mandated industry-sponsored and 91% of mandated NIH cancer-related trials were registered.
4)For non-cancer trials, participation appeared to be in the single-digit range for some serious disease categories.

In June 2004, the American Medical Association (AMA) recommended that HHS create a comprehensive, centralized clinical trials registry. In 2004 the International Committee of Medical Journal Editors (ICMJE) published an editorial in the New England Journal of Medicine stating that ICMJE member journals will require, as a condition of consideration for publication, registration of the clinical trials being reported on in a public trials registry such as ClinicalTrials.gov, effective for any trial starting enrollment after July 1, 2005. The Congressional Research Service reports that the pharmaceutical industry's reaction to clinical trials reporting has been mixed, although as litigation and FDA and congressional interest have increased, some individual manufacturers and groups have volunteered to make some of their clinical trials data public.

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

AMENDED IN SENATE APRIL 18, 2005

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division 112 (commencing with Section 130600) to the Health and Safety Code, relating to pharmacy ~~assistance,~~ *assistance,* and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug ~~manufactures~~ *manufacturers* are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California *State* Pharmacy Assistance Program (Cal Rx) under the oversight of the department. The bill would authorize the department to implement and administer Cal Rx through a contract with a 3rd-party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department ~~or 3rd-party vendor~~ to attempt to negotiate ~~drug~~ *manufacturer* rebate agreements for Cal Rx with drug manufacturers. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to provide services under Cal Rx. The bill would establish eligibility criteria and application procedures for California residents to participate in Cal Rx. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. ~~The bill would authorize the department to terminate the program if any one of 3 determinations are made.~~

The bill would establish the California State Pharmacy Assistance Program Fund into which all payments received under Cal Rx would be deposited. The bill would continuously appropriate the fund to the department for purposes of Cal Rx.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Division 112 (commencing with Section
2 130600) is added to the Health and Safety Code, to read:
3
4 DIVISION 112. CALIFORNIA STATE PHARMACY
5 ASSISTANCE PROGRAM (CAL RX)
6
7 CHAPTER 1. GENERAL PROVISIONS
8
9 130600. This division shall be known, and may be cited, as
10 the California State Pharmacy Assistance Program or Cal Rx.
11 130601. For the purposes of this division, the following
12 definitions shall apply:
13 (a) "Benchmark price" means the price for an individual drug
14 or aggregate price for a group of drugs offered by a manufacturer
15 equal to the lowest commercial price for the individual drug or
16 group of drugs.
17 (b) "Cal Rx" means the California State Pharmacy Assistance
18 Program.
19 (c) "Department" means the State Department of Health
20 Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "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.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) ~~"Manufacturers~~ *"Manufacturer's* rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) *"Multiple-source drug" means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.*

(j) "National Drug Code" or "NDC" means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(k) "Participating manufacturer" means a drug manufacturer that has contracted with the department to provide an individual

drug or group of drugs for Cal Rx participants at a price that is equal to or lower than the benchmark price.

(l) "Participating pharmacy" means a pharmacy that has executed a pharmacy provider agreement with the department for Cal Rx.

(m) "Pharmacy contract rate" means the negotiated per prescription reimbursement rate for drugs dispensed to Cal Rx recipients.

(n) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only,"or words of similar import.

~~(j)~~

(o) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

~~(k)~~

(p) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

~~(l)~~

(q) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

~~(m) "Third-party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.~~

(r) "Therapeutic category" means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer. *An individual who has reached the annual limit on his or her outpatient prescription drug coverage provided by a third-party payer shall also be eligible for Cal Rx if he or she meets the eligibility requirements pursuant to paragraphs (1) and (2).*

(B) The Medi-Cal program.

(C) The children's health insurance program.

~~(D) The disability medical assistance program.~~

~~(E)~~

(D) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the ~~extent allowed by federal law, for prescription drugs not covered by Medicare.~~ *extent allowed by federal law and consistent with federal state pharmacy assistance program standards, for prescription drugs not covered by Medicare prescription drug coverage or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.*

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third-party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi-Cal program, children's health insurance program, or disability medical assistance program.

(D) The individual is no longer eligible for prescription drug coverage due to loss of employment and is not eligible for continued prescription drug coverage through the previous employer.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third-party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the ~~applicable form~~ *application form through a pharmacy, physician office, or clinic* is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx~~, through a Web site or call center staffed by trained operators approved by the department, or through the third-party vendor.~~. A pharmacy, physician office, clinic, or third-party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) *Application and annual reapplication may be made through a Web site or call center staffed by trained operators approved by the department.*

(f) The department or third-party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third-party vendor to enroll applicants in Cal Rx.

~~(f) During normal~~

(g) During the department's regular business hours, the department or third-party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third-party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

~~(g)~~

(h) For applications submitted through a pharmacy, the department or third-party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

(i) Any person that signs and dates an application shall certify that the information in the application is true under penalty of perjury.

130607. (a) *The department shall encourage a participating manufacturer to maintain the level of private discount drug programs provided at a comparable level to that provided prior to the enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.*

(b) The department or third-party vendor 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 those private discount drug programs.

~~(b)~~

(c) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

~~(c)~~

(d) For those drugs available pursuant to subdivision ~~(a)~~ *(b)*, the department or third-party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

~~(d)~~

(e) The recipient identification card issued pursuant to subdivision ~~(g)~~ *(h)* of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision ~~(a)~~ *(b)* and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions ~~(a)~~ *(b)* and ~~(d)~~ *(e)* of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b)

may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(d) The department may negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs pursuant to Division 2 (commencing with Section 5000) of Title 1 of the Corporations Code, for the purpose of conducting outreach for Cal Rx.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable ~~manufacturers~~ *manufacturer's* rebate.

(c) The department or third-party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third-party vendor.

(d) The department or third-party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third-party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third-party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third-party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

(h) A participating pharmacy is not precluded from offering the recipient a pharmacy contract reimbursement rate pursuant to subdivision (c) for prescription drugs produced by manufacturers not participating in Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the ~~department or third-party vendor shall attempt to negotiate drug~~ *department shall attempt to negotiate manufacturer* rebate agreements for Cal Rx with drug manufacturers. *The department shall pursue manufacturer rebate agreements for all drugs in each therapeutic category.*

~~(b) Each drug rebate agreement shall do all of the following:~~

(b) Each participating manufacturer rebate agreement executed pursuant to this division shall do all of the following:

(1) Specify which of the *participating* manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the *participating* manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

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

(7) Require the *participating* manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

~~(8) Permit a~~

(8) Require the participating manufacturer to report to the department the lowest commercial price at the NDC level for each drug available through Cal Rx.

(9) Require the participating manufacturer to pay interest on late or unpaid rebates pursuant to subdivision (h).

(10) Permit a participating manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(11) Contain provisions for the timely reconciliation and payment of rebates and interest penalties on disputed units.

(12) Permit the department to audit or review participating manufacturer records and contracts as necessary to implement this division.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) *To obtain the most favorable discounts on multiple-source drugs, the department may contract with private or public purchasing groups.*

(e) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

~~(e)~~

(f) The department or third-party vendor may collect prospective rebates from *participating* manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

~~(f) Drug rebate contracts negotiated by the third-party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.~~

(g) The third-party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third-party vendor.

(h) (1) A participating manufacturer shall calculate and pay interest on late or unpaid rebates.

(2) Interest described in paragraph (1) shall begin accruing 38 calendar days from the date of mailing the quarterly invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date the manufacturer's payment is mailed.

(3) Interest rates and calculations for purposes of this subdivision shall be at ____ percent.

(i) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for Cal Rx, in a manner designated by the department.

