

AMENDED IN SENATE JUNE 23, 2005  
AMENDED IN ASSEMBLY APRIL 20, 2005  
AMENDED IN ASSEMBLY APRIL 6, 2005  
CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 74**

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**Introduced by Assembly Members Gordon and Frommer  
(Coauthors: Assembly Members Chan, Chavez, Koretz, Laird,  
Matthews, Pavley, Ridley-Thomas, and Ruskin)  
(Coauthor: Senator Alquist)**

January 3, 2005

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An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as amended, Gordon. California R Prescription Drug Hotline.

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.

This bill would require the department to establish the California R Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

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) Increased spending on prescription drugs is a significant  
6 driver of increases in overall health care costs.

7 (c) Rising out-of-pocket costs for prescription drugs are  
8 placing a growing burden on California consumers, as federal  
9 government statistics show that in 2002 the increase in  
10 consumers' out-of-pocket costs for prescription drugs was greater  
11 than the increase in out-of-pocket costs for all other health care  
12 expenditures.

13 (d) The price of brand name drugs is rising faster than the rate  
14 of inflation, with a recent study showing that the price of 30  
15 drugs most frequently used by the elderly rose by over four times  
16 the rate of inflation in 2003 and that some drugs increased in  
17 price by 10 times the rate of inflation in that period.

18 (e) The rising cost of prescription drugs jeopardizes the health  
19 of seniors, the disabled, and other consumers who cannot afford  
20 the medication they need to stay healthy.

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

24 SEC. 2. Article 5 (commencing with Section 110243) is  
25 added to Chapter 2 of Part 5 of Division 104 of the Health and  
26 Safety Code, to read:

27

28 Article 5. California Rx Prescription Drug Hotline

29

30 110243. (a) The State Department of Health Services shall  
31 establish the California Rx Prescription Drug Hotline to provide  
32 information to consumers and health care providers about options  
33 for obtaining prescription drugs at affordable prices.

34 (b) The department shall establish a low-cost 1-900 telephone  
35 number on or before July 1, 2006. Callers shall be provided with

1 information about options for obtaining prescription drugs at  
2 affordable prices. The cost per call to the hotline shall not exceed  
3 50 cents (\$0.50) and the hotline shall, at a minimum, provide  
4 information about all of the following:

5 ~~(1) Prescription drug benefits available to Medicare~~  
6 ~~beneficiaries, including the Voluntary Prescription Drug Benefit~~  
7 ~~Program and the Medicare Prescription Drug Discount and~~  
8 ~~Transitional Assistance Program.~~

9 ~~(2)~~

10 (1) State programs that provide drugs at discounted prices for  
11 California residents.

12 ~~(3)~~

13 (2) Federal programs that provide drugs at discounted prices  
14 for United States residents.

15 ~~(4)~~

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

19 ~~(5)~~

20 (4) Other informational resources as deemed appropriate by  
21 the department that help California residents to safely obtain  
22 prescription drugs at affordable prices, including, but not limited  
23 to, both of the following:

24 (A) Information regarding the availability of prescription  
25 drugs from Canada that are distributed from pharmacies licensed  
26 in that country and that meet standards and regulations prescribed  
27 by the state or federal government.

28 (B) Telephone numbers and *Internet* Web sites of health plans  
29 and health insurers regarding their prescription drug formularies.

30 ~~(6)~~

31 (5) Price comparisons of at least 50 commonly prescribed  
32 brand name prescription drugs, including typical prices charged  
33 by all of the following:

34 (A) Licensed pharmacies in the state.

35 (B) Licensed pharmacies in other states.

36 (C) Pharmacies located in Canada that are licensed by that  
37 country and that meet standards prescribed by the state and  
38 federal government.

39 (c) The department shall ensure that the hotline established  
40 pursuant to this section is coordinated with and does not

1 duplicate other state-funded programs and services, including,  
2 but not limited to, programs such as the Health Insurance  
3 Counseling and Advocacy Program (HICAP) established  
4 pursuant to Chapter 7.5 (commencing with Section 9540) of  
5 Division 8.5 of the Welfare and Institutions Code, that provide  
6 information about prescription drug options and costs.  
7 (d) Any information provided via the hotline shall first be  
8 approved by professional staff of the department.

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# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 74**

**VERSION: AMENDED APRIL 20, 2005**

**AUTHOR: GORDON**

**SPONSOR: GORDON**

**RECOMMENDED POSITION:**

**SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE**

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### **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 California Department of Health Services (DHS). (H&S 109875)

### **This Bill:**

1) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:

- a. State programs that provide drugs at discounted prices for California residents.
- b. Federal programs that provide drugs at discounted prices for United States residents.
- c. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.
- d. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.
- e. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.
- f. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

3) Requires that DHS ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services, including, but not limited to, the Health Insurance Counseling and Advocacy Program (HICAP), that provide information about prescription drug options and costs.

(H&S 1010243 Added)

## Comment:

**1) Author's Intent.** The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

**2) Oversight.** One of the many roles a pharmacist fills is acting as a second check for prescribers to insure that the medication a patient has been prescribed is the right medication for the patient's health condition, and that multiple medications will not adversely interact with each other to negatively effect a patient's health. As patients see specialist doctors for multiple health problems, the pharmacist's oversight role become increasingly more important, as any one doctor may not be aware of all the prescription drugs a patient is taking. Additionally, as patients seek lower cost drugs from more than one source (mail order, Internet, or local pharmacy), they will loose the benefit of one pharmacy or pharmacist knowing all the medications a patient is taking and ensuring that the medications will not result in harm to the patient. AB 74 and other bills that direct patients to multiple sources to obtain low cost drugs, may have the unintended result of putting peoples health at risk.

**3) Drug Pricing.** This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

**4) Substantive Amendments since the April 27<sup>th</sup> Board Meeting.** Deletion of the provision that would require the hotline to provide information on prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

## **6) History.**

2005

- June 30 Assembly Rule 47.1 invoked. (Frommer)
- June 29 In committee: Set, first hearing. Hearing canceled at the request of author.
- June 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
- June 15 Referred to Com. on HEALTH.
- June 6 In Senate. Read first time. To Com. on RLS. for assignment.
- June 2 Read third time, passed, and to Senate. (Ayes 47. Noes 31. Page 2104.)
- May 27 Read second time. To third reading.
- May 26 From committee: Do pass. (Ayes 12. 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 7. Noes 1.) (April 26).
- Apr. 21 Re-referred to Com. on B. & P.
- Apr. 20 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
- Apr. 13 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
- Apr. 7 Re-referred to Com. on HEALTH.
- Apr. 6 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.

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**AB 74**

**As Amended: June 23, 2005**

**SENATE HEALTH**

COMMITTEE ANALYSIS  
Senator Deborah V. Ortiz, Chair

FISCAL: Appropriations  
4

CONSULTANT:  
Bohannon / ak

**SUBJECT**

California Rx Prescription Drug Hotline

**SUMMARY**

This bill would require the Department of Health Services (DHS) to establish the California Rx Prescription Drug Hotline (hotline), on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

**ABSTRACT**

Existing law:

1. Establishes the Sherman, Food, Drug, and Cosmetics Act to regulate the processing, packaging, labeling, advertising, and sale of food, drugs, devices, and cosmetics under the administration of DHS.
2. Expresses the intent of the Legislative to ensure that older individuals and functionally impaired adults receive needed services that will enable them to maintain maximum independence and remain in their home or communities for as long as possible.
3. Declares that the purpose of the Health Insurance Counseling and Advocacy Program (HICAP) is to provide Medicare beneficiaries and those imminent of becoming eligible for Medicare with counseling and advocacy as to Medicare, private health insurance, and related health care coverage plans, on a statewide basis.
4. Requires the California Department of Aging (CDA) to be responsible for acting as a clearinghouse for information

and materials relating to Medicare, managed care, health and long-term care related life and disability insurance, and related health care coverage plans and to develop additional information and materials as necessary.

This bill:

1. Makes the following legislative findings and declarations:

Prescription drugs have become essential for ensuring the health of millions of Californians;

Increased spending on prescription drugs is a significant driver of increases in overall health care costs;

Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers;

The price of brand name drugs is rising faster than the rate of inflation;

The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy; and,

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

1. Requires DHS to establish the hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2. Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006.

3. Requires the cost per call to the hotline not to exceed 50 cents and at a minimum, provide information about all of the following:

State programs that provide drugs at discount prices for California residents;

Federal programs that provide drugs at discount prices for United States residents;

Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription

drugs to qualifying individuals;

Other informational resources as deemed appropriate by DHS that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

- a. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government;
- b. Telephone numbers and Internet Web sites of health plans and health insurers regarding their prescription drug formularies.

Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in California and in other states as well as those charged by Canadian pharmacies that are licensed by the state and federal government.

- 1.Requires DHS to ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services, including, but not limited to, programs such as the HICAP that provide information about prescription drug options and costs.
- 2.Requires any information provided via the hotline to first be approved by professional staff of the department.

#### FISCAL IMPACT

According to the Assembly Appropriations Committee, there will be full-year General Fund (GF) costs of approximately \$800,000 to establish and maintain the database to support the hotline, including keeping the hotline message current, establishing and keeping prescription price comparison information, and responding to hotline inquiries. Additionally, there are indeterminate, but potentially significant GF costs to establish and maintain the "900" service, depending upon the number of calls to the hotline.

#### BACKGROUND AND DISCUSSION

##### Purpose of bill

According to the author, there are a multitude of programs and services offered by a variety of sources that can

provide eligible seniors with immediate relief from high prescription drug costs. The author argues that few seniors take advantage of these benefits because they are not aware that such programs exist or are either deterred by complex enrollment processes. He insists that studies show that only 40 percent of seniors have ever used a computer and even less have ever gone online to access information on the Internet. As such, he believes AB 74 is needed to provide Californians, especially seniors, with a non-web based alternative for finding affordable prescription drugs. He believes the measure will provide the support necessary to help Californians navigate the complicated web of services for which they might be eligible.

#### Rising prescription drug costs

As a number of studies document, access to affordable prescription drugs is a growing problem in California and in the U.S. 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.

#### Seniors and the Internet

A report released by the KFF in January 2005 found that there is a substantial digital divide among seniors based on income, education, age, and gender. According to KFF, seniors whose annual household income was under \$20,000 a year were much less likely to have gone online than those with incomes between \$20,000 and \$49,000 or those with incomes of \$50,000 a year or more. However, most seniors fall into the lower income category - 64% of all seniors on Medicare have an annual income under \$20,000 a year, while just 8% have an income of \$50,000 a year or more.

Additionally, the report found that while the Internet is a source of health information for some seniors, the vast majority still rely on traditional media such as television and newspapers to obtain health information. However, of those seniors who do utilize the Internet for health information, KFF found that most are looking for information on prescriptions drugs.

#### 1-800-MEDICARE

In March 1999, the Center for Medicare and Medicaid Services (CMS) implemented a nationwide toll-free telephone helpline, 1-800-MEDICARE, which Medicare beneficiaries, their families, and other members of the public can call to ask questions about program eligibility, enrollment, and benefits. By 2001, the helpline had customer service representatives (CSR) answering calls 24 hours a day, seven days a week.

In 2004, the helpline significantly expanded its operations in order to handle an increased number of calls. During the six months following the enactment of the Medicare Prescription Drug Improvement and Modernization of 2003 (MMA), the 1-800-MEDICARE helpline handled over nine million calls, more than triple the number handled in the previous six months. In response to the increased call volume, in the first half of 2004, CMS added over 800 CSRs, more than doubling the number of staff who had previously been available to respond to helpline inquiries.