130619. (a) The department or third-party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third-party vendor shall deposit all payments received pursuant to Section 130618 into

the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, any interest earned on any rebates collected from participating manufacturers on drugs purchased through Cal Rx implemented pursuant to this chapter shall be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

~~130624. The department may terminate Cal Rx if the department makes any one of the following determinations:~~

~~(a) That there are insufficient discounts to participants to make Cal Rx viable.~~

1 ~~(b) That there are an insufficient number of applicants for Cal~~
2 ~~Rx.~~
3 ~~(c) That the department is unable to find a responsible~~
4 ~~third-party vendor to administer Cal Rx.~~
5 *(c) Drug rebate contracts entered into pursuant to this*
6 *division are exempt from disclosure under the California Public*
7 *Records Act (Chapter 3.5 (commencing with Section 6250) of*
8 *Division 7 of Title 1 of the Government Code).*
9 130625. Notwithstanding Chapter 3.5 (commencing with
10 Section 11340) of Part 1 of Division 3 of Title 2 of the
11 Government Code, the director may implement this division in
12 whole or in part, by means of a provider bulletin or other similar
13 instructions, without taking regulatory action.
14 SEC. 2. No reimbursement is required by this act pursuant to
15 Section 6 of Article XIII B of the California Constitution because
16 the only costs that may be incurred by a local agency or school
17 district will be incurred because this act creates a new crime or
18 infraction, eliminates a crime or infraction, or changes the
19 penalty for a crime or infraction, within the meaning of Section
20 17556 of the Government Code, or changes the definition of a
21 crime within the meaning of Section 6 of Article XIII B of the
22 California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 19 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: ORTIZ **SPONSOR: DEPT. OF HEALTH SERVICE GOVERNOR**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA Rx PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)

2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)

3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturer's rebate, prescription drug, private discount drug program, recipient, resident, third-party vendor, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, and therapeutic category. (H&S 130600 Added)

4. Establishes eligibility criteria for the program as:

   a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - $28,710 for an individual and $58,050 for a family of four)

   b. A family that does not have outpatient prescription drug coverage paid for in whole or in part by any of the following: a third-party payer, the Medi-Cal program, the children's health insurance program, or another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. (H&S 130605Added)

5. Set a yearly fee of $15 for application or reapplication for the program. (H&S 130606 Added)

6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program.

(H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturer's rebate. (H&S 130616 Added)

Comment:

1) Author's Intent. This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide $10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those 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 twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have 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. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

5) Support / Opposition.

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
CA Academy of Family Physicians
CA Arthritis Foundation Council
CA Black Chamber of Commerce
CA Council of Community Mental Health Agencies
CA Healthcare Institute
CA Hepatitis C Task Force
CA Latino Medical Association
CA Medical Association
CA Pharmacists Association
CA Psychiatric Association
CA Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network
Novartis

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Opposition: California Alliance for Retired Americans
California Federation of Teachers
California School Employees Association, AFL-CIO
International Alliance of Theatrical State
Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States
Amalgamated Transit Union Local 1555
Unless American Federation of Government Employees, Local 1061
American Federation of State, County, & Municipal Employees
American Federation of Television and Radio Arts
Butchers' Union Local 120
CA Conference Board of the Amalgamated Transit Union
CA Conference of Machinists
CA Labor Federation,
CA Nurses Association
CA Professional Firefighters
CA Public Interest Research Group
CA Teamsters Public Affairs Council
Central Labor Council of Butte, Contra Costa, and Glenn Counties
Consumer Federation of California
Communications Workers of America (CWA), Local 9412
CWA, Locals 9415, 9423, 9431, 9503, and 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Greenlining Institute
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers, District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569
International Cinematographers Guild Local 600
Ironworkers Locals 433 and 509
Kern County Fire Fighters Union Inc.
Laborers' International Union of North America
Laborers' International Union of North America, Local 89
League of United Latin American Citizens
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific
San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council

San Mateo County Central Labor Council Santa Clara & San Benito Counties
Building & Construction Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Locals 660, 1280, and 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Unions 104 and 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Unions 683 and 896
Teamsters Locals 912and 853
Teamsters Union Locals 572, 601, and 630
Transport Workers Union of America, AFL- CIO
Tri-Counties Central Labor Council
UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49
United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles

6) History.

2005

May 4	Hearing postponed by committee.
Apr. 28	Set for hearing May 4 pending suspension of rules.
Apr. 27	Set, first hearing. Failed passage in committee. (Ayes 5. Noes 5. Page 845.) Reconsideration granted.
Apr. 21	Set for hearing April 27.
Apr. 20	Hearing postponed by committee.
Apr. 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 14	Set for hearing April 20.
Apr. 13	Testimony taken. Hearing postponed by committee.
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.

2004

Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.

BILL ANALYSIS
SB 19

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

AUTHOR: Ortiz
AMENDED: April 18, 2005
HEARING DATE: April 20, 2005
FISCAL: Appropriations

CONSULTANT: Bohannon / ak

TESTIMONY TAKEN - VOTE ONLY

SUBJECT

California Rx Program

SUMMARY

This bill would establish the California State Pharmacy Assistance Program (Cal Rx), a state pharmacy assistance program under the authority of the Department of Health Services (DHS), to provide prescription drug discounts for California residents with income up to 300% of the federal poverty level (FPL).

ABSTRACT

Existing federal law:

1. Requires, for the purposes of the federal Medicaid program, drug manufacturers to enter into rebate agreements with the United States Secretary of Health and Human Services (the Secretary) for states to receive federal funding for outpatient prescription drugs dispensed to Medicaid enrollees.

2. Defines Medicaid "best price" as the lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments, excluding nominal prices.

3. Requires manufacturers under agreement with the Secretary to provide rebates to state Medicaid agencies for outpatient prescription drugs provided to Medicaid beneficiaries. For brand name drugs, requires the amount of the rebate owed to be the greater of 15.1% of the average manufacturers price (AMP) or the difference between AMP and the best price. Requires rebates for

generic drugs to be 11% of AMP.

4. Excludes the prices charged to certain governmental purchasers from best price provisions including prices charged to the Veterans Administration, Department of Defense, Indian tribes, Federal Supply Schedule, state pharmaceutical assistance programs (SPAPs), Medicaid, and 340B covered entities.

5. Permits a state, upon authorization from the Secretary, to enter directly into agreements with drug manufacturers to negotiate deeper (supplemental) discounts for state Medicaid programs.

6. Specifies that a state may require, as a condition of coverage or payment for a covered outpatient drug, the approval of the drug before its dispensing if the system of providing for such approval meets specified criteria.

Existing federal guidance:

1. Authorizes states to establish SPAPs for the purposes of providing pharmaceutical benefits for low-income non-Medicaid eligible residents.

2. Establishes the following criteria for federal SPAP designation:

   The program is a state developed program specifically for 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 so that payment is provided
   The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefit or services; and,

   The program does not allow for the diversion, resale or transfer of benefits reimbursed under the SPAP to individuals who are not beneficiaries of the SPAP.

Existing state law:

1. Establishes the Medi-Cal program, California's Medicaid program, which provides health insurance coverage and prescription drug benefits for low-income families, children, and aged, blind, and disabled individuals.

2. Authorizes DHS to be the purchaser of prescribed drugs

under the Medi-Cal program in order to obtain the most favorable prices from drug manufacturers. Authorizes DHS to obtain discounts, rebates, or refunds based on the quantities purchased by the program, as permissible by federal law.

3. Defines "state rebate" as any negotiated rebate under the Drug Discount Program (Medi-Cal) in addition to the Medicaid rebate.

4. Authorizes DHS to enter into contracts with drug manufacturers, on a bid or nonbid basis, for drugs from each therapeutic category and requires DHS to maintain a list of those drugs for which contracts have been executed.

5. Authorizes DHS or the state's fiscal intermediary to impose prior authorization requirements on the drug products of manufacturers for which DHS has not received rebate or interest payments as specified.

6. Exempts specified drugs from prior authorization requirements and authorizes the director of DHS to exempt any drug from prior authorization if it is determined that an essential need exists for that drug and there are no other drugs available without prior authorization that meet that need.

7. Requires all manufacturers to provide DHS with a state rebate, in addition to rebates pursuant to other provisions of state or federal law, for any drug products added to the Medi-Cal list of contract drugs and those reimbursed through the Medi-Cal outpatient fee-for-service drug program. Renders this provision inoperative on July 1, 2005 and repealed January 1, 2006, unless otherwise extended or repealed.

8. Authorizes DHS to use existing administrative mechanisms for any drug for which DHS does not obtain a rebate.

9. Provides that no beneficiary be denied continued use of a drug that is part of a prescribed therapy that is the subject of an administrative mechanism until the prescribed therapy is no longer prescribed.

This bill:

1. Establishes Cal Rx, a SPAP, under the authority of DHS.

2. Provides that to be eligible for Cal Rx, individuals must meet all of the following requirements:
   Be a resident;

Have family income that does not exceed 300% of FPL;

Not have outpatient prescription drug coverage paid for in part or in whole by a third-party payer (exempts individuals who have reached the annual cap on their prescription drug coverage), the Medi-Cal program, the children's health insurance program, another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of an individual's outpatient prescription drug costs.

Medicare beneficiaries may participate to the extent allowed by federal law and SPAP standards for prescription drugs not covered by Medicare prescription drug coverage or those currently responsible for paying 100% of the cost of a prescription drug under the coverage gap provisions of the Medicare prescription drug benefit.

Not have had outpatient prescription drug coverage during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, with certain exceptions.

1. Requires application and annual reapplication and establishes program application criteria and procedures. Specifies that the application and annual reapplication fee due upon submission through a pharmacy, physician office, or clinic is $15.

2. Requires DHS to use the income information reported on the application and not require additional documentation.

3. Authorizes a pharmacy, physician office, or clinic to keep the fee as reimbursement for its processing costs. The fee shall be returned to the applicant if the applicant is already enrolled in Cal Rx.

4. Specifies that application and annual reapplication may also be made through a Web Site or call center staffed by trained operators approved by DHS.

5. Requires DHS or a third party vendor to utilize a secure electronic application process that can be utilized to enroll applicants in Cal Rx.

6. Requires DHS or a third party vendor, during regular business hours, to make an eligibility determination within 4 hours of receipt of a Cal Rx completed application.

7. Requires applicants to certify under penalty of perjury that the information in the application is true.

8.Requires DHS to encourage participating manufacturers to maintain their private discount drug programs at a level comparable to which they were offered prior to the enactment of Cal Rx and, to the extent possible, simplify the application and eligibility processes for those programs.

9.Requires DHS or a third party vendor to 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 those programs.

10. Prohibits an applicant from having to disclose information that would determine eligibility for a private drug discount program in order to participate in Cal Rx.

11. Requires DHS or a third party vendor to develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private drug discount programs.

12. Requires the recipient to be issued an identification card, which shall meet the legal requirements for a uniform prescription drug card.

13. Requires DHS to conduct outreach programs to the extent that funds are available. Prohibits the outreach material from containing the name or likeness of a drug. Specifies that the name of the organization sponsoring the material may appear on the material once and in a font no larger than 10 point.

14. Allows DHS to accept, on behalf of the state, any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Exempts these gifts and advertisements provided as gifts as specified.

15. Authorizes DHS to negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs for the purpose of conducting outreach for Cal Rx.

16. Authorizes any licensed pharmacy and manufacturer, as defined, to participate in Cal Rx.

17. Specifies that the amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract

rate, as defined, plus a dispensing fee, less the applicable manufacturers rebate.

18. Requires DHS or a third party vendor to provide a claims processing system as specified.

19. Requires DHS to attempt to negotiate manufacturer rebate agreements for Cal Rx with drug manufacturers. Requires DHS to pursue manufacturer rebate agreements for all drugs in each therapeutic category.

20. Requires each participating manufacturer rebate agreement to:

Specify which drugs are included in the agreement.

Permit DHS to remove a drug from the agreement in a dispute over the drug's utilization.

Require the manufacturer to make a rebate payment for each drug specified.

Require the rebate payment for a drug be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

Define a unit, for the purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

Require the manufacturer to make the rebate payments to DHS on at least a quarterly basis.

Require the manufacturer to provide documentation to validate the per unit rebate.

Require the manufacturer to report to DHS the lowest commercial price, as specified, for each drug available through Cal Rx.

Require the manufacturer to pay interest on late or unpaid rebates.

Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx.

Contain provisions for the timely reconciliation of payment of rebates and interest penalties on disputed units.

Permit DHS to audit or review manufacturer records and contracts as necessary.

1.Authorizes DHS to limit the number of drugs available within Cal Rx to obtain the most favorable discounts.

2.Authorizes DHS to contract with private or public purchasing groups to obtain the most favorable discounts

3.Requires the entire amount of the negotiated drug rebates to go towards reducing the cost to Cal Rx recipients of purchasing drugs.

4. Authorizes DHS or a third party vendor to collect prospective rebates from manufacturers for payment to pharmacies. Authorizes a third party vendor to directly collect rebates from manufacturers in order to facilitate the payment to pharmacies. Requires DHS to develop a system to prevent the diversion of funds.

5. Requires participating manufacturers to calculate and pay interest on late or unpaid rebates, which shall begin accruing 38 calendar days from the date of mailing the quarterly invoice.

6. Specifies that interest rates and calculations shall be "X" percent.

7. Requires participating manufacturers to clearly identify all rebates, interest, and other payments for Cal Rx in a manner designated by DHS.

8. Requires DHS or a third party vendor to generate a monthly report as specified.

9. Establishes the California State Pharmacy Assistance Program Fund in the State Treasury and requires DHS or a third party vendor to deposit all payments received as specified.

10. Specifies that moneys in the fund are appropriated to DHS without regard to fiscal years for the purpose of providing payment to participating pharmacies and for defraying the costs of administrating Cal Rx. Specifies that no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

11. Requires that interest earned on rebates collected from participating manufacturers also be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

12. Authorizes DHS to hire any staff needed for the implementation and oversight of Cal Rx.

13. Requires DHS to seek and obtain confirmation from the Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a SPAP.

14. Exempts contracts and change orders entered into from competitive bidding requirements and specified provisions of the Public Contract and Government Codes.

15. Specifies that change orders entered into shall not require contract amendment.

16. Exempts drug rebate contracts entered into from disclosure under the Public Records Act.

17. Permits the director to implement this division in whole or in part by means of provider bulletin or other similar instructions, without taking regulatory action.

18. Requires that no reimbursement be required pursuant to Section 6 of Article XIII B of the California Constitution.

FISCAL IMPACT

The Governor's FY 05-06 budget plan for DHS appropriates $3.9 million dollars from the General Fund for program staff and administrative costs. Unknown one-time costs associated with the timing of rebates and initial payments to pharmacies.

BACKGROUND AND DISCUSSION

Rising prescription drug costs
As a number of studies document, access to affordable prescription drugs is a growing problem in California and in the US. According to the Kaiser Family Foundation (KFF), almost a quarter of Americans under age 65 have no prescription drug coverage. In California, according to the UCLA Center for Health Policy Research, nearly one in five Californians under age 65 lacked health coverage altogether in 2001, a substantial percentage of whom are not eligible for most public assistance or drug assistance programs due to excess income or assets. Of those who do have health coverage, over 2 million report that they do not have coverage for prescription drugs.

Further, prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow at roughly twice the rate of inflation in California and the rest of the U.S. Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was $1,439. The five most frequently prescribed medications for the elderly all had annual costs of between $500 and $1,500 per year. According to surveys, substantial percentages of seniors forego taking their medications due to the high cost.

Canadian importation
In an effort to facilitate immediate access to affordable

prescription drugs for seniors and people with disabilities, several members of the legislature introduced bills that would have allowed the importation of prescription drugs from Canada in some capacity. Although it is currently illegal, an estimated 1 million Americans buy drugs from Canada, accounting for at least $1 billion in annual sales. According to various sources, comparable drugs in Canada sell for 40 percent less than in the U.S. on average, and can sometimes sell for 50 - 70 percent less, because the Canadian government limits what drug companies can charge for prescription drugs. In addition, exchange rates can contribute to lower costs of Canadian drugs.

The Food and Drug Administration's (FDA) consistent policy has been that foreign medicines are unsafe because they cannot assure that they are not counterfeit, mislabeled, expired, or contaminated. Although it cannot point to cases in which US residents have been harmed by drugs purchased from foreign pharmacies, the FDA cites evidence from several border checks of drugs bound for consumers in the US that have found large percentages of unidentified drugs, counterfeit drugs, mislabeled drugs, and drugs not approved for use in the U.S.

The FDA has adopted a personal importation policy which permits individuals and physicians to import up to a three-month supply of drugs for treatment of a patient's condition for which effective treatment may not be available domestically, which do not present an unreasonable risk, and for which there is no intent to market to U.S. residents. In practice, the FDA generally has not prosecuted individuals who are importing drugs for their own use.

In a letter dated August 19, 2004, the Secretary of the Health and Human Services Agency expressed concern that the importation measures were contrary to federal law and would expose the state to potential tort liability. As an alternative approach, the Secretary proposed amending the bills to establish a SPAP to harness the purchasing power of low-income seniors and uninsured Californians to secure prescription drug discounts from pharmaceutical manufacturers.

Governor Arnold Schwarzenegger, subsequently, sent a letter to Tommy Thompson, Secretary of the U.S. Department of Health and Human Services, detailing his concern with the Canadian drug importation legislation and expressing his desire to reduce the costs of prescription drugs by establishing a drug discount program or by extending

Medi-Cal prescription drug prices to targeted low-income uninsured residents.

On September 21, 2004, the Senate Health and Human Services Committee held an informational hearing on the Administration's pharmacy assistance proposal where representatives from DHS provided a detailed overview of the proposal including the estimated discounts, number of enrollees, and timeline for implementation. The committee also heard extensive testimony from representatives from senior and consumer advocacy organizations who believed the administration's proposal needed considerably more work before it could provide the band of discounts available under a Canadian importation model.