In December 2004, the United States Government Accountability Office (GAO) released a report evaluating accuracy of responses from the 1-800-MEDICARE helpline. Among other things, the report found that the accuracy rate varied significantly by question and that inaccurate responses were largely due to ineffective use of call scripts. The report concluded that although the CSRs had met CMS's training requirements, such training was not sufficient to ensure accurate responses to beneficiary inquiries.

#### HICAP

The HICAP program, under the purview of CDA, is charged with providing assistance to and advocacy for individuals and families for problems with Medicare and other health insurance related concerns. Over 600 trained and registered volunteer counselors provide objective information on Medicare (including Medicare Part D - the voluntary outpatient prescription drug benefit available January 1, 2006), Medicare supplement insurance, managed care, long-term care planning and health insurance.

Community education, individual counseling and some legal services are available in all 58 counties. HICAP counselors can be reached via toll free number (1-800-434-0222) for appointments and questions.

#### Arguments in support

Supporters of the bill believe AB 74 will assist consumers, especially those without Internet access, to find affordable prescription drugs. They believe the state is the proper administrator for such a program since it has access to information and research that ordinary consumers do not. Supporters state that existing information about international pharmacies and various government and private assistance programs is notoriously unreliable and difficult to navigate. They believe AB 74 will facilitate access to information that will allow consumers to obtain the preventative medication they need to avoid more complicated and expensive emergency procedures.

#### Arguments in opposition

DHS argues that AB 74's proposed low-cost hotline will frustrate, not alleviate, a patient's ability to receive appropriate prescription drug information. DHS also believes the bill's requirements are unnecessary and duplicate other hotlines that are already available. DHS additionally insists that compliance with providing price comparison information on at least 50 commonly prescribed drugs, as required by AB 74, would be difficult as such a comparison assumes that information is readily available, accurate, and based on the same quantity per prescription. Lastly, DHS argues that requiring the hotline to provide other information, including the availability of prescriptions from Canadian pharmacies; would establish a mechanism to facilitate an illegal practice and possibly jeopardize patient safety.

#### Related legislation

AB 73 (Frommer, 2005) would require DHS to 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, including information about and electronic links to certain federal, state, and private pharmaceutical programs, pharmacies located in Canada, the United Kingdom, and Ireland that meet specified requirements, and other web sites. This bill has been referred to the Senate Business, Professions and Economic Development Committee.

1.Low cost may be a deterrent for low-income. AB 74

requires the cost per call not to exceed 50 cents. However, as DHS asserts, if callers are not prepared with paper and pencil, they may need to call again, causing them to incur additional charges. As stated earlier in the analysis, 64% of all seniors on Medicare have an annual income under \$20,000 a year, while just 8% have an income of \$50,000 a year or more. Additionally, many of those who would qualify for the public and private pharmaceutical assistance programs specified in the bill are low income as well, with income between 100% and 300% of the federal poverty level to qualify for most programs. While the 50 cent fee may help offset some of the administrative costs associated with the program, it may have the unintended consequence of serving as a deterrent for some or an additional financial hardship for others in some cases.

2. Administrative details are unclear. Does the author intend for the hotline created pursuant to AB 74 to be automated or operator run? Automated phone trees can be frustrating and confusing particularly when callers are unfamiliar with the options presented to them. Further, as evidenced by the CSRs staffing the 1-800-MEDICARE helpline, training and additional support materials (i.e. call scripts) for live operators still may not prevent callers from receiving misleading or inaccurate information.
3. Linguistic competency standards. AB 74 does not provide for the appropriate linguistic competency and technological support services necessary to ensure the hotline is accessible to California's diverse population, including those who may be hearing-impaired.
4. Lack of outreach. The bill does not require DHS to conduct outreach to publicize the hotline. While potentially very costly, particularly for low-income populations, outreach is a vital component to the success of any program which requires participants to actively engage in a specified activity in order to receive information or services.
5. Inherent duplication may be inevitable and ultimately confusing. While the bill expressly requires DHS to ensure that the hotline established pursuant to AB 74 does not duplicate any other state-funded programs and services, inherent duplication may be inevitable not only among other state-funded programs and services, but among those funded by federal and private dollars as well. Many of those who call the hotline will undoubtedly be Medicare beneficiaries who are eligible for the

low-income subsidy under Medicare Part D, as they would also qualify for many of the programs AB 74 seeks to centralize via hotline. Amendments taken on June 23, 2005 removed language that would have required the hotline to provide information regarding prescription drug benefits available to Medicare beneficiaries. While the information required by the bill may be useful to this population, they would undoubtedly fair better under the new drug benefit, however the bill provides no avenue for these individuals to access this information should they call the hotline first. Should the bill be amended to require the hotline to provide referral service to HICAP for the purposes of informing callers about prescription drug benefits available to Medicare beneficiaries?

6. Is AB 74 well intentioned, but impractical? Prescription drug pricing and discount programs are increasingly difficult to understand and maneuver given complicated eligibility requirements which may vary depending on the program or drug. Arguably a centralized hub of information that is accessible by telephone may be beneficial in terms of informing patients that these programs actually exist, particularly for seniors who are not as comfortable using the Internet. However if individuals are not prepared to properly record the information they receive or lack the resources and assistance to proactively apply for assistance after they call, it is unclear what tangible benefit the hotline would realistically provide.

#### PRIOR ACTIONS

Assembly Floor: 47 - 31 Pass  
Assembly Appropriations: 12 - 5 Do Pass  
Assembly Bus. & Prof.: 7 - 1 Do Pass  
Assembly Health: 10 - 4 Do Pass

#### POSITIONS

Support: AFSCME  
AIDS Healthcare Foundation  
California Federation of Teachers  
California Medical Association  
California Nurses Association  
California School Employees Association  
California State Employees Association  
California Teachers Association  
CALPIRG  
Gray Panthers  
Greenlining Institute

Health Access  
Mental Health Association in California  
NAMI California  
Independent Employees of Merced County  
Protection and Advocacy  
Retired Public Employees Association  
San Bernardino Public Employees Association  
San Joaquin County

SEIU

Oppose: Department of Health Services

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AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005-06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 75**

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**Introduced by Assembly Members Frommer and Chan**

**(Principal coauthor: Assembly Member Baca)**

**(Coauthors: Assembly Members Bass, Berg, Cohn, Coto,  
De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs,  
Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas,  
Ruskin, Saldana, and Salinas Salinas, and Torrico)**

**(Coauthor: Senator Alquist)**

January 3, 2005

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An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance 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 manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements

with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program, upon appropriation by the Legislature.

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: majority. Appropriation: no. 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 130500) is added to the Health and Safety Code, to read:

3  
4 DIVISION 112. CALIFORNIA RX PLUS STATE  
5 PHARMACY ASSISTANCE PROGRAM

6  
7 CHAPTER 1. GENERAL PROVISIONS

8  
9 130500. (a) This division shall be known, and may be cited,  
10 as the California Rx Plus State Pharmacy Assistance Program.

11 (b) For purposes of this division, the following definitions  
12 apply:

- 13 (1) "Department" means the State Department of Health
- 14 Services.
- 15 (2) "Fund" means the California Rx Plus Program Fund.

1 (3) “Manufacturer” means a drug manufacturer, as defined in  
2 Section 4033 of the Business and Professions Code.

3 (4) “Program” means the California Rx Plus State Pharmacy  
4 Assistance Program.

5 (5) (A) “Qualified resident” means a resident of California  
6 who has a *gross* family income equal to or less than 400 percent  
7 of the federal poverty guidelines, as updated periodically in the  
8 Federal Register by the United States Department of Health and  
9 Human Services under the authority of Section 673(2) of the  
10 Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec.  
11 9902(2)).

12 (B) “Qualified resident” also means a resident of the state  
13 whose family incurs unreimbursed expenses for prescription  
14 drugs that equal 5 percent or more of *gross* family income or  
15 whose total unreimbursed medical expenses equal 15 percent or  
16 more of *gross* family income.

17 (C) For purposes of this paragraph, the cost of drugs provided  
18 under this division is considered an expense incurred by the  
19 family for eligibility determination purposes.

20 (6) “Resident” means a resident of California pursuant to  
21 Section 17014 of the Revenue and Taxation Code.

22 130501. There is hereby established in the State Department  
23 of Health Services, the California Rx Plus State Pharmacy  
24 Assistance Program.

25  
26 CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES  
27

28 130505. (a) To be eligible for the program, a person shall be  
29 a qualified resident, as defined in paragraph (4) of subdivision (b)  
30 of Section 130500 and shall not have outpatient prescription drug  
31 coverage paid for in whole or in part by the Medi-Cal program or  
32 the Healthy Families Program, or any other program that uses  
33 federal funds to pay part or all of the cost of the person’s  
34 outpatient prescription drugs.

35 (b) Notwithstanding subdivision (a), a person enrolled in  
36 Medicare may participate in the program to the extent allowed by  
37 federal law for prescription drugs not covered by Medicare.

38 130506. (a) The department shall establish application forms  
39 and procedures for enrollment in the program. The application  
40 form shall include a requirement that the applicant or the

1 applicant's guardian or custodian attest that the information  
2 provided in the application is accurate to the best knowledge and  
3 belief of the applicant or the applicant's guardian or custodian.

4 (b) In assessing the income requirement for program  
5 eligibility, the department shall use the income information  
6 reported on the application and shall not require additional  
7 documentation.

8 (c) Any person who intentionally makes a false declaration as  
9 to his or her eligibility or any person who intentionally makes a  
10 false declaration as to eligibility on behalf of any other person  
11 seeking eligibility under this division for which that person is not  
12 eligible shall be guilty of a misdemeanor.

13 (d) Any person who intentionally makes a false declaration as  
14 to his or her eligibility or any person who intentionally makes a  
15 false declaration as to eligibility on behalf of any other person  
16 seeking eligibility under this division for which that person is not  
17 eligible may be denied a drug discount card under this program  
18 for up to one year from the date of the denial of coverage by the  
19 department.

20 (e) Upon determination of eligibility, the department shall  
21 mail the qualified resident a California Rx Plus Discount Card.

22 130507. (a) The department shall execute agreements with  
23 drug manufacturer patient assistance programs to provide a  
24 single point of entry for eligibility determination and claims  
25 processing for drugs available through those programs.

26 (b) The department shall develop a system to provide a  
27 participant under this division with the best discounts on  
28 prescription drugs that are available to the participant through  
29 this program or through a drug manufacturer patient assistance  
30 program.

31 (c) (1) The department may require an applicant to provide  
32 additional information to determine the applicant's eligibility for  
33 other discount card and patient assistance programs.

34 (2) The department shall not require an applicant to participate  
35 in a drug manufacturer patient assistance program or to disclose  
36 information that would determine the applicant's eligibility to  
37 participate in a drug manufacturer patient assistance program in  
38 order to participate in the program established pursuant to this  
39 division.

1 (d) In order to verify that California residents are being served  
2 by drug manufacturer patient assistance programs, the  
3 department shall require drug manufacturers to provide the  
4 department annually with all of the following information:

5 (1) The total value of the manufacturer's drugs provided at no  
6 or very low cost to California residents during the previous year.

7 (2) The total number of prescriptions or 30-day supplies of the  
8 manufacturer's drugs provided at no or very low cost to  
9 California residents during the previous year.

10 (3) The total number of prescriptions or 30-day supplies, and  
11 total value, of each of the manufacturer's brand name drugs  
12 provided at no or very low cost to California residents during the  
13 previous year.

14 (e) The California Rx Plus Discount Card issued pursuant to  
15 subdivision (e) of Section 130506 shall serve as a single point of  
16 entry for drugs available pursuant to subdivision (a) and shall  
17 meet all legal requirements for a uniform prescription drug card  
18 pursuant to Section 1363.03.

19  
20 CHAPTER 3. ADMINISTRATION AND SCOPE

21  
22 130515. (a) The department shall conduct an outreach  
23 program to inform California residents of their opportunity to  
24 participate in the California Rx Plus State Pharmacy Assistance  
25 Program. The department shall implement an outreach,  
26 education, and enrollment program with Health Insurance  
27 Counseling and Advocacy Program agencies, the California  
28 Department of Aging and other state agencies, local agencies,  
29 and nonprofit organizations that serve residents who may qualify  
30 for the program.

31 (b) The department shall implement a plan to prevent the  
32 occurrence of fraud in the program.

33 130516. (a) Any pharmacy licensed pursuant to Chapter 9  
34 (commencing with Section 4000) of Division 2 of the Business  
35 and Professions Code may participate in the program.

36 (b) Any drug manufacturer may participate in the program.

37 130517. (a) The amount a program participant pays for a  
38 drug through the program shall be equal to the participating  
39 provider's usual and customary charge or the pharmacy contract  
40 rate pursuant to subdivision (c), less a program discount for the

1 specific drug or an average discount for a group of drugs or all  
2 drugs covered by the program.

3 (b) In determining program discounts on individual drugs, the  
4 department shall take into account the rebates provided by the  
5 drug's manufacturer and the state's share of the discount.

6 (c) The department may contract with participating  
7 pharmacies for a rate other than the pharmacies' usual and  
8 customary rate.

9 130518. (a) The department shall negotiate drug rebate  
10 agreements with drug manufacturers to provide for discounts for  
11 prescription drugs purchased through the program.

12 (b) The department shall seek to obtain an initial rebate  
13 amount equal to or greater than the rebate calculated under the  
14 Medi-Cal rebate program pursuant to Section 14105.33 of the  
15 Welfare and Institutions Code.

16 (c) Upon receipt of a determination from the federal Centers  
17 for Medicare and Medicaid Services that the program is a state  
18 pharmaceutical assistance program as provided in Section  
19 130522, the department shall seek to contract for drug rebates  
20 that result in a net price lower than the Medicaid best price for  
21 drugs covered by the program.

22 (d) To obtain the most favorable discounts, the department  
23 may limit the number of drugs available through the program.

24 (e) All of the drug rebates negotiated pursuant to this section  
25 shall be used to reduce the cost of drugs purchased by  
26 participants in the program.

27 (f) Each drug rebate agreement shall do all of the following:

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

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

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

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

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

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

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

6 (8) Require the manufacturer to calculate and pay interest on  
7 late or unpaid rebates. The department may, by regulation,  
8 establish the date upon which the interest payments by drug  
9 manufacturers shall begin to accrue as well as any other  
10 regulations it deems necessary for the implementation of this  
11 paragraph.

12 (g) The department may collect prospective rebates from  
13 manufacturers for payment to pharmacies. The amount of the  
14 prospective rebate shall be contained in the drug rebate  
15 agreements executed pursuant to this section.

16 130519. (a) (1) The department may require prior  
17 authorization in the Medi-Cal program pursuant to Section 1927  
18 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for  
19 any drug of a manufacturer that does not agree to provide rebates  
20 to the department for prescription drugs purchased under this  
21 division, to the extent the department determines *that* it is  
22 appropriate to do *so* in order to encourage manufacturer  
23 participation in the program, ~~and~~ to the extent permitted by  
24 federal law, and subject to any necessary federal approvals or  
25 waivers.

26 (2) In making a determination to require prior authorization in  
27 the Medi-Cal program pursuant to paragraph (1), the department  
28 shall ensure that there are as many single-source drugs within  
29 each therapeutic category or subcategory as the department  
30 determines necessary to meet the health needs of the Medi-Cal  
31 population. In no event shall a Medi-Cal beneficiary be denied  
32 continued use of a drug that is part of a prescribed therapy unless  
33 that drug is no longer prescribed for that beneficiary.

34 (b) The names of manufacturers that do and do not enter into  
35 rebate agreements with the department pursuant to this division  
36 shall be public information and shall be released to the public.

37 130520. Contracts entered into for purposes of this division  
38 are exempt from Part 2 (commencing with Section 10100) of  
39 Division 2 of the Public Contract Code. Contracts with

1 pharmacies and drug manufacturers may be entered into on a bid  
2 or nonbid basis.

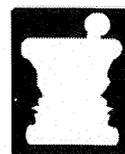
3 130522. The department shall seek a determination from the  
4 federal Centers for Medicare and Medicaid Services that the  
5 program established pursuant to this division complies with the  
6 requirements for a state pharmaceutical assistance program  
7 pursuant to Section 1927 of the federal Social Security Act (42  
8 U.S.C. Sec. 1396r-8) and that discounts provided under the  
9 program are exempt from the Medicaid best price requirement.

10 130523. (a) The department shall deposit all payments the  
11 department receives pursuant to this division into the California  
12 Rx Plus Program Fund, which is hereby established in the State  
13 Treasury.

14 (b) Upon appropriation by the Legislature, moneys in the fund  
15 shall be used for the purpose of providing payment to  
16 participating pharmacies pursuant to Section 130517 and for  
17 defraying the costs of administering this division.  
18 Notwithstanding any other provision of law, no money in the  
19 fund is available for expenditure for any other purpose or for  
20 loaning or transferring to any other fund, including the General  
21 Fund.

22 (c) Notwithstanding Section 16305.7 of the Government Code,  
23 the fund shall also contain any interest accrued on moneys in the  
24 fund.

25 SEC. 2. No reimbursement is required by this act pursuant to  
26 Section 6 of Article XIII B of the California Constitution because  
27 the only costs that may be incurred by a local agency or school  
28 district will be incurred because this act creates a new crime or  
29 infraction, eliminates a crime or infraction, or changes the  
30 penalty for a crime or infraction, within the meaning of Section  
31 17556 of the Government Code, or changes the definition of a  
32 crime within the meaning of Section 6 of Article XIII B of the  
33 California Constitution.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 75**

**VERSION: AMENDED MAY 26, 2005**

**AUTHOR: FROMMER**

**SPONSOR: FROMMER**

**RECOMMENDED POSITION:**

**SUBJECT: PHARMACEUTICAL ASSISTANCE 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 Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)
2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)
3. Establishes the criteria for a qualified resident as:
  - a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - \$38,280 for an individual and \$77,400 for a family of four)
  - b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)
4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)
5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)
6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater than Medi-Cal rebates. (H&S 130518 Added)
7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

**Comment:**

**1) Author's Intent.** The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

**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, Rhode 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.**

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is now a two-year bill.

## 5) Support / Opposition.

Support: AIDS Healthcare Foundation  
Alzheimer's Association  
American Federation of State, County and Municipal Employees  
California Alliance for Retired Americans  
California Federation of Labor  
California Federation of Teachers  
California Labor Federation  
California Nurses Association  
California Pharmacists Association  
California Public Interest Research Group  
Consumers Union  
Health Access California  
NAMI California (if amended)  
Older Women's League of California  
Retired Public Employees Association  
Senior Action Network  
Service Employees International Union

Opposition: BIOCUM  
California Chamber of Commerce  
Department of Health Services (unless amended)  
National Association of Chain Drug Stores (unless amended)  
Mental Health Association of California  
Novartis Pharmaceuticals  
Pharmaceutical Research and Manufacturers of America  
Western Center on Law & Poverty  
Wyeth Pharmaceuticals

## 6) History.

2005

June 28 In committee: Set, first hearing. Hearing canceled at the request of author.  
June 15 Referred to Com. on HEALTH.  
June 6 In Senate. Read first time. To Com. on RLS. for assignment.  
June 2 Read third time, passed, and to Senate. (Ayes 43. Noes 34. Page 2141.)  
May 27 Read second time. To third reading.  
May 26 From committee: Amend, and do pass as amended. (Ayes 11. Noes 4.) (May 25). Read second time and amended. Ordered returned to second reading.  
May 11 In committee: Set, first hearing. Referred to APPR. suspense file.  
May 3 Re-referred to Com. on APPR.  
May 2 Read second time and amended.  
Apr. 28 From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 1.) (April 26).  
Apr. 20 Re-referred to Com. on B. & P.  
Apr. 19 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.  
Apr. 13 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).  
Apr. 6 Re-referred to Com. on HEALTH.  
Apr. 5 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.

**Blank**

AB 75

As Amended May 26, 2005

ASSEMBLY THIRD READING

HEALTH 9-2 BUSINESS & PROFESSIONS  
7-1

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Ayes:	Chan, Cohn, Dymally,	Ayes:	Negrete McLeod, Bass,
	Frommer,		Frommer, Koretz, Nation,
	De La Torre, Jones,		Vargas, Yee
	Montanez, Negrete McLeod,		
	Ridley-Thomas		
-----+-----+-----+-----			
Nays:	Aghazarian, Strickland	Nays:	Maze
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APPROPRIATIONS 11-4

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Ayes:	Chu, Bass, Berg,		
	Karnette, Klehs, Leno,		
	Nation, Oropeza,		
	Ridley-Thomas, Saldana,		
	Yee		
-----+-----+-----+-----			
Nays:	Sharon Runner, Emmerson,		
	Haynes, Walters		
-----

SUMMARY : Establishes the California Rx Plus State Pharmacy Assistance Program (Program), to be administered by the Department of Health Services (DHS). Specifically, this bill :

- 1)Authorizes DHS to negotiate drug rebate agreements with drug manufacturers.
- 2)Limits Program eligibility to qualified residents of California who do not have outpatient prescription drug coverage under any program funded in whole or part by the federal government except that a qualified resident enrolled in Medicare may participate in the program to the extent allowed by federal law.
- 3)Defines "qualified resident" to mean either of the following:

- a) A resident of California who has a family income equal to or less than 400% of the federal poverty guidelines (FPL); or,
  - b) A resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5% or more of family income or whose total unreimbursed medical expenses equal 15% or more of family income.
- 4) Requires DHS to execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.
- 5) Requires DHS to develop a system, as specified, to provide a Program participant with the best discounts on prescription drugs that are available to the participant through the Program or through a drug manufacturer patient assistance program.
- 6) Requires drug manufacturers to report annually to DHS regarding the utilization of drug company assistance programs.
- 7) Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in the Program.
- 8) Requires the amount a participant pays for a drug through the Program to be equal to the participating pharmacies usual and customary charge, or contract rate as specified, less a Program discount, as specified.
- 9) Requires DHS to negotiate drug rebate agreements with drug manufacturers and to seek rebate amounts equal to or greater than the Medi-Cal rebate, as specified. Requires various provisions in rebate agreements.
- 10) Permits DHS to limit the number of drugs available through the Program to obtain the most favorable discounts.
- 11) Requires all drug rebates negotiated pursuant to this bill to be used to reduce the cost of drugs purchased by Program participants.
- 12) Permits DHS to require Medi-Cal prior authorization for any drug of a manufacturer that does not agree to provide rebates to the Program. Requires DHS, in making the determination to require prior authorization in the Medi-Cal program, to ensure that there are as many single-source drugs within each drug therapeutic category or subcategory as DHS

determines necessary to meet the health needs of the Medi-Cal population. Prohibits a Medi-Cal beneficiary from being denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary.