State Pharmaceutical Assistance Programs (SPAPs)
SPAPs refer to a broad category of state policies designed to help residents pay for prescription drugs. States submit program proposals meeting specified criteria to the federal government in order to receive a SPAP designation. This designation incentivizes manufacturer participation by exempting the prices the state negotiates for program beneficiaries from Medicaid "best price" laws, thereby allowing the state to negotiate deeper drug discounts. As of August 2004, at least 39 states have 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. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number use discounts or bulk purchasing approaches. Many of these programs were established prior to the enactment of the Medicare prescription drug benefit and provide an opportunity for states to provide "wrap around" coverage to Medicare beneficiaries who will be receiving prescription drug benefits under Medicare. SPAPs usually provide discounts using the following mechanisms:

Medicaid Rate. Enrollees will pay no more than the state's Medicaid price. An additional pharmacy dispensing fee may be added to the drug price, but that is generally set by the program and, therefore, the same across all pharmacies. Enrollees will pay the same amount for a particular manufacturer's drug at all pharmacies that participate in the program.

Manufacturer Rebates. Some states will negotiate directly with manufacturers for lower drug prices. These states then set a drug price for program enrollees that are based on the state-negotiated price.

Medicaid Rebate. The drug discount is based on the manufacturers' rebates through the state's Medicaid programs.

Pharmacy Benefits Manager (PBM)-Negotiated Rate. The PBMs negotiate discounts with manufacturers and pharmacists. If the state uses multiple PBMs, the discounted price will vary.

Maine and the Medicaid "Hammer"
Maine's Act to Establish Fairer Prices for Prescription Drugs was enacted in 2000, and established the MaineRx program, which was open to all residents who did not have prescription drug coverage. Under MaineRx, the state was to serve as a PBM by negotiating rebates and discounts, with the discount offered by pharmacies being reimbursed by the state out of funds raised from participating manufacturer rebates.

Pharmacy participation was voluntary, but compulsory for manufacturers with Medicaid contracts in the state. MaineRx provided disincentives for nonparticipating manufacturers, such as subjecting their drugs to prior authorization requirements in the state Medicaid program (the "hammer") and advertising their refusal to participate to health care providers and the public.

MaineRx was immediately challenged by the pharmaceutical industry. PhRMA sued the state, won a preliminary injunction from the federal district court, and then lost a subsequent appeal by the state before a federal court of appeals panel. In particular, the appellate court rejected PhRMA's argument that MaineRx's prior authorization requirement was inconsistent with federal Medicaid law. The appellate court further found that the local benefits of the program outweighed any incidental burdens on interstate commerce. In July 2001, PhRMA asked the U.S. Supreme Court to review the decision.

On May 19, 2003, the U.S. Supreme Court ruled 6 to3 that the MaineRx Program was not preempted because the Medicaid Act "gives the States substantial discretion to choose the proper mix of amount, scope and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." The Court also ruled that the MaineRx statute on its face did not violate the Interstate Commerce Clause.

The legislature revised MaineRx soon after the Supreme Court acted by creating the MaineRx Plus program. The new

program requires participating pharmacies to provide drugs that are on Maine's Medicaid preferred drug list to state residents whose family income is 350% or less of the FPL or whose family incurs unreimbursed prescription drug expenses equal to 5% or more of family income or unreimbursed medical expenses of 15% or more of family income.

As of January 2004, pharmacies began providing drugs to MaineRx Plus participants at the same cost as Medicaid participants pay. If the state is able to negotiate further discounts, pharmacies must offer the drugs at this lower price, and the state must reimburse them for the price difference. The new program does not include the $3 dispensing fee that pharmacies were to receive under MaineRx.

The MaineRx law required the state to impose prior authorization requirements in its Medicaid program on drug manufacturers and drug labelers that did not participate in the program. MaineRx Plus softens this somewhat, by removing the mandatory requirement and instead granting the state the authority to impose prior authorization if DHS determines that doing so is an appropriate way to encourage manufacturer participation and is consistent with the state Medicaid plan and federal law. It makes the names of manufacturers and labelers who do not provide rebates public information and requires DHS to release them to the public and health care providers. The names of manufacturers and labelers who provide rebates also become public, and DHS is supposed to publicize their participation. As with MaineRx, the manufacturers' rebates are to be paid into a dedicated fund that is used to reimburse pharmacies for the drug discounts and DHS for contracted services related to the program, including pharmacy claims processing fees.

In January 2005, the Federal District Court in Maine ruled that under the legal doctrine of "ripeness," it would be premature to conclude that the permissive prior authorization scheme in MaineRx Plus in any way violates federal Medicaid law; that we cannot know this unless and until it is actually applied and we can factually determine whether any Medicaid beneficiaries were hurt by its use. The court stated that since the Maine statute explicitly requires prior authorization be implemented only "as permitted by law" and "in a manner consistent with the goals of the MaineCare program and the requirements of the Social Security Act," it is possible for Maine to implement its prior authorization without violating the law. The court concluded that while the Maine program was not

reviewable at this time, due to lack of ripeness, it remains subject to review by the Secretary of Health and Human Services at the appropriate time.

Arguments in support
Supporters of the bill, including AARP, the California Medical Association, and several disease management groups across the state insist that SB 19 is an important first step in providing significant and immediate relief to those who are paying the highest costs for their prescription drugs. They insist that the proposal will deliver discounts of 40% to 70% off the retail price of prescription drugs and provide nearly 5 million low-income Californians better access to private drug discount programs which often offer free or deeply discounted prescription drugs.

They believe that Cal Rx is an essential element in the complex care system that will support the needs of seniors and persons with disabilities and chronic conditions who have reduced incomes due to their limited ability to work or in the case of those who are dependant, limited income due to family members who must give their own jobs in order to be caregivers. They insist that the discounts this proposal contemplates should be given the opportunity to materialize before more aggressive measures that could potentially risk the health and well-being of our most vulnerable seniors, children, and persons with disabilities are pursued. They believe that SB 19 is the only legislative proposal that provides the best hope of being implemented quickly and with relatively low risk of litigation.

Arguments in opposition
Opponents of SB 19 raise the following concerns:

1.Lowest commercial price as a benchmark
Opponents believe the lowest commercial price is a fictitious price that is not commonly known and has not been adequately referenced in the bill. They insist that SB 19 should include a more commonly recognized benchmark price such as the Medicaid price for DHS to target in drug company negotiations. They insist that using the Medicaid price would also reduce the administrative overhead required, since the prices of the Medi-Cal program are already known to the state.

2.Income eligibility
Opponents insist that given California's high cost of living, SB 19's income eligibility should be expanded to cover individuals with income up to 400% of the federal

poverty level. They insist that many Californians most in need of drug discounts are those who are sick and underinsured. They also believe that individuals who spend significant portions of their incomes on medications also deserve discounted prices.

3.Drug availability
Opponents of the bill argue that SB 19 allows pharmaceutical manufacturers to determine which drugs will be included in the discount program and for what period of time. They believe SB 19 contains no assurance that the drugs that are the highest cost to the uninsured or the most frequently needed by affected populations will be included.

4.Outreach
Opponents of the bill believe that it is problematic to allow DHS to accept branded outreach materials from drug manufacturers for use in a public health program.

5.Lack of Medicaid leverage or "hammer"
Opponents of SB 19 insist that participation by pharmaceutical manufacturers and pharmacists is entirely voluntary leaving the state without a mechanism to punish those who fail to provide drug discounts. They insist that the bill's exclusive reliance on voluntary participation provides little assurance that any drug discounts the state is able to secure will be maintained. They believe that rather than relying on voluntary participation, SB 19 should be amended to allow the state to impose prior authorization requirements in the Medi-Cal program if a drug manufacturer refuses to offer meaningful discounts in Cal Rx.

Prior / relevant legislation
AB 73 (Frommer, 2005) provides information to consumers about international pharmacies that meet state standards for safety and accessibility. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 75 (Frommer, 2005) establishes a state pharmacy assistance program for Californians with income up to 400% of the federal poverty level. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 76 (Frommer, 2005) consolidates drug purchasing for state programs to negotiate lower drug prices. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 77 (Frommer, 2005) creates a pilot program for the

California Department of Corrections to purchase prescription drugs at federal discount prices. Set for hearing in the Assembly Health Committee on April 12, 2005.

SB 1333 (Perata, 2004) allowed DHS to reimburse pharmacies for drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that were purchased from a Canadian pharmacy, and established a new reimbursement rate for such drugs. Vetoed by the Governor.

SB 1144 (Burton, 2004) required Canadian sources be included among the companies with which the Department of General Services (DGS) is permitted to contract for prescription drugs, that all contracts include appropriate safeguards, and that DGS seek appropriate federal waivers. Vetoed by the Governor.