- 13) Requires the names of manufacturers that do and do not agree to Program rebates to be public information.
- 14) Exempts Program contracts from the Public Records Act.
- 15) Requires DHS to seek a determination from the federal Centers for Medicare and Medicaid Services that the Program established pursuant to this bill complies with the requirements for a state pharmaceutical assistance program and that discounts provided under the Program are exempt from the Medicaid best price requirement.
- 16) Requires DHS to deposit all payments received pursuant to this bill into the California Rx Plus Program Fund (Fund) to be established in the State Treasury. Requires the moneys in the Fund to be used to pay participating pharmacies and to defray costs of administering the provisions of this bill.

FISCAL EFFECT : According to the Assembly Appropriations Committee analysis:

- 1)Based on funding in the Governor's fiscal year 2005-06 Budget for his similar proposal, general Fund (GF) costs of \$3.9 million for Program staff and administrative costs. Unknown costs, likely one-time in nature and dependent upon enrollment, associated with the delayed receipt of rebates and initial payments to pharmacies.
- 2)On-going state costs, potentially in the millions to low tens of millions of dollars annually, for outreach activities to implement the new drug discount program.
- 3)Unknown foregone revenue from Medi-Cal supplemental rebates if drug manufacturers fail to provide rebates under this bill and their drugs are removed from the Medi-Cal preferred drug list. The state currently projects receiving \$322 million (GF) in supplemental Medi-Cal rebates in 2005-06.
- 4)Unknown savings on state and county health program costs due to the availability of drug discounts.

COMMENTS : According to the author, this bill is needed to help Californians cope with the rising cost of prescription drugs by creating a drug discount card program for state residents. The author states that despite the skyrocketing cost of drugs, to

date the state has done little, compared to other states, to help residents afford their medication.

State Pharmacy Assistance Programs (SPAPs) are state-sponsored programs that generally provide selected populations with increased access to prescription drugs. As of March 2005 at least 39 states had established or authorized some type of program, to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Currently, 32 state programs are in operation. Most programs utilize state funds to subsidize a portion of an individual's drug costs, but an increasing number use discounts or bulk purchasing approaches.

Though most SPAPs target low-income individuals who are not eligible for Medicaid, many states have expanded their programs to serve individuals with higher incomes as well. All states provide coverage to those aged 65 and older, and half of the programs cover individuals with disabilities under age 65. Eligibility levels range from 100% FPL (\$9,310 for an individual in 2004) in Arkansas and Louisiana to 500% FPL in Massachusetts (\$46,550 for an individual in 2004). A few states have moved toward offering the benefits regardless of income, adjusting cost sharing requirements accordingly. In addition, a few programs have adjusted eligibility limits for individuals who have prescription drug expenses that are considered "catastrophic" (ranging from 3% to 40% of income).

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

FN: 0010841

AMENDED IN SENATE JUNE 22, 2005  
AMENDED IN ASSEMBLY MAY 2, 2005  
AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 76**

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

(Coauthor: Senator Alquist)

January 3, 2005

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An act to amend Section 12803 of, to add Part 5.4 (commencing with Section 14570) to, and to repeal Chapter 12 (commencing with Section 14977) of Part 5.5 of; Division 3 of Title 1 of, the Government Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 76, as amended, Frommer. Office of Pharmaceutical Purchasing.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law requires 4 state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. Existing law grants the Department of General Services

authority with respect to contracting with a pharmaceutical benefits manager or other entity and exploring additional strategies for managing drug costs.

This bill would repeal these provisions. The bill would instead establish within the California Health and Human Services Agency the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies similar to that granted to the Department of General Services under the above-described provisions. The bill would also, however, require the office to be the purchasing agent for the California State University and any other state agency as directed by the Governor, would add to those entities that may elect to participate in the purchasing program, and would authorize the office to conduct specified activities in order to negotiate the lowest prices possible for prescription drugs. ~~The bill would require the office, on or before February 1, 2007, and annually thereafter, to submit a report containing specified information to certain committees of the Legislature regarding the program.~~

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. Section 12803 of the Government Code is  
2 amended to read:  
3 12803. (a) The California Health and Human Services  
4 Agency consists of the following departments: Health Services;  
5 Mental Health; Developmental Services; Social Services;  
6 Alcohol and Drug Abuse; Aging; Rehabilitation; and Community  
7 Services and Development.  
8 (b) The agency also includes the Office of Statewide Health  
9 Planning and Development and the State Council on  
10 Developmental Disabilities.  
11 (c) The Department of Child Support Services is hereby  
12 created within the agency commencing January 1, 2000, and  
13 shall be the single organizational unit designated as the state's  
14 Title IV-D agency with the responsibility for administering the  
15 state plan and providing services relating to the establishment of  
16 paternity or the establishment, modification, or enforcement of  
17 child support obligations as required by Section 654 of Title 42  
18 of the United States Code. State plan functions shall be

1 performed by other agencies as required by law, by delegation of  
2 the department, or by cooperative agreements.

3 (d) The Office of Pharmaceutical Purchasing is hereby  
4 established within the agency and shall purchase prescription  
5 drugs for state agencies pursuant to Part 5.4 (commencing with  
6 Section 14570).

7 SEC. 2. Part 5.4 (commencing with Section 14570) is added  
8 to Division 3 of Title 1 of the Government Code, to read:

9  
10 PART 5.4. OFFICE OF PHARMACEUTICAL PURCHASING

11  
12 14570. As used in this part, "office" means the Office of  
13 Pharmaceutical Purchasing within the California Health and  
14 Human Services Agency.

15 14571. (a) Notwithstanding any other provision of law, the  
16 office may enter into exclusive or nonexclusive contracts on a  
17 bid or negotiated basis with manufacturers and suppliers of single  
18 source or multisource drugs. The office may obtain from those  
19 manufacturers and suppliers, discounts, rebates, or refunds based  
20 on quantities purchased insofar, as permissible under federal law.  
21 Contracts entered into pursuant to this part may include price  
22 discounts, rebates, refunds, or other strategies aimed at managing  
23 escalating prescription drug prices.

24 (b) Contracts under this part shall be exempt from Chapter 2  
25 (commencing with Section 10290) of Part 2 of Division 2 of the  
26 Public Contract Code.

27 ~~(c) The State Department of Health Services may require prior~~  
28 ~~authorization in the Medi-Cal program pursuant to Section 1927~~  
29 ~~of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for~~  
30 ~~any drug of a manufacturer that does not agree to provide rebates~~  
31 ~~to the office for prescription drugs purchased under this part to~~  
32 ~~the extent the department determines it is appropriate to do so in~~  
33 ~~order to encourage manufacturer participation, and to the extent~~  
34 ~~permitted by federal law and subject to any necessary federal~~  
35 ~~approvals or waivers. In making the determination to require~~  
36 ~~prior authorization in the Medi-Cal program under this~~  
37 ~~subdivision, the department shall ensure that there are as many~~  
38 ~~single-source drugs within each drug therapeutic category or~~  
39 ~~subcategory as the department determines necessary to meet the~~  
40 ~~health needs of the Medi-Cal population. In no event shall a~~

1 ~~Medi-Cal beneficiary be denied continued use of a drug that is~~  
2 ~~part of a prescribed therapy unless that drug is no longer~~  
3 ~~prescribed for that beneficiary. It is the intent of the Legislature~~  
4 ~~to limit any rebates that are obtained as a result of the~~  
5 ~~establishment of a prior authorization requirement in Medi-Cal to~~  
6 ~~drugs prescribed to financially needy individuals who, through~~  
7 ~~the use of these prescribed drugs, would improve their health~~  
8 ~~status and become less likely to enroll in the Medi-Cal program.~~

9 14572. (a) The office shall be the purchasing agent for  
10 prescription drugs for all of the following state entities:

- 11 (1) Department of Corrections.
- 12 (2) State Department of Mental Health.
- 13 (3) Department of the Youth Authority.
- 14 (4) State Department of Developmental Services.
- 15 (5) California State University.
- 16 (6) Any other state agency as directed by the Governor.

17 (b) Any state, district, county, city, municipal, school district,  
18 joint powers agreement or trust that administers or pays public  
19 employee benefits, or public agency governmental entity, other  
20 than a state entity specified in subdivision (a), may elect to  
21 participate in the coordinated purchasing program.

22 ~~14573. (a) The office shall work with the University of~~  
23 ~~California to identify opportunities for consolidating the drug~~  
24 ~~purchases made by both agencies in order to lower the state's~~  
25 ~~costs for purchasing prescription drugs. It is the intent of the~~  
26 ~~Legislature that the University of California cooperate with the~~  
27 ~~office in these efforts. *It is the intent of the Legislature that the*~~  
28 ~~*office, the University of California, and the Public Employees'*~~  
29 ~~*Retirement System regularly meet and share information*~~  
30 ~~*regarding each agency's procurement of prescription drugs in an*~~  
31 ~~*effort to identify and implement opportunities for cost savings in*~~  
32 ~~*connection with this procurement. It is the intent of the*~~  
33 ~~*Legislature that the University of California and the Public*~~  
34 ~~*Employees' Retirement System cooperate with the office in order*~~  
35 ~~*to reduce each agency's costs for prescription drugs.*~~

36 ~~(b) The office shall develop an annual workplan that provides~~  
37 ~~a comprehensive approach to reducing the state's procurement~~  
38 ~~costs for prescription drugs. The workplan shall detail the~~  
39 ~~office's annual activities and the estimated savings that these~~  
40 ~~activities are expected to achieve. The office shall use the~~

1 ~~workplan when reporting to the Legislature on estimated and~~  
2 ~~achieved savings resulting from the office's activities.~~

3 ~~(e) The office shall participate in at least one independent~~  
4 ~~group that develops information on the relative effectiveness of~~  
5 ~~prescription drugs.~~

6 ~~(d) (1) It is the intent of the Legislature that the state provide~~  
7 ~~parolee medications in the most cost-effective manner. In~~  
8 ~~deciding how to purchase parolee medications, the office shall~~  
9 ~~consider, but not be limited to, all of the following:~~

10 ~~(A) Contracting with a pharmacy benefits manager.~~

11 ~~(B) Purchasing medications under pharmacy contracts used for~~  
12 ~~prison inmates.~~

13 ~~(C) To the extent feasible, requiring prior authorization in the~~  
14 ~~Medi-Cal program pursuant to Section 1927 of the federal Social~~  
15 ~~Security Act (42 U.S.C. Sec. 1396r-8) to obtain drug discounts~~  
16 ~~for the parolee population.~~

17 ~~(2) The office shall compare the cost of these options and~~  
18 ~~choose the lowest cost option.~~

19 ~~(b) The office shall do all of the following:~~

20 ~~(1) Share information on a regular basis with the University of~~  
21 ~~California and the Public Employees' Retirement System~~  
22 ~~regarding each agency's procurement of prescription drugs,~~  
23 ~~including, but not limited to, prices paid for the same or similar~~  
24 ~~drugs and information regarding drug effectiveness.~~

25 ~~(2) Identify opportunities for the office, the University of~~  
26 ~~California, and the Public Employees' Retirement System to~~  
27 ~~consolidate drug procurement or engage in other joint activities~~  
28 ~~that will result in cost savings in the procurement of prescription~~  
29 ~~drugs.~~

30 ~~(3) Participate in at least one independent association that~~  
31 ~~develops information on the relative effectiveness of prescription~~  
32 ~~drugs.~~

33 ~~(4) No later than January 1, 2007, and annually thereafter,~~  
34 ~~develop a work plan that includes, but is not limited to, a~~  
35 ~~description of the office's annual activities to reduce the state's~~  
36 ~~costs for prescription drugs and an estimate of cost savings.~~

37 ~~(5) No later than January 10, 2007, and annually thereafter,~~  
38 ~~report to the chairperson of the Joint Legislative Budget~~  
39 ~~Committee and the chairs of the fiscal committees of the~~  
40 ~~Legislature on any joint activities of the office, the University of~~

1 *California, and the Public Employees' Retirement System in the*  
2 *last 12 months in connection with procurement of prescription*  
3 *drugs and any resulting cost savings. This report shall include*  
4 *the work plan prescribed in paragraph (4).*

5 *(c) Nothing in this section shall be construed to require*  
6 *sharing of information that is prohibited by any other provision*  
7 *of law or contractual agreement, or the disclosure of information*  
8 *that may adversely effect potential drug procurement by any state*  
9 *agency.*

10 14574. (a) In order to negotiate the lowest prices possible for  
11 prescription drugs for purposes of this part, the office may do all  
12 of the following:

13 (1) Establish a formulary or formularies for state programs in  
14 consultation with the affected agencies.