SB 1149 (Ortiz, 2004) required the Board of Pharmacy to develop a website that included information on Canadian pharmacies that met recognized standards for safe dispensing of drugs to California residents and information concerning prescription drugs suppliers outside the United States that violated safe dispensing standards. Vetoed by the Governor.

AB 1957 (Frommer, 2004) required DGS to coordinate a review of state agencies to determine potential savings if prescription drugs were purchased from Canada and to establish pilot programs. Required DHS to establish a California Rx Program, including a website to facilitate purchasing prescription drugs at reduced prices. Required the website to include price comparisons, including Canadian prices and links to Canadian pharmacies. Vetoed by the Governor.

QUESTIONS AND COMMENTS

1.The Maine Mystery. The MaineRx Plus program is widely regarded as the vanguard of prescription drug policy at the state level; however the success of MaineRx Plus remains ambiguous. It is currently unclear what level of discounts the program has been able to secure on brand name and generic drugs and to what extent those discounts are derived from manufacturer rebates. Additionally, it is also uncertain whether or not Maine's "hammer", their statutory authority to place the drugs of non-MaineRx Plus-participating manufacturers on prior authorization in the state Medicaid program, has encouraged or discouraged manufacturer participation.

According to the Legislative Analyst's Office (LAO), Maine's program has secured rebates with 20 drug companies for 200 drugs with prices up to 60% below the retail pharmacy price. However, other sources indicate that the state has only secured discounts of up to 15% for brand name drugs and 60% for generics through voluntary agreements with drug manufacturers, while others maintain that the state has not begun negotiating with drug manufacturers at all.

What is clear, however, is that MaineRx Plus is not an SPAP. Arguably, federal SPAP designation is the "hammer" that incentivizes manufacturer participation and allows states to negotiate deep discounts. If California is able to secure SPAP designation for Cal Rx, the program could negotiate discounts far below what MaineRx Plus is currently able to provide. The LAO recommends a "hybrid hammer" approach whereby, the state would move forward with a voluntary program, but would require the director of DHS to automatically phase out the voluntary model if drug manufacturers fail to participate. In such a circumstance, the eligibility standard for the program would automatically be expanded to 400% of the federal poverty level.

Should this bill be amended to include benchmark and accountability measures to measure manufacturer participation and program discounts over time and to determine whether a more stringent approach is needed?

If such leverage could increase manufacturer participation, secure significantly deeper discounts, and be implemented in such a way that it is consistent with federal law and the goals of the Medicaid program, including preserving prescription drug access for the most vulnerable Medi-Cal beneficiaries, without jeopardizing federal SPAP designation, should it be considered for this proposal?

1. Income Eligibility and Catastrophic Coverage. While 300% of the federal poverty guideline covers more than 75% of California's uninsured, arguably some provision should be made for individuals with higher incomes who, because of chronic conditions, must spend a disproportionate amount of their family income on unreimbursed medical expenses or prescription drug costs. MaineRx Plus extends eligibility to all residents whose family incurs unreimbursed prescription drug expenses and unreimbursed medical expenses equal to 5% and 15% or more of family income, respectively.

California's AIDS Drug Assistance Program (ADAP), an SPAP for individuals infected with HIV/AIDS, sets program eligibility at 400% of the FPL. ADAP establishes state precedent for moving beyond 300% of the FPL due to exorbitant prescription drug costs and medical necessity.

Federal SPAP designation requires that a program be means tested and specifically designed to serve low-income vulnerable populations. While Maine's generous catastrophic coverage provision would probably not meet federal approval, the author may wish to consider including some form of catastrophic coverage, within the bounds of federal SPAP criteria, to expand program eligibility to this population.

POSITIONS

POSITIONS

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
CA Academy of Family Physicians
CA Arthritis Foundation Council
CA Black Chamber of Commerce
CA Council of Community Mental Health Agencies
CA Healthcare Institute
CA Hepatitis C Task Force
CA Latino Medical Association
CA Medical Association
CA Pharmacists Association
CA Psychiatric Association
CA Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network
Novartis

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Oppose:
California Alliance for Retired Americans
California Federation of Teachers
California School Employees Association, AFL-CIO
International Alliance of Theatrical State
Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States
Amalgamated Transit Union Local 1555
Unless American Federation of Government Employees, Local 1061
American Federation of State, County, & Municipal Employees
American Federation of Television and Radio Arts
Butchers' Union Local 120
CA Conference Board of the Amalgamated Transit Union
CA Conference of Machinists
CA Labor Federation,
CA Nurses Association
CA Professional Firefighters
CA Public Interest Research Group
CA Teamsters Public Affairs Council
Central Labor Council of Butte, Contra Costa, and Glenn Counties
Consumer Federation of California
Communications Workers of America (CWA), Local 9412
CWA, Locals 9415, 9423, 9431, 9503, and 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Greenlining Institute
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers, District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569
International Cinematographers Guild Local 600
Ironworkers Locals 433 and 509
Kern County Fire Fighters Union Inc.
Laborers' International Union of North America
Laborers' International Union of North America, Local 89
League of United Latin American Citizens
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific

San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council
San Mateo County Central Labor Council Santa Clara & San Benito Counties Building & Construction Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Locals 660, 1280, and 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Unions 104 and 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Unions 683 and 896
Teamsters Locals 912and 853
Teamsters Union Locals 572, 601, and 630
Transport Workers Union of America, AFL- CIO
Tri-Counties Central Labor Council
UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49
United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles

AB 522

As Amended June 23, 2005

SENATE COMMITTEE ON PUBLIC SAFETY
Senator Elaine K. Alquist, Chair A
2005-2006 Regular Session B
Penal, Welfare and Institutions Codes (URGENCY)

REGISTERED SEX OFFENDERS :
MEDI-CAL COVERAGE FOR SPECIFIED CONDITIONS
HISTORY

Source: Health and Human Services Agency; Department of Health Services
Prior Legislation: None
Support: California Department of Corrections
Opposition:None known
Assembly Floor Vote: N/A

KEY ISSUES

SHOULD THE Department of Health Services ("DHS") BE PROHIBITED from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders, as specified?

SHOULD THE Department of Justice BE AUTHORIZED TO share information with DHS concerning registered sex offenders for this purpose, as specified?

PURPOSE

The purpose of this bill is to 1) prohibit the Department of Health Services ("DHS") from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders, as specified; 2) authorize the Department of Justice to share information with DHS concerning registered sex offenders for this purpose, as specified; and 3) make unrelated substantive changes to the law concerning pharmacy services.

Current law generally requires people who have been convicted of specified sex offenses to register at least annually with the chief of police of the city in which he or she is residing, or the sheriff of the county if where he or she is residing is located in an unincorporated area or city that has no police department, and, additionally, with the chief of police of a campus of the University of California, the California State University, or community college if he or she is residing upon the campus or in any of its facilities, within five working days of coming into, or changing his or her residence within, any city, county, or city and county, or campus in which he or she temporarily resides, for the rest of his or her life while

residing in California, or while attending school or working in California, as specified. (Penal Code 290.)

Current law expressly provides that except as specifically allowed, the statements, photographs, and fingerprints required by this provision shall not be open to inspection by the public or by any person other than a regularly employed peace officer or other law enforcement officer. (Penal Code 290(i).)

Under current law , the Department of Justice ("DOJ") is required to make information about registered sex offenders available to the public via an Internet Web site, as specified. (Penal Code 290.46.)

Current law specifically provides that except as authorized, use of any information that is disclosed pursuant to these provisions for purposes relating to any of the following is prohibited:

Health insurance;
Insurance;
Loans;
Credit;
Employment;
Education, scholarships, or fellowships;
Housing or accommodations; and
Benefits, privileges, or services provided by any business establishment. (Penal Code 290.469j)(2).)

Current law provides that the Medi-Cal Benefits Program comprises a department-administered uniform schedule of health care benefits. (Welfare and Institutions Code ("WIC") 14131; see 14132.) Current law provides that the "purchase of prescribed drugs is covered subject to the Medi-Cal List of Contract Drugs and utilization controls." (WIC 14132(d).)

This bill would provide that, notwithstanding any other law, DHS "shall not provide or pay for any prescription drug or other therapy to treat erectile dysfunction for any person who is required to register pursuant to Section 290 of the Penal Code, except to the extent required under federal law."

This bill would provide that DHS "may require from the Department of Justice the information necessary to implement this section."

This bill would provide that, "notwithstanding any other law, DOJ would be required to provide, upon written request, the names and relevant information pertaining to persons who are required to register pursuant to Section 290 to any state

governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of those persons. State governmental entities shall use information received pursuant to this section to protect public safety by preventing the use of prescription drugs or other therapies to treat erectile dysfunction by convicted sex offenders."

This bill would provide that the use "or disclosure of the information obtained pursuant to this section is prohibited for any purpose other than authorized," as specified in this bill.

This bill would authorize DOJ to establish a fee for requests including all actual and reasonable costs associated with the service.

This bill additionally would provide that "(n)otwithstanding any other law, any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction may use the sex offender data base authorized by Section 290.46 (the Megan's Law Web site) to protect public safety by preventing the use of such drugs or therapies to convicted sex offenders."

This bill is an urgency measure.

COMMENTS

1. Stated Need for This Bill

The author states:

> AB 522 would give state agencies access to the information necessary to ensure that taxpayers do not finance erectile dysfunction treatments for known sex offenders. Federal guidelines prohibit state Medicaid programs (Medi-Cal in California) from covering erectile dysfunction treatments for convicted sex offenders, and California could be subject to financial penalties if Medi-Cal does not comply with these guidelines. Without access to the registered sex offender database, state agencies will have no way of knowing if a beneficiary should be denied access to such treatments.
>
> As Governor Schwarzenegger correctly noted in his executive order on May 26, 2005, this is also a public safety issue. We have an obligation to exercise an abundance of caution and ensure that state agencies have access to the criminal databases necessary to prevent the use of these treatments by

known sex offenders.

2. What This Bill Would Do

As explained in detail above, this bill would prohibit DHS from providing or paying for any prescription drug or therapy to treat erectile dysfunction for a registered sex offender. The bill would provide a mechanism for DHS to access, either by using the Megan's Law Web site or obtaining information from DOJ, information from DOJ identifying persons who are registered sex offenders. This bill also would authorize DOJ to establish a fee for its costs associated with providing this information.

3. Background - Medicaid, Erectile Dysfunction Drugs and Registered Sex Offenders

Numerous press accounts this Spring reported that registered sex offenders in at least 14 states got Medicaid-paid prescriptions for Viagra and other prescription drugs used to treat erectile dysfunction. In response to these and other reports, on May 23 of this year the Center for Medicaid and State Operations issued a "guidance to remind states there are a number of options to prevent the inappropriate use of such drugs and to inform states that we believe they should restrict the coverage of such drugs in the case of individuals convicted of a sex offense. . . . We believe that, . . . the use of these drugs in the case of a sex offender is not appropriate and Medicaid should not pay for the cost of such drugs in such circumstances.

> Effective immediately, states should use their drug use review program and procedures . . . and work with physicians and pharmacists to prevent inappropriate Medicaid payment for such drugs in the case of a sex offender. Failure to perform such a review and implement appropriate controls may result in sanctions.<1>

On May 26, 2005, Governor Schwarzenegger announced that he had issued a directive to all applicable state agencies in California to immediately stop providing known sex offenders with taxpayer-funded medications such as Viagra, Levitra or Cialis, to treat erectile dysfunction ("ED").

It is estimated that 137 registered sex offenders in California may have been prescribed ED drugs under Medi-Cal in the last year.

4. Background: ED Treatment

The following information, compiled by the Senate Office of Research, explains the purpose and effect of Viagra, which is a

commonly-used prescription drug for ED.

From the FDA's Center for Drug Evaluation and Research :

Viagra is used to treat impotence in men. Viagra increases the body's ability to achieve and maintain an erection during sexual stimulation. How does Viagra work? An erection is the result of an increase in blood flow into certain internal areas of the penis. Viagra works by enhancing the

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<1> Letter dated May 23, 2005 from Dennis G. Smith, Director of the Center for Medicaid and State Operations, Department of Health & Human Services, addressed to "Dear State Medicaid Director."

effects of one of the chemicals the body normally releases into the penis during sexual arousal. This allows an increase of blood flow into the penis.

Patient Summary Information about Viagra from Pfizer :

VIAGRA is a pill used to treat erectile dysfunction (impotence) in men. It can help many men who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated). You will not get an erection just by taking this medicine. VIAGRA helps a man with erectile dysfunction get an erection only when he is sexually excited. VIAGRA does not cure erectile dysfunction. It is a treatment for erectile dysfunction. VIAGRA is not a hormone or an aphrodisiac.

From Aetna InteliHealth :

In most men, erectile dysfunction is caused by inadequate flow of blood into the penis. PDE5 drugs (Viagra) work by helping the blood vessels relax, which increases blood flow. They do not cause an erection without sexual stimulation, and the penis will return to its normal size and flaccid state after ejaculation. They also have no effect on sexual desire (libido) and do not change sensation in the penis. PDE5 drugs are not habit forming or addictive. They do not increase sexual desire or sexual enjoyment, other than by helping a man to achieve and maintain an erection.

5. Background: Sex Offending; ED Drugs and Sex Offense Behavior

Medical treatment for ED, many assert, helps sex offenders commit sex offenses. "The federal government is inadvertently facilitating the sexual assault of children," Laura Ahearn, executive director of Parents for Megan's Law, told the Associated Press earlier this year.<2> In his May 26 press release, Governor Schwarzenegger stated:

> Our first responsibility is to keep our citizens safe, and providing these drugs to known sex offenders is a policy that only threatens more innocent people.

Others, however, contend that drugs treating ED are unrelated to sexual offending:

> Viagra is often misunderstood to be an aphrodisiac - actually it does nothing to enhance sexual motivation, said Dr. Fred Berlin, a psychiatrist at Johns Hopkins University and an expert on the treatment of sex offenders. . . .
>
> Berlin said he's never heard of a sex offender using Viagra to reoffend.<3>

According to a 2004 law review article on sex offender management written by authors from the Center for Effective Public Policy and the Center for Sex Offender Management, the generally accepted treatment approach for sex offenders addresses a broad range of factors, none of which necessarily appear to center on physical performance:

> While historical efforts to treat sex offenders were widely varied, sex offender treatment has been refined significantly over the past few decades, and has a generally accepted approach. At present,

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<2> USA Today, May 23, 2005.
<3> Associated Press, June 22, 2005 (State Helped Pay for Viagra for 137 Sex Offenders.)

> most sex offender treatment programs throughout the country employ cognitive-behavioral methods that include relapse prevention components.
> Contemporary etiological theories suggest that sex offending behaviors are the result of a complex interaction of sociocultural, biological, and psychological processes . As such, sex offender

> treatment is designed to be relatively comprehensive and holistic, with goals that generally include accepting responsibility for sex offending and other harmful behaviors; modifying cognitive distortions that support offending behaviors; managing negative mood or affect; developing positive relationship skills; managing deviant sexual arousal or interest; maintaining control over unhealthy impulses; enhancing empathy for victims; understanding the sequence of events and risk factors associated with offending; and developing effective coping skills to manage identified risk factors.<4>

Sexual assault has come to be generally understood as a crime of power and control. As explained by the federal Office on Violence Against Women on its Web site:

<4> Carter, Bumby and Talbot, SYMPOSIUM: Promoting Offender Accountability and Community Safety through the Comprehensive Approach to Sex Offender Management (34 Seton Hall L. Rev. 1273 (2004) (citations omitted) (emphasis added).)

> The belief that only young, pretty women are sexually assaulted stems from the myth that sexual assault is based on sex and physical attraction. Sexual assault is a crime of power and control and offenders often choose people whom they perceive as most vulnerable to attack or over whom they believe they can assert power.<5>

Similarly, in its Megan's Law Web site, the California Attorney General's Office includes the following fact about sex offenders:

> While some offenders do seek sexual gratification from the act, sexual gratification is often not a primary motivation for a rape offender. Power, control, and anger are more likely to be the primary motivators.<6>

Members of the Committee may wish to explore further the causes of sexual offending, and how the relationship between ED treatments and sexual offending may impact these causes and public safety.

6. Constitutional Considerations

"An ex post facto law is a retrospective criminal statute applying to crimes committed before its enactment, and substantially injuring the accused, by punishing an act innocent when done, or increasing the punishment , or taking away a

defense related to an element of the crime or an excuse or justification for the conduct, or altering the rules of evidence so that a conviction may be obtained on less or different testimony than was required when the crime was committed."<7> In upholding California's sex offender registration laws against an ex post facto challenge, the California Supreme Court reasoned:

<5> http://www.ojp.usdoj.gov/vawo/SexAssaultInfo.htm.
<6> http://www.meganslaw.ca.gov/facts.htm.
<7> 1 Witkin Cal. Crim. Law Intro. Crimes 10.