15 (2) Pursue all opportunities for the state to achieve savings  
16 through the federal 340B program, as established under Section  
17 340B of the Public Health Service Act (42 U.S.C. Sec. 256b),  
18 including the development of cooperative agreements with  
19 entities covered under the 340B program that increase access to  
20 340B program prices for individuals receiving prescription drugs  
21 through programs in departments described in Section 14572.

22 (3) Develop an outreach program to ensure that hospitals,  
23 clinics, and other eligible entities participate in the program  
24 authorized under Section 340B of the Public Health Service Act  
25 (42 U.S.C. Sec. 256b).

26 (b) The office, in consultation with the agencies listed in  
27 subdivision (a) of Section 14572, may investigate and implement  
28 other options and strategies to achieve the greatest savings on  
29 prescription drugs with prescription drug manufacturers and  
30 wholesalers.

31 14575. The office may appoint and contract with a  
32 pharmaceutical benefits manager or other entity for purposes of  
33 the prescription drugs purchased under this part. The  
34 pharmaceutical benefits manager or other entity may do all of the  
35 following:

36 (a) Negotiate price discounts, rebates, or other options that  
37 achieve the greatest savings on prescription drugs with  
38 prescription drug manufacturers and wholesalers.

39 (b) Purchase prescription drugs for participating state, district,  
40 county, or municipal governmental entities.

1 (c) Act as a consultant to the office.

2 14576. The office may explore additional strategies for  
3 managing the increasing costs of prescription drugs, including,  
4 but not limited to, all of the following:

5 (a) Coordinating programs offered by pharmaceutical  
6 manufacturers that provide prescription drugs for free or at  
7 reduced prices.

8 (b) Studying the feasibility and appropriateness of including in  
9 the bulk purchasing programs entities in the private sector,  
10 including employers, providers, and individual consumers.

11 (c) Implementing other strategies, as permitted under state and  
12 federal law, aimed at managing escalating prescription drug  
13 prices.

14 ~~(d) It is the intent of the Legislature that the office, State  
15 Department of Health Services, University of California, and  
16 Public Employees' Retirement System share information on a  
17 regular basis on drug purchasing activities.~~

18 14577. On or before February 1, 2007, and annually  
19 thereafter, the office shall submit a report to the appropriate  
20 policy and fiscal committees of the Legislature on activities that  
21 have been or will be undertaken pursuant to this part. The report  
22 shall include, but not be limited to, all of the following:

23 (a) The number and a description of contracts entered into  
24 with manufacturers and suppliers of drugs pursuant to Section  
25 14571, including any discounts, rebates, or refunds obtained.

26 (b) The number and a description of entities that elect to  
27 participate in the coordinated purchasing program pursuant to  
28 subdivision (b) of Section 14572.

29 (c) Other options and strategies that have been or will be  
30 implemented pursuant to Sections 14573 and 14575.

31 (d) Estimated costs and savings attributable to activities that  
32 have been or will be undertaken pursuant to this part.

33 ~~(e) The identification of the collaborative activities that the  
34 office, State Department of Health Services, University of  
35 California, and Public Employees' Retirement System conducted  
36 in the past 12 months to reduce the cost of drug purchasing by  
37 the state and the savings attributable to those activities.~~

38 ~~(f) The identification of opportunities to consolidate drug  
39 purchases with the University of California.~~

1 SEC. 3. Chapter 12 (commencing with Section 14977) of Part  
2 5.5 of Division 3 of Title 1 of the Government Code is repealed.

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# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 76**

**VERSION: AMENDED JULY 5, 2005**

**AUTHOR: FROMMER et. al.**

**SPONSOR: FROMMER**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: OFFICE OF PHARMACEUTICAL PURCHASING**

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### **Existing Law:**

- 1) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)
- 2) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

### **This Bill:**

- 1) Repeals these provisions authorizing DGS's drug purchasing program. (Govt Code 14977-14981 Repealed)
- 2) Creates the Office of Pharmaceutical Purchasing (office) within California Health and Human Services Agency to purchase prescription drugs for the following entities:
  - a. California Department of Corrections (CDC)
  - b. Department of Mental Health (DMH)
  - c. California Youth Authority (CYA)
  - d. Department of Developmental Services (DDS)
  - e. Department of Veterans Affairs
  - f. California State University (CSU)
  - g. Any other state agency as directed by the Governor.
  - h. Any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity that may elect to participate in the coordinated purchasing program. (Govt Code 12803 Amended, 14572 Added)
- 3) States that is the intent of the Legislature that the office, the University of California, and the Public Employees' Retirement System regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings in connection with this procurement. It is also the intent of the Legislature that

the University of California and the Public Employees' Retirement System cooperate with the office in order to reduce each agency's costs for prescription drugs. (Govt Code 14573 Added)

4) Authorizes the office to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law.

(Govt Code 14571 Added)

5) Authorizes the office to appoint and contract with a pharmaceutical benefits manager (PBM) or other entity to do all of the following:

a. Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

b. Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

c. Act as a consultant to the office.

(Govt Code 14575 Added)

6) Requires the office, on or before February 1, 2007, to submit a report to the Legislature on activities that have been or will be undertaken. The report would include the following:

a. The number and a description of contracts entered into with manufacturers and suppliers of drugs including any discounts, rebates, or refunds obtained.

b. The number and a description of entities that elect to participate in the coordinated purchasing program.

c. Other options and strategies that have been or will be implemented pursuant to receive the lowest cost drugs.

d. Estimated costs and savings attributable to activities that have been or will be undertaken by the office.

e. Identify the collaborative activities that the office, State Department of Health Services, University of California, and Public Employees' Retirement System conducted in the past 12 months to reduce the cost of drug purchasing by the state and the savings attributable to those activities.

(Govt Code 14577 Added)

7) Requires the office to, no later than January 1, 2007, and annually thereafter, develop a work plan that includes, but is not limited to, a description of the office's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings. Also requires the office to, no later than January 10, 2007, and annually thereafter, report to the Chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature on any joint activities of the office, the University of California, and the Public Employees' Retirement System in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings.

(Govt Code 14573 Added)

### **Comment:**

**1) Author's Intent.** The author's intent is to implement drug-purchasing recommendations made by the California Performance Review (CPR). CPR estimates that its drug purchasing proposals would result in \$75 million in annual state savings.

**2) Current DGS Drug Purchasing Program.** DGS is responsible for procuring drugs for CDC DMH, DDS, CYA, and CSU's student health centers. DGS contracts with a vendor, McKesson Corporation, to process departmental drug orders and then distribute those orders to the departments. McKesson acquires the drugs through 1) competitively procured state contracts

for generic drugs, 2) negotiated state contracts for brand-name drugs, or 3) the Massachusetts Alliance, a GPO consisting of both public and private agencies. For drugs that are not available through these methods, McKesson acquires the drugs at discounted wholesale prices.

**3) LAO Report.** A February 2005 Legislative Analyst Office (LAO) Report, Lowering the State's Costs for Prescription Drugs, examines how the state purchases drugs for its program recipients. The LAO report was critical of many elements in CPR's drug purchasing proposal, which are also found in AB 76. Specifically, the LAO found:

- a. The use of a PBM would not benefit the state since the state already has established a drug formulary, authority to negotiate drug rebates, and usually does not purchase drugs from private pharmacies.
- b. There is a limited need for a drug purchasing office given that the creation of a new office could be costly, create organizational difficulties, and provide little strategic advantage to the state over the current arrangement in which procurement duties are already largely concentrated.

Overall the LAO found the state's various drug-purchasing programs could take specific actions to improve on getting the lowest price possible for prescription drugs. Legislation would be required to implement most of the actions recommended by the LAO.

#### **4) Support / Opposition.**

Support: American Federation of State, County and Municipal Employees  
California Alliance of Retired Americans  
California Federation of Labor  
California Public Interest Research Group  
Consumers Union  
Health Access  
Mental Health Association of California  
Older Women's League of California  
Senior Action Network  
Service Employees Union International

Opposition: Biocom  
California Chamber of Commerce  
Novartis Pharmaceuticals  
Pharmaceutical Research and Manufacturers of America  
Western Center on Law & Poverty (unless amended)  
Wyeth Pharmaceuticals

#### **5) History.**

July 5	Read second time, amended, and re-referred to Com. on APPR.
July 1	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 4.)
June 22	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 20	In committee: Set, first hearing. Hearing canceled at the request of author.
June 15	Referred to Coms. on HEALTH and G.M., E. & A.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 42. Noes 34. Page 2141.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 12. Noes 5.) (May 25).
May 18	In committee: Set, first hearing. Referred to APPR. suspense file.

May 3 Re-referred to Com. on APPR.  
May 2 Read second time and amended.  
Apr. 28 From committee: Amend, and do pass as amended, and re-refer to Com. on  
APPR. (Ayes 7. Noes 1.) (April 26).  
Apr. 13 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred.  
(Ayes 9. Noes 3.) (April 12).  
Apr. 6 Re-referred to Com. on HEALTH.  
Apr. 5 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.

**AB 76**

**AMENDED: June 22, 2005**

**SENATE HEALTH  
COMMITTEE ANALYSIS  
Senator Deborah V. Ortiz, Chair**

**FISCAL:** Government Modernization and Economic  
Development 6  
/Appropriations

**CONSULTANT:**  
Bohannon / ak

**SUBJECT**

Office of Pharmaceutical Purchasing

**SUMMARY**

This bill would repeal provisions of existing law authorizing the Department of General Services (DGS) to negotiate contracts for prescription drugs for specified state agencies and other entities. This bill would instead establish the Office of Pharmaceutical Purchasing (OPP) within the California Health and Human Services Agency (Agency) with authority and duties to purchase prescription drugs for state agencies similar to that granted to DGS. The bill would additionally require the OPP to be the purchasing agency for the California State University (CSU), any other state agency as directed by the Governor, and other entities that elected to participate in the purchasing program. The measure would also require the OPP to conduct specified activities in order to negotiate the lowest prices possible for prescription drugs.

**ABSTRACT**

Existing federal law:

- 1.Requires drug manufacturers, for the purposes of the federal Medicaid program, to enter into rebate agreements with the United States Secretary of Health and Human Services for states to receive federal funding for outpatient prescription drugs dispensed to Medicaid enrollees.
- 2.Permits a state, upon authorization from the Secretary, to enter directly into agreements with a drug

manufacturer to negotiate deeper discounts for state Medicaid programs.

3. Authorizes, for the purposes of the federal 340B program, the Secretary of Health and Human Services to enter into agreements with drug manufacturers to provide specified drugs to cover entities at discounted prices.