> The sex offender registration requirement serves an important and proper remedial purpose, and it does not appear that the Legislature intended the registration requirement to constitute punishment. Nor is the sex offender registration requirement so punitive in fact that it must be regarded as punishment, despite the Legislature's contrary intent. Although registration imposes a substantial burden on the convicted offender, this burden is no more onerous than necessary to achieve the purpose of the statute.<8>

Members may wish to discuss whether the provisions of this bill, notwithstanding the stated purposes of public safety contained in its provisions, would be so punitive in fact as to constitute punishment and violate the ex post facto clauses of the California (Art. I 9) and U.S. (Art. I 10) Constitutions.

7. Similar Bill

This bill is similar to AB 240 (Berm?dez), which was amended on June 20, 2005; that measure appears to reflect an earlier version of this bill. Both of these bills are before the Committee on June 28. With respect to limiting ED drugs and treatment for registered sex offenders, these bills appear to be identical in intent. The bills differ in the following respects:

AB 240 is silent on who would pay to identify Medi-Cal ED claims deriving from registered sex offenders; this bill would authorize DOJ to establish a fee for their actual and reasonable costs;

<8> People v. Castellanos, 21 Cal. 4th 785 (1999) (citations omitted).

statute (Penal Code 290) to authorize DOJ to provide the identifying information about registrants to other

AMENDED IN ASSEMBLY MARCH 17, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 73

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members *Baca,* Bass, *Berg, Coto, De La Torre,* Evans, *Goldberg,* Gordon, *Hancock, Klehs,* Koretz, *Leno, Levine,* Nava, Pavley~~, and Salinas~~, *Ridley-Thomas, Ruskin, Salinas, and Torrico*)

January 3, 2005

An act to ~~add Section 14982 to the Government Code, and to~~ add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as amended, Frommer. Prescription drugs: importation: procurement.

~~(1)~~ Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation,

compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

~~(2) Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.~~

~~This bill would require the department to coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements to be listed on the California Rx Prescription Drug Web site. The bill would require the department, on or before January 1, 2007, to conduct the review and report to the Legislature. The bill would require the report to~~

~~recommend options to facilitate more cost-effective acquisition of prescription drugs. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from international pharmacies would be made at reduced prices for purposes of state departments and agencies.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) Prescription drugs have become essential for ensuring the
4 health of millions of Californians.
5 (b) The United States is the largest trade market for
6 pharmaceuticals in the world, yet American consumers pay the
7 highest prices for brand name pharmaceuticals in the world.
8 (c) Increased spending on prescription drugs is a significant
9 driver of increases in overall health care costs, with spending
10 nationwide on prescription drugs rising over 15 percent each year
11 from 2000 to 2002.
12 (d) Rising out-of-pocket costs for prescription drugs are
13 placing a growing burden on California consumers, as evidenced
14 by federal government statistics *that* show that in 2002 the
15 increase in consumers' out-of-pocket costs for prescription drugs
16 was greater than the increase in out-of-pocket costs for all other
17 health care expenditures.
18 (e) The price of brand name drugs is rising faster than the rate
19 of inflation, with a recent study showing that the price of 30
20 drugs most frequently used by the elderly rose by over four times
21 the rate of inflation in 2003 and that some drugs increased in
22 price by 10 times the rate of inflation in that year.
23 (f) The rising cost of prescription drugs also places a
24 significant burden on state government, with the cost of
25 providing prescription drugs to Medi-Cal beneficiaries, to
26 inmates of the Department of Corrections, and to other
27 participants in state programs growing in some cases at over 20
28 percent annually in recent years.
29 (g) The rising cost of prescription drugs jeopardizes the health
30 of seniors, the disabled, and other consumers who cannot afford

the medication they need to stay healthy, as shown by a study by the RAND Corporation that 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 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

~~SEC. 2. Section 14982 is added to the Government Code, to read:~~

~~14982. (a) The Department of General Services shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements of Section 110242 of the Health and Safety Code. State departments to be reviewed shall include, but not be limited to, all of the following:~~

~~(1) The State Department of Health Services.~~

~~(2) The Managed Risk Medical Insurance Board.~~

~~(3) The Department of General Services.~~

~~(4) The Department of Corrections.~~

~~(5) The California Public Employees' Retirement System (CalPERS).~~

~~(b) The Department of General Services shall, on or before January 1, 2007, conduct the review required under subdivision (a) and report its findings based on that review to the Legislature. The report shall recommend options to the Legislature, including conducting pilot programs, to facilitate more cost-effective acquisition of prescription drugs. The recommendations shall~~

~~include a determination of the need to seek any federal approvals or waivers.~~

~~(c) The Department of General Services may establish pilot programs under which purchases of prescription drugs from international pharmacies are made at reduced prices for purposes of state departments and agencies.~~

~~(d) As a condition of implementing any pilot program under this section, the Department of General Services shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.~~

~~SEC. 3.~~

SEC. 2. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs

at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States, unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the

department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 73 **VERSION: AS AMENDED MARCH 17, 2005**

AUTHOR: FROMMER et al. **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUG IMPORTATION

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Requires the Department of Health Services (DHS) to establish a Web site on or before July 1, 2006 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web site would include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

3) Requires the Web site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs.

(H&S 110242 Added)

4) Establishes the requirements that must be met for DHS to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
d. Requires a patient medical history.
e. Requires a signed patient agreement.

f. Requires prescriptions to be mailed in original packaging.
g. Requires physical address and phone number for the pharmacy on the pharmacy Web site.
h. Prohibits the pharmacy from furnishing the following drugs:
    i. Controlled substances.
    ii. Biologics.
    iii. Infused drugs.
    iv. Intravenous drugs.
    v. Drugs inhaled during surgery.
    vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
i. Sale of only drugs approved by the country in which the pharmacy is located.
j. Comply with California law relating to drug pedigree.
k. Prohibits requiring patients to sign a waiver of liability.
l. Requires the pharmacy to maintain a customer service department.
m. Requires the pharmacy to employ professionals that are licensed in good standing.
n. Requires the pharmacy to comply with California privacy laws.
o. Prohibits filling a prescription if the patient hasn't taken the drug previously.
p. Prohibits furnishing drugs that have no equivalent approved by the FDA.
(H&S 110242 Added)

5) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

6) Permits the department to assess a fee on international pharmacies to fund this act. (H&S 110242 Added)

Comment:

1) Author's Intent. The author's intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." AB 73 is part of an eight-bill package being offered by Assembly Democrats to bring down the cost of prescription drugs sold in California.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries.

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian

pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. Consumers are seeking Canadian and EC drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Federal Legislation. Three bills have been introduced in Congress that would amend the Federal Food, Drug, and Cosmetic Act to permit the importation of prescription drugs from outside the United States. The bills place limits on the types of drugs that could be imported and from which countries the importation can take place. The bills are S 334, HR 328 and HR 700; none of the bills has yet to be heard in committee.

6) Other States. Seven states (Illinois, Minnesota, Nevada, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

7) State Legislation. AB 1957 (Frommer et.al. 2004), Drug Importation, was introduced last session, AB 73 is similar to AB 1957 except AB 73 expands the list of countries for drug importation to include England and Ireland, or any other country. The board opposed AB 1957 and the Governor vetoed the measure. In the Governor's veto message he states "...importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability.... In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians."

8) Support & Opposition.

Support:

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Oppose:

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

9) History.

2005

June 23	From committee: Do pass, and re-refer to Com. on B., P. & E.D. Re-referred. (Ayes 6. Noes 4.). Read second time, amended, and re-referred to Com. on APPR.
June 15	Referred to Coms. on HEALTH and B., P. & E.D.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 46. Noes 31. Page 2142.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 11. Noes 5.) (May 25).
May 4	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 1.) (April 26).
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 17	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

BILL ANALYSIS
AB 73

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 73 (Frommer) - As Amended: March 17, 2005

SUBJECT : Prescription drugs: importation: procurement.

SUMMARY : Requires the Department of Health Services (DHS) to establish a Web site to facilitate purchasing prescription drugs at reduced prices. Requires the Web site to include price comparisons, including prices of, and links to, international pharmacies that meet specified requirements. Specifically, this bill :

1)Establishes the California Rx Prescription Drug Web Site Program, administered by DHS, to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

2)Requires DHS to establish a Web site on or before July 1, 2006, to provide at a minimum information about, and electronic links to, all of the following:

a) Prescription drug benefits available to Medicare beneficiaries;

b) State programs that provide drugs at discounted prices for California residents;

c) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals;

d) Pharmacies in Canada, the United Kingdom, and Ireland that provide mail-order service to the United States and which meet specified requirements to assure safety, accessibility, and affordability of prescription drugs; and,

e) Other Web sites as deemed appropriate by DHS.

3)Requires the Web site to include price comparisons of at least 50 commonly prescribed brand name prescription drugs, as specified.