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 the Department of Health Services (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, as permissible by federal law.
  3. Specifies that the Agency consists of the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities and includes the following departments:
    - Health Services;
    - Mental Health;
    - Developmental Services;
    - Social Services;
    - Alcohol and Drug Abuse;
    - Aging;
    - Rehabilitation;
    - Community Services and Development; and,
    - Child Support Services.
1. Authorizes DGS to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with drug manufacturers and suppliers, and authorizes DGS to obtain discounts, rebates, or refunds as permissible under federal law.
  2. Allows contracts entered into by DGS to include discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. Exempts these contracts from specified provisions of the Public Contract Code.
  3. Authorizes DGS to establish a bulk purchasing program and requires the following state entities to purchase drugs through the bulk purchasing program:
    - State Department of Mental Health;
    - Department of Corrections;

Department of the California Youth Authority; and,  
State Department of Developmental Services.

1. Allows any state, district, county, city, municipal, or public agency governmental entity to elect to participate in the coordinated purchasing program.
2. Authorizes DGS, in consultation with the entities listed in #4, to investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with drug manufacturers and wholesalers.
3. Authorizes DGS to appoint and contract with pharmaceutical benefits manager (PBM) or other entity to, among other things, negotiate price discounts, purchase prescription drugs, and act as a consultant to DGS.
4. Authorizes DGS to explore additional strategies for managing the increasing costs of prescription drugs including:
  - Coordinating programs offered by drug manufacturers that provide prescription drugs for free or at reduced prices;
  - Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers; or,
  - Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

This bill:

1. Establishes the OPP within the Agency to purchase prescription drugs for state agencies as specified.
2. Authorizes the OPP to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with drug manufacturers and suppliers, and authorizes the OPP to obtain discounts, rebates, or refunds as permissible under federal law.
3. Allows contracts entered into by the OPP to include discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. Exempts these contracts from specified provisions of the Public Contract Code.
4. Requires the OPP to be the purchasing agency for prescription drugs for all of the following state

entities:

Department of Corrections;  
State Department of Mental Health;  
Department of the Youth Authority;  
State Department of Developmental Services;  
CSU; and  
Any other state agency as directed by the Governor.

1. Allows any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity to elect to participate in the coordinated purchasing program.
2. States legislative intent for the OPP, the University of California (UC), and the Public Employees' Retirement System (PERS) to regularly meet and share drug procurement information to identify and implement opportunities for cost savings.
3. Expresses the intent of the Legislature that UC and PERS cooperate with the OPP in order to reduce each agency's costs for prescription drugs.
4. Requires the OPP to do all of the following:
  - Share information on a regular basis with UC and PERS regarding each agency's procurement of prescription drugs;
  - Identify opportunities for the OPP, UC, and PERS to consolidate drug procurement or engage in other joint activities that will result in cost savings;
  - Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs;
  - Develop a work plan that includes, but is not limited to, a description of the OPP's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings, no later than January 1, 2007, and annually thereafter; and,
  - Report to the chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature on any joint activities of the OPP, UC, and PERS in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings, including the work plan described above, no later than January 10, 2007, and

annually thereafter.

1. Specifies that nothing shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely effect potential drug procurement by any state agency.
2. Authorizes the OPP to do all of the following in order to negotiate the lowest prices possible for prescription drugs:

Establish a formulary or formularies for state programs in consultation with the affected agencies;

Pursue all opportunities for the state to achieve savings through the federal 340B program including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for specified individuals; and,

Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the 340B program.

1. Authorizes the OPP, in consultation with the agencies listed in #4, to investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with drug manufacturers and wholesalers.
2. Authorizes the OPP to appoint and contract with a PBM or other entity to, among other things, negotiate price discounts, purchase prescription drugs, and act as a consultant to the OPP.
3. Authorizes the OPP to explore additional strategies for managing the increasing costs of prescription drugs including, but not limited to,:

Coordinating programs offered by drug manufacturers that provide prescription drugs for free or at reduced prices;

Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers; or,

Implementing other strategies, as permitted under state and federal law, aimed at managing escalating

prescription drug prices.

1.Requires the OPP to submit a report to the appropriate policy and fiscal committees of the Legislature, on or before February 1, 2007, on activities that have been or will be undertaken.

2.Requires the report to include, but not be limited to, all of the following:

The number and description of contracts entered into with drug manufacturers and suppliers as specified, including any discounts, rebates, or refunds obtained;

The number and description of entities that elect to participate in the coordinated purchasing program as specified;

Other options and strategies that have been or will be implemented as specified; and,

Estimated costs and savings attributable to activities that have been or will be undertaken.

1.Repeals provisions of the Government Code authorizing DGS to negotiate contracts for prescription drugs for specified state agencies and other entities.

#### FISCAL IMPACT

According to the Assembly Appropriations Committee: Assuming establishing an OPP results in increased staffing positions by three additional positions above the DGS staffing level, increased General Fund (GF) cost of \$306,000. This assumes that the two staff positions and \$224,000 in spending in DGS are transferred to the OPP.

Assuming the OPP meets the requirement that it participate in at least one independent group that develops information on the relative effectiveness of prescription drugs by participating in the Oregon Effectiveness Review Project, a total funds cost of approximately \$100,000 annually.

Unknown, potentially significant increased out-year revenue from increased state purchasing power in negotiating with drug manufacturers. Based on 2003 - 04 expenditures, if drug expenditures for the Departments of Corrections, Mental Health, Youth Authority, Developmental Services, and the California State

University were reduced by 10 percent annually, total fund savings of \$17.7 million would result.

## BACKGROUND AND DISCUSSION

### Purpose of bill

According to the author, AB 76 will enable the state to take better advantage of its bargaining power to hold down the cost of prescription drugs. The author maintains that both the Legislative Analyst's Office (LAO) and the California Performance Review (CPR) found major deficiencies in the way the state is currently purchasing prescription drugs and recommend a number of changes, many of which are incorporated in this bill. The author believes the state can save millions of dollars in programs that purchase prescription drugs and redirect those savings to maintain health, education, transportation, and other programs that are threatened by the state's current budget deficit.

### State drug purchasing and costs

According to the Congressional Budget Office, the growth in prescription drug costs has outpaced every other category of health expenditure. California, like all other states, has experienced this growth in prescription drug costs. According to a 2002 Bureau of State Audits review, the five state agencies that most frequently purchase drugs experienced an annual average increase of 34 percent in their drug costs from 1996 to 2001. The overall cost of drug expenditures for these five agencies rose from \$41.6 million in 1996-97 to \$153.6 million in 2002-03. According to the LAO, state agencies purchase approximately \$4.2 billion annually in prescription and nonprescription drugs.

These agencies use different methods to purchase discounted drugs which include contracting directly with drug manufacturers and wholesalers, utilizing Group Purchasing Organizations or PBMs, or negotiating directly with health care benefit plans.

### The CPR

The CPR, initiated by the Governor, called for the state to take immediate steps to purchase drugs in a more coordinated, unified fashion. The CPR noted that several state agencies purchase drugs independently of each other, weakening the state's ability to bargain aggressively for better prices. The CPR said that:

"Although the state's purchasing power should equate to a strong market position and lower drug prices, this is not the case. Several of the state agencies purchasing drugs do so independently of each other and

thus segment themselves into smaller markets. Although each state entity may do an admirable job of negotiating drug prices, this practice weakens their market position and results in higher drug costs. Working together to combine drug purchases would significantly increase their volume purchasing power thus establishing a stronger market position leading to lower drug costs."

The CPR recommended that the Governor and Legislature should work together to create a new Central Pharmaceutical Office that should be responsible for the procurement and management of all pharmaceutical programs. The CPR also recommended that this office should have the authority to establish cooperative relationships with local governments, other state entities and drug manufacturers in order to maximize the state's purchasing power. Finally, the CPR recommended that DGS, or its successor, enter into a contract with a PBM to administer the state's drug purchasing program.

Additionally, the CPR showed that safety net providers are able to obtain prescription drugs for their patients at a 50 percent discount off of retail prices through the federal 340B program. The federal 340B program permits various "covered entities," mostly safety net health care providers like community clinics and disproportionate-share public and private hospitals, to obtain steeply-discounted drugs for patients of those providers. Utilizing 340B prices for state programs could save the state millions of dollars through the use of cooperative agreements between the state and safety net providers that would allow the state to access these prices.

The LAO report

A recent LAO report, Lowering the State's Costs for Prescription Drugs, identified a range of deficiencies in the state's procurement of prescription drugs which lead to higher costs than necessary. For example, the report found that DGS is not providing sufficient leadership in drug procurement. Specifically, the report found that DGS has no comprehensive work plan or strategy for aggressively lowering drug costs; DGS purchases almost half of its drugs without contracts, which results in the state paying higher prices; and DGS does not participate in independent groups that review the comparative effectiveness of similar drugs.

The report also found that there is insufficient collaboration among state agencies in their drug purchasing.

Among other things, the LAO recommended the Legislature

should:

Require collaboration and information sharing on drug purchasing among DGS, the DHS, UC and PERS;

Direct DGS and UC to identify consolidated purchasing opportunities;

Require DGS to develop an annual work plan for purchasing drugs;

Require DGS participation in evidence-based drug reviews by outside entities; and,

Direct DHS to modify formulary regulations to permit the Department of Mental Health and the Department of Developmental Services to have one formulary committee to serve all of an agency's facilities, rather than require each facility to have a formulary.

AB 76 essentially transfers the drug purchasing and coordination authority in existing law from DGS to the newly created OPP and builds upon that authority based upon the aforementioned recommendations by the CPR and LAO.

Drug purchasing coordination efforts in other states  
In 2003, the Governor of Illinois created a Special Advocate for Prescription Drugs to provide strategic coordination of prescription drug contracts and programs by a central state purchasing agent. In late 2004, the Governor of West Virginia created a cabinet level Pharmaceutical Special Advocate to direct state government procurement of prescription drugs. The state of Maine, in its recently enacted 2005-06 budget, established a Pharmaceutical Cost Management Council to jointly purchase drugs for a number of state programs. Currently, Massachusetts and Pennsylvania also have centralized purchasing initiatives underway.

Arguments in support

Supporters of the bill believe AB 76 would significantly increase the state's purchasing clout and enable California to garner lower prescription drug prices. They insist that the state's current drug procurement process is fragmented resulting in higher costs than necessary to California taxpayers. They believe that while recent legislation has sought to improve coordination, progress toward real collaboration among state drug purchasers has been slow and limited. They also believe the purchasing power amassed under AB 74 will result in significant savings to the state budget. Further, supporters maintain that the new Medicare

prescription drug law will reduce the effectiveness of Medi-Cal prescription drug purchasing efforts while requiring the state to pay the federal government. Supporters insist that by helping to reduce prescription drug costs for other state programs, AB 76 helps to remedy the damage done by the new Medicare prescription drug law.

#### Arguments in opposition

Opponents of the bill believe AB 76 is premature and unnecessary since DGS was just granted authority to negotiate discounts with drug companies in 2002. They argue that abolishing a program created only two years ago, in order to create a new bureaucracy for the same purpose is not only premature, but is also an inappropriate waste of state resources. Further, they insist that proposed aggregate purchasing programs for multiple patient populations may not meet the medical needs of individual patients given that diverse patient populations have unique

clinical needs that must be met in their

own distinctive

manner. As such, they insist the state may find it more complicated than anticipated to combine purchasing for each population without compromising the quality of care and the integrity of the program benefits. Lastly, opponents believe AB 76 contains provisions that allow for closed formularies. They believe that limited formularies are counter to the mission of biotechnology which is based on the premise that even within classes of drugs, there are significant differences in products. As such, they insist that limiting the number of drugs within a formulary essentially limits therapeutic options for patients.

#### Relevant legislation

SB 708 (Speier, 2005) would require DHS to develop a standard contract for use in any agreement with a not-for-profit hospital that elects to participate in the federal 340B program.

SB 1315 (Sher, Chapter 483, Statutes of 2002) requires DGS to purchase pharmaceuticals on behalf of the Department of Corrections, Department of Mental Health, Department of Youth Authority, and Department of Developmental Services. Allows any other state, county, city, municipal or public agency government entity, to elect to participate in the coordinated purchasing program.

### QUESTIONS AND COMMENTS

1.PBM protections. AB 76 authorizes the OPP to appoint and contract with a PBM or other entity to provide consulting

and pharmacy benefit management services. Last week the committee passed AB 78 (Pavley) which seeks to provide transparency in PBM contracting by requiring a PBM to annually disclose specified confidential proprietary information to a purchaser. AB 78 is premised on the notion that some PBMs engage in questionable business practices resulting in higher prescription drug costs for the purchaser. As such, should AB 76 be amended to require the OPP to develop a system to prevent diversion of funds collected by the PBM or other entity it may appoint and contract with to provide consulting and pharmacy benefit management services?

2. Is AB 76 duplicative of SB 1315? AB 76 essentially transfers the drug purchasing and coordination authority in existing law created pursuant to SB 1315 (Sher, Chapter 483, Statutes of 2002) from DGS to the newly created OPP and builds upon that authority based upon recommendations by the CPR and LAO. LAO recommendations, however, focused on bolstering DGS' capacity, leadership and coordination in drug purchasing, but nonetheless, left that authority within the department. Given the same statutory authority and additional requirements, does the author believe DGS could accomplish the same goals as the OPP?

#### PRIOR ACTIONS

Assembly Floor: 42 - 34 Pass  
Assembly Appropriations: 12 - 5 Do Pass  
Assembly Bus. & Prof: 7 - 1 Do Pass as Amended  
Assembly Health: 9 - 3 Do Pass

#### POSITIONS

Support: AFSCME  
California Alliance for Retired Americans  
California Consumers United  
California Labor Federation  
California School Employees Association  
CALPIRG  
Consumers Union  
Gray Panthers  
Health Access  
Health Care for All - California  
Mental Health Association in California  
Older Women's League of California  
Planned Parenthood Affiliates of California  
Retired Public Employees Association  
SEIU

Oppose: BIOCUM  
California Chamber of Commerce  
Novartis  
PhRMA

AMENDED IN SENATE JUNE 22, 2005  
AMENDED IN ASSEMBLY APRIL 26, 2005  
CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 77**

**Introduced by Assembly Member Frommer**

January 3, 2005

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An act to amend Section 14132.01 of the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 77, as amended, Frommer. Medi-Cal: clinics: reimbursement.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits, including drugs, prosthetic and orthotic devices, durable medical equipment, medical supplies, and enteral formulae.

Pursuant to a federal waiver, the Medi-Cal program administers a program known as the Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program, under which comprehensive clinical family planning services are provided to any person who has a family income at or below 200% of the federal poverty level and who is eligible to receive those services pursuant to the terms of the waiver.

Under this program, *reimbursement for take-home drugs and supplies provided by a licensed community-clinics clinic or free clinics are reimbursed in accordance with a prescribed formula clinic, or an intermittent clinic, is required to be the lesser of the amount billed or the Medi-Cal reimbursement rate and shall not exceed the net cost of the drugs or products as provided to retail pharmacies under the Medi-Cal program.*

*This bill would revise this reimbursement formula and would provide that reimbursement to these clinics for take-home drugs and supplies covered under these provisions shall not be at a rate less than the reimbursement rate in effect on June 1, 2005.*

Existing law exempts from ~~this~~ *the reimbursement* formula federally qualified health centers and rural health clinics that have elected to be reimbursed for pharmacy costs based on certain other provisions.

~~This bill would revise the pharmaceutical goods and services reimbursement formula for federally qualified health centers and rural health clinics, and would require certain clinics that elect not to utilize drugs purchased through the 340B federal program for its Medi-Cal patients to provide notification of this fact to the Health Resources and Services Administration's Office of Pharmacy Affairs authorize federally qualified rural health centers and rural health clinics electing pursuant to this provision to bill and be reimbursed pursuant to the bill. The bill would also provide for reimbursement under an alternative rate, for drugs and supplies for which the state receives a state rebate, to a licensed community clinic or free clinic, or an intermittent clinic that uses billing forms reporting the National Drug Code number of the drug or supply, facilitating the state's collection of rebates.~~

*Existing law also requires these clinics to comply with billing amount standards for take-home drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program.*

*This bill would revise the billing amount standards. The bill would require these clinics to bill the Medi-Cal program and Family PACT Waiver Program for drugs and supplies covered under these programs at the lesser of cost or the clinic's usual charge made to the general public. The bill would define "at cost" for purposes of this provision.*

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

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

- 1 SECTION 1. Section 14132.01 of the Welfare and
- 2 Institutions Code is amended to read:
- 3 14132.01. (a) Notwithstanding any other provision of law, a
- 4 community clinic or free clinic licensed pursuant to subdivision
- 5 (a) of Section 1204 of the Health and Safety Code or an

1 intermittent clinic operating pursuant to subdivision (h) of  
2 Section 1206 of the Health and Safety Code, that has a valid  
3 license pursuant to Article 13 (commencing with Section 4180)  
4 of Chapter 9 of Division 2 of the Business and Professions Code,  
5 and is a covered entity, as defined in Section 256b(a)(4) of Title  
6 42 of the United States Code, shall bill the Medi-Cal program  
7 and the Family PACT Waiver Program for any take-home drugs,  
8 eligible for reimbursement pursuant to Section 340B of the  
9 federal Public Health Service Act (42 U.S.C. Sec. 256b),  
10 provided to beneficiaries, an amount equal to the lesser of the  
11 clinic's average annual actual acquisition cost for that drug plus a  
12 per cycle, per month, per unit, or per prescription clinic  
13 dispensing fee up to twelve dollars (\$12), or its usual charge  
14 made to the general public. Take-home drugs that are dispensed  
15 for use by the patient within a specific timeframe of five or less  
16 days from the date medically indicated shall be billed at the  
17 actual acquisition cost for that drug plus a clinic dispensing fee,  
18 not to exceed seventeen dollars (\$17) per prescription, or its  
19 usual charge made to the general public. Take-home supplies  
20 may be billed at the usual charge made to the general public.  
21 Reimbursement shall be at the lesser of the amount billed or the  
22 Medi-Cal reimbursement rate and shall not exceed the net cost of  
23 these drugs or products as provided to retail pharmacies under  
24 the Medi-Cal program. Code shall be reimbursed, as described in  
25 this section and at a rate no less than the reimbursement rate in  
26 effect on June 1, 2005, for drugs and supplies covered under the  
27 Medi-Cal program and Family PACT Waiver Program.

28 (b) (1) A clinic described in subdivision (a) shall bill the  
29 Medi-Cal program and Family PACT Waiver Program for drugs  
30 and supplies covered under those programs at the lesser of cost  
31 or the clinic's usual charge made to the general public.

32 (2) For purposes of this section, "at cost" means an aggregate  
33 amount equivalent to the sum of the actual acquisition cost of a  
34 drug or supply plus a reasonable dispensing fee not to exceed  
35 twelve dollars (\$12) per billing unit as identified in the  
36 applicable provider manual and consistent with the National  
37 Drug Code. For purposes of this section, "at cost" for a  
38 take-home drug that is dispensed for use by the patient within a  
39 specific timeframe of five or less days from the date medically  
40 indicated means actual acquisition cost for that drug plus a

1 *clinic dispensing fee, not to exceed seventeen dollars (\$17) per*  
2 *prescription.*

3 ~~(b) Federally qualified health centers and rural health clinics~~  
4 ~~that are “covered entities” as described in subdivision (a) may be~~  
5 ~~reimbursed at the rates established in subdivision (a), upon~~  
6 ~~electing to be reimbursed for pharmaceutical goods and services~~  
7 ~~on a fee-for-service basis, as permitted by subdivision (k) of~~  
8 ~~Section 14132.100.~~

9 *(c) A clinic described in subdivision (a) that furnishes services*  
10 *free of charge or at a nominal charge, as described in Section*  
11 *413.13(a) of Title 42 of the Code of Federal Regulations, or that*  
12 *can demonstrate to the department, upon request, that a*  
13 *significant portion of its patients are low income, shall not be*  
14 *subject to reimbursement reductions based on its usual charge to*  
15 *the general public.*

16 *(d) Federally qualified health centers and rural health clinics*  
17 *that are clinics as described in subdivision (a) may bill and be*  
18 *reimbursed as described in this section, upon electing to be*  
19 *reimbursed for pharmaceutical goods and services on a*  
20 *fee-for-service basis, as permitted by subdivision (k) of Section*  
21 *14132.100.*

22 ~~(e)~~

23 *(e) A clinic that otherwise meets the qualifications set forth in*  
24 *subdivision (a), that is eligible to, but that has elected not to,*  
25 *utilize drugs purchased under the 340B Discount Drug Program*  
26 *for its Medi-Cal patients, shall provide notification to the Health*  
27 *Resources and Services Administration’s Office of Pharmacy*  
28 *Affairs that it is utilizing non-340B drugs for its Medi-Cal*  
29 *patients in the manner and to the extent required by federal law.*

30 *(f) Notwithstanding the provisions of this section or any other*  
31 *provision of law, a clinic described in subdivision (a) may bill for*  
32 *drugs and supplies covered under the Medi-Cal program and*  
33 *Family PACT Waiver Program and for which the state receives a*  
34 *state rebate, using billing forms reporting the National Drug*  
35 *Code number of the drug or supply dispensed in order to*  
36 *facilitate the state’s collection of the Medicaid rebate and the*  
37 *state rebate as described in Section 14105.31. A clinic billing in*  
38 *this manner shall be reimbursed at the rate applicable to a*  
39 *pharmacy under subdivision (b) of Section 14105.45.*  
40 *Participation shall be voluntary on the part of the clinic.*

- 1     (g) Any new billing methodology that the department develops  
2 pursuant to this section shall create minimal financial burden to  
3 the state and to the clinics. Until the time that the department  
4 provides clear guidance through the applicable provider manual  
5 regarding the billing methodology required to comply with this  
6 section, clinics may continue to utilize the billing methodology  
7 being used on December 31, 2004.
- 8     (h) Any new billing methodology or requirement shall be  
9 effective 90 days from the date of publication in the applicable  
10 provider manuals.

**Blank**

**AB 77**

**AMENDED: June 22, 2005**

**SENATE HEALTH**

COMMITTEE ANALYSIS  
Senator Deborah V. Ortiz, Chair

HEARING DATE: June 29, 2005

FISCAL: Appropriations

CONSULTANT:  
Vazquez / ak

**SUBJECT**

Medi-Cal: clinics: reimbursement

**SUMMARY**

This bill revises the pharmaceutical goods and services reimbursement formula for federally qualified health centers and rural health clinics.

**ABSTRACT**

Existing law:

1. Establishes the Medi-Cal program, administered by the Department of Health Services (DHS), which provides comprehensive health benefits to low-income children, their parents or caretaker relatives, pregnant women, elderly, blind or disabled persons, nursing home residents, and refugees who meet specified eligibility criteria.
2. Requires, in general, community clinics, free clinics and intermittent clinics, that are licensed to dispense prescription drugs, and that meet specified federal requirements for the 340B program, to bill Medi-Cal and the Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program for any take-home drugs provided to beneficiaries of those programs, an amount equal to the lesser of: a) the clinic's average annual actual acquisition cost for that drug plus a per cycle, per unit, per month or per prescription clinic dispensing fee up to \$12; or, b) its usual charge made to the general public.