4)Permits DHS to enter into a contract with an international pharmacy that meets requirements specified in this bill.

Permits DHS to terminate a contract with, and delete an electronic link to, or information about, an international pharmacy that no longer complies with the requirements of this bill.

5)Requires a contracted international pharmacy to be licensed by the province or country in which it is located and to comply with the requirements of a nonresident pharmacy, as specified.

6)Permits DHS to assess a fee on international pharmacies to offset the cost of reviewing applications of those pharmacies.

7)Requires DHS to ensure that the Web site required by this bill is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs. Requires that any information posted on the Web site first be approved by DHS professional staff.

8)Requires DHS to include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. Requires other specified notices.

EXISTING LAW :

1)Provides that any pharmacy located outside of California that delivers prescription drugs into the state is considered a nonresident pharmacy. Requires a nonresident pharmacy to register with the Board of Pharmacy and comply with all lawful directions of and requests for information from the state in which it is a resident.

2)Prohibits, under the federal law, the importation or reimportation of prescription drugs except by the original manufacturer.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill provides relief from the high costs consumers are paying for prescription drugs. These high prices are hurting many Californians, including one-quarter of seniors who skip doses or fail to get medications because of cost. The author reports that the high cost of drugs has a disproportionate effect on African-Americans, who are 75% more likely than whites not to have bought a prescription drug because of cost. Latinos are 50% more likely than whites not to have bought drugs because they cannot afford them. As a result of these

high costs, the author notes that many consumers are turning to Canada and other countries, where brand-name drugs can be 30 to 75 % cheaper than in the United States. According to the author, this bill would enable the state of California to provide a valuable service to its residents by giving them information about safe, reputable mail-order pharmacies located in Canada, the UK and Ireland.

2)BACKGROUND . 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 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.

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, Europe, and Southeast Asia. The recent development of Canadian Internet pharmacies has demonstrated the true demand for inexpensive medication. Researchers estimate that over six million Americans have obtained needed 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.

3)SAFETY CONCERNS . It is generally agreed that the Canadian regulatory systems for approving and distributing drugs is very similar to that in the US. In the US, the approval and marketing of prescription drugs is governed under the Federal Food, Drug, and Cosmetic Act, with enforcement administered by the Food and Drug Administration (FDA). In Canada, the approval and marketing practices are regulated under the Food and Drugs Act, with enforcement by the Therapeutic Products Directorate, an arm of Health Canada, which is responsible for assuring the safety and quality of all medicines sold in Canada. Both countries' statutes require drugs to be proven safe and effective through clinical studies and manufactured to strict quality standards before they can be approved and distributed for general use. In addition, both countries have analogous requirements for licensing of retail pharmacies and pharmacists; in Canada, licensing is conducted by provinces or territories, whereas in the U.S. it is done by states.

Studies by two federal agencies, the Congressional Research Service (CRS) and the Government Accountability Office, report that the drug distribution system in Canada is as safe as or safer than our own. The CRS study, for example, shows that Health Canada regulates the drug supply system in Canada in ways that make drug distribution there safer than in the U.S. because drugs pass through the hands of fewer middlemen, reducing the opportunity for counterfeit drugs to enter the supply chain. In June 2004, the GAO issued a report that found that Canadian internet pharmacies had safer pharmacy practices than American internet pharmacies. All of the Canadian pharmacies examined by the GAO required a prescription, for example, while only one in six American internet pharmacies did so. In contrast, a U.S. Department of Health and Human Services report, mandated by the MMA and released in December 2004, recommended against legalizing personal importation, after concluding it would result in significant safety risks, decreased research and development, liability issues and small national savings. The conclusions of the study were severely critiqued by proponents of importation as having been preordained.

4)FEDERAL LAW . Federal law allows only the manufacturer to import, or reimport, prescription drugs into the U.S. However, the FDA and U.S. Customs, because of their enforcement discretion and finite resources, have not enforced the importation ban on individuals bringing limited supplies of drugs for personal use across the border. Prescription drugs sent to American consumers through the mail also appear to enjoy the benefit of this enforcement discretion. Attempts to legalize importation at the federal level have been unsuccessful thus far. In each of the past 5 years a number measures to allow importation from Canada and other countries

have been introduced in both houses of Congress without success.

5)LIABILITY ISSUES . The author has received a formal opinion from Legislative Counsel regarding liability issues. Legislative Counsel has concluded that the state could be subject to liability for negligence under state law in limited circumstances, such as negligent ministerial errors committed by the Board or its employees (as in listing an incorrect pharmacy on the web site), unless the Legislature enacts a statute providing immunity from liability to cover those activities and the Board includes on its web site adequate notice and disclaimers regarding applicable federal law. Most of the activities of the Board and its employees in establishing and maintaining the web site would be considered discretionary, rather than ministerial, acts; the state is immune from liability for errors in discretionary acts under the California Tort Claims Act. An example of a potential ministerial error related to this bill would be the listing of an unapproved pharmacy in the place of an approved one on the website, or listing an approved pharmacy at the Internet address of an unapproved pharmacy, where the error resulted in the purchase of a drug that caused harm. A discretionary act would include deciding which Canadian pharmacies meet the standards this bill requires. The state would not be liable for making that decision in error because the decision making is a discretionary act.

6)CANADIAN SUPPLY ISSUES . In response to pressure from the Bush Administration, late in 2004 the Health Minister of Canada reversed his previous position that existing levels of sales to Americans posed no threat to the drug supply of Canada. Instead, the Health Minister and the Canadian government have begun to discuss the possibility of shutting down mail-order pharmacies. Although no action has been taken to date, in light of this threat to the supply of drugs sold to Americans, and in response to continuing efforts by drug manufacturers to restrict the supply of drugs into Canada, a number of states have examined whether their programs should link consumers to pharmacies in other countries besides Canada.

In the past year, representatives of the state of Illinois and of the state of Minnesota made separate visits to Europe to assess the quality of European pharmacies and pharmacists. Findings from these visits included: European pharmacist training is substantially equivalent to the US; pharmacy storage rules are similar; European distribution systems are similar to Canada (closed system with fewer opportunities for counterfeit drugs than in the U.S.); and European drug dispensing is safer and less prone to error (drugs are dispensed in manufacturer's precounted blister packs). In

October 2004, after receiving the results of his state's research on European importation, Illinois Governor Blagojevich launched the I-SaveRx program to provide access to Canadian, British and Irish pharmacies. Initially the program was open only to residents of Illinois and Wisconsin, but in recent months the states of Missouri, Kansas and Vermont have also joined. Minnesota Governor Pawlenty has yet to decide whether to expand the Minnesota RxConnect program, which links to Canada, to include European pharmacies.

Despite some narrowing of price differentials between the United States and Canada in the past year due to the weakening American dollar, consumers can still find substantial savings purchasing drugs from Canadian or British pharmacies. The author's office reports that a survey of prices of nine commonly prescribed medications listed on pharmacychecker.com on April 1, 2005, comparing costco.com prices with those available at Canadian and British pharmacies, revealed savings on a per pill basis of from 24 to 65% from the Canadian or British pharmacies.

7)SUPPORT . The California Medical Association, in support, argues that many patients are unable to follow a prescribed drug regime due to the high cost of prescription drugs and need the options this bill will provide. Other supporters argue that Californians are overburdened by overpriced drugs and need information on affordable and safe domestic and international sources of drugs. Supporters also argue that Democratic and Republican governors in other states have established websites for their residents to buy affordable drugs safely from other countries and that the time has come for California to join this nationwide effort.

8)OPPOSITION . Opponents argue that this bill puts consumer safety at risk, raises state liability concerns, and has a negative impact on biomedical research. The Pharmaceutical Research and Manufacturers of America (PhRMA) also argues that there are better and readily available programs to enable patients to access safe and affordable medicines. These include existing patient assistance programs which provided medicine to 244,000 Californians in 2002, a recently launched industry sponsored website, rxhelpforca.org, and the new Medicare prescription drug benefit that will go into full effect on January 1, 2006.

9)PREVIOUS LEGISLATION . AB 1957 (Frommer) of 2004, 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) of 2004 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) of 2004 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. AB 1957, SB 1149, and SB 1333 were all vetoed by the Governor, who stated that importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. However, in a formal legal opinion dated April 1, 2005, Legislative Counsel opined that the federal Food, Drug and Cosmetic Act would not have preempted the provisions of AB 1957 that would have established a prescription drug website with Canadian links.

10)RELATED LEGISLATION . AB 74 (Gordon) establishes the California Rx Prescription Drug Hotline to provide information about affordable prescription drug prices using a low-cost 1-900 telephone number.

11)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

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