3. Exempts federally qualified health centers (FQHCs), and rural health clinics (RHCs), that elect to be reimbursed on a fee-for-service basis, as specified.
4. Permits a FQHC or RHC to elect to have pharmacy or dental services reimbursed on a fee-for-service basis, utilizing the current fee schedules established for those services.  
Requires these costs to be adjusted out of the FQHC's or RHC's clinic base rate as scope-of-service changes.  
Requires a FQHC or RHC that reverses its election to revert to its prior rate, subject to an increase to account for all Medicare Economic Index increases occurring during the intervening time period, and subject to any increase or decrease associated with applicable scope-of-services adjustments as specified.

This bill:

1. Eliminates the differentiation in billing and reimbursement between 340B and non-340B drugs for community clinics, free clinics, or intermittent clinics, as defined and licensed pursuant to current law and provides that the reimbursement rate shall not be less than the reimbursement rate in effect on June 1, 2005 for drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program.
2. Requires clinics, as defined, to bill the Medi-Cal program and Family PACT Program for drugs and supplies covered under those programs at the lesser of cost or the clinic's usual charge made to the general public.
3. Defines "at cost" for purposes of this section, as an aggregate amount equivalent to the sum of the actual acquisition cost of a drug or supply plus a reasonable dispensing fee not to exceed twelve dollars (\$12) per billing unit, consistent with the National Drug Code.
4. States that for purposes of this section, "at cost" for a take-home drug that is dispensed for use by the patient within a specific timeframe of five or less days from the date medically indicated means actual acquisition cost for that drug plus a maximum clinic dispensing fee of \$17 per prescription, which is consistent with current law.
5. Exempts from reimbursement reductions based on its usual charge to the general public a clinic, as defined, that furnishes services free of charge or at a nominal charge, or that demonstrates to DHS, upon request, that a significant portion of its patients are low income.

6. Permits FQHCs and RHCs that are clinics, as defined, to bill and be reimbursed as described in this section, upon electing to be reimbursed for pharmaceutical goods and services on a fee-for-service basis, as permitted under current law.
7. Requires a clinic, as defined, that otherwise meets the qualifications in current law, that is eligible to, but that has elected not to, utilize drugs purchased under the federal 340B Discount Drug Program for its Medi-Cal patients to provide notification to the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) that it is utilizing non-340B drugs for its Medi-Cal patients in the manner and to the extent required by federal law.
8. Permits, notwithstanding this section or current law, a clinic, as defined, to bill for drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program and for which the state receives a state rebate, using billing forms reporting the National Drug Code number of the drug or supply dispensed in order to facilitate the state's collection of the Medicaid rebate and the state rebate. States that a clinic billing in this manner shall be reimbursed at a rate applicable to a pharmacy under existing law and that participation shall be voluntary on the part of the clinic.
9. Requires that any new billing methodology that DHS develops pursuant to this section create minimal financial burden to the state and to the clinics.
10. Permits clinics, as defined, to continue utilizing the billing methodology being used on December 31, 2004 until DHS provides clear guidance through the applicable provider manual regarding the billing methodology required to comply with this section.
11. Requires that any new billing methodology or requirement be effective 90 days from the date of publication in the applicable provider manuals.

#### FISCAL IMPACT

The amendments adopted on June 22, 2005 newly identify this bill as fiscal.

#### BACKGROUND AND DISCUSSION

Purpose of the bill

According to the author, this bill is intended to clarify

and simplify last year's AB 2151 (Jackson, Chapter 851, Statutes of 2004). AB 2151 was passed on an emergency basis in the last weeks of the prior session in order to address the question of how safety net clinics were to bill and to be reimbursed for drugs distributed to Medi-Cal and Family PACT beneficiaries. Following passage of the bill, clinic stakeholders met with DHS staff and discussed the need to simplify the new law in order to remove practical obstacles rendering clinics unable to determine and adjust billing in order to comply with its terms, as well as to resolve various technical errors which have prevented DHS from moving forward with implementation. This bill resolves technical issues with AB 2151 and brings California law in line with federal law in order to comply with the regulations of the Federal 340B Drug Discount Program.

#### 340B Program

The 340B Drug Pricing Program was established in response to the passage of Section 340B of U.S. Public Law 102-585, the Veterans Health Care Act of 1992. Section 340B limits the cost of drugs to federal purchasers and to certain grantees of federal agencies. The program is administered by the OPA of HRSA, under the federal Department of Health and Human Services (HHS). According to the National Conference of State Legislatures (NCSL), the federal 340B Drug Pricing Program provides access to reduced price prescription drugs to more than 10,000 health care facilities certified by HHS as "covered entities." These clinics, centers and hospitals in turn serve more than 10 million people in all 50 states, plus commonwealths and territories. The Office of Pharmacy Affairs established the Pharmacy Services Support Center under contract with the American Pharmaceutical Association (APhA) to provide, among other things, education and technical assistance on 340B issues.

#### Arguments in support

The sponsors state that the bill clarifies billing provisions that are presently unclear and codifies interpretations reflected in the relevant provider manuals.

One such problem is the use of the phrase "usual charges to the general public" in the context of free clinics and sliding fee scale clinics, which do not charge the public the actual costs of their services. AB 77 codifies the provider manual's clarification that the exceptions to the lesser of cost or charges principle set out in federal law apply.

The sponsors additionally state that the bill proposes to allow community and free clinics that dispense drugs to

their patients to bill Medi-Cal and Family PACT in the same way that pharmacies bill for such drugs. Currently, clinics bill based on specific codes and the Medi-Cal program is not able to collect supplemental rebates on the drugs dispensed by the clinics. If the clinics are allowed to bill the same as pharmacies, the state could receive its rebates, the clinics would receive a higher reimbursement rate, and the patient would have their medications in hand when they leave the clinic, ensuring higher compliance and better health outcomes. Because this transition entails a significant up-front investment, the bill allows clinics to opt to "test" this change in billing practices to assess its benefit.

#### Prior legislation

AB 2151 (Jackson, Chapter 851, Statutes of 2004) requires, in general, community clinics, free clinics and intermittent clinics, that are licensed to dispense prescription drugs, and that meet specified federal 340B program requirements, to bill Medi-Cal and the Family PACT Waiver Program for any take-home drugs provided to beneficiaries of those programs and exempted FQHCs and RHCs that elect to be reimbursed on a fee-for-service basis from the provisions of the bill.

SB 36 (Chesboro, Chapter 527, Statutes of 2003) requires DHS to implement specified Medi-Cal payment methodologies for FQHCs and RHCs, in conformance with requirements under federal law.

#### PRIOR ACTIONS

Assembly Floor: 77 - 0 Pass on Consent  
Assembly Health: 13 - 0 Do Pass on Consent

#### POSITIONS

Support: California Family Health Council (co-sponsor)  
California Primary Care Association (co-sponsor)  
Planned Parenthood Affiliates of California (co-sponsor)

Oppose: None received.

AMENDED IN SENATE JUNE 23, 2005  
AMENDED IN ASSEMBLY APRIL 18, 2005  
AMENDED IN ASSEMBLY APRIL 5, 2005  
CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

**ASSEMBLY BILL**

**No. 78**

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

January 3, 2005

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An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as amended, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers, including specified information about the pharmacy benefit manager's revenues. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts.

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

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

1 SECTION 1. Division 113 (commencing with Section  
2 150000) is added to the Health and Safety Code, to read:

3  
4 DIVISION 113. PHARMACY BENEFITS MANAGEMENT

5  
6 150000. For purposes of this division, the following  
7 definitions shall apply:

8 (a) "Labeler" means any person who receives prescription  
9 drugs from a manufacturer or wholesaler and repackages those  
10 drugs for later retail sale and who has a labeler code from the  
11 federal Food and Drug Administration under Section 207.20 of  
12 Title 21 of the Code of Federal Regulations.

13 (b) "Pharmacy benefits management" is the administration or  
14 management of prescription drug benefits. Pharmacy benefits  
15 management shall include all of the following: the procurement  
16 of prescription drugs at a negotiated rate for dispensation within  
17 this state, the processing of prescription drug claims, and the  
18 administration of payments related to prescription drug claims.

19 (c) "Pharmacy benefits manager" is any entity that performs  
20 pharmacy benefits management. The term does not include a  
21 health care service plan or health insurer if the health care service  
22 plan or health insurer offers or provides pharmacy benefits  
23 management services and if those services are offered or  
24 provided only to enrollees, subscribers, or insureds who are also  
25 covered by health benefits offered or provided by that health care  
26 service plan or health insurer, nor does the term include an  
27 affiliate, subsidiary, or other related entity of the health care  
28 service plan or health insurer that would otherwise qualify as a  
29 pharmacy benefits manager, as long as the services offered or  
30 provided by the related entity are offered or provided only to  
31 enrollees, subscribers, or insureds who are also covered by the  
32 health benefits offered or provided by that health care service  
33 plan or health insurer.

34 (d) "Purchaser" is any entity that enters into an agreement with  
35 a pharmacy benefits manager for the provision of pharmacy  
36 benefit management services.

1 150001. (a) The contract entered into between the pharmacy  
2 benefits manager and the purchaser shall include both of the  
3 following:

4 (1) A disclosure in writing of any fees to be charged for drug  
5 utilization reports requested by the purchaser.

6 (2) The terms of confidentiality for any information received  
7 by the purchaser pursuant to subdivision (b).

8 (b) Except as provided in Section 150002, a pharmacy benefits  
9 manager shall provide all of the following information no less  
10 frequently than once each year and, at the request of the  
11 purchaser, within 30 days of receipt of the request by the  
12 purchaser:

13 (1) The aggregate amount, for a list of drugs to be specified in  
14 the contract, of all rebates and other retrospective utilization  
15 discounts that the pharmacy benefits manager receives, directly  
16 or indirectly, from pharmaceutical manufacturers or labelers in  
17 connection with the purchasing or dispensing of prescription  
18 drugs for individuals receiving *services* under the purchaser's  
19 contract.

20 (2) The nature, type, and amount of all revenue the pharmacy  
21 benefits manager receives, directly or indirectly, from each  
22 pharmaceutical manufacturer or labeler for any other products or  
23 services provided by the pharmacy benefits manager with respect  
24 to programs that the purchaser contracts with the pharmaceutical  
25 benefits manager to provide.

26 (3) Any prescription drug utilization information requested by  
27 the purchaser relating to utilization by the purchaser's enrollees  
28 or aggregate utilization data that is not specific to an individual  
29 consumer, prescriber, or purchaser.

30 (4) Any financial arrangements with prescribing providers,  
31 medical groups, individual practice associations, pharmacists, or  
32 other entities that are associated with activities of the pharmacy  
33 benefits manager to encourage formulary compliance or  
34 otherwise manage prescription drug benefits.

35 (5) Any financial arrangements related to the provision of  
36 pharmacy benefits management for the purchaser that exist  
37 between the pharmacy benefits manager and any brokers,  
38 consultants, consulting companies, or other intermediaries.

39 150002. (a) A pharmacy benefits manager is not required to  
40 make the disclosures required in Section 150001 unless and until

1 the purchaser agrees in writing to maintain the disclosed  
2 information as confidential proprietary information. The  
3 agreement may provide for equitable and legal remedies in the  
4 event of a violation of this confidentiality provision. The  
5 agreement may authorize the purchaser to disclose the  
6 confidential proprietary information to persons or entities with  
7 whom the purchaser contracts to provide consultation regarding  
8 pharmacy services and may require those persons or entities to  
9 treat the information as confidential proprietary information.

10 (b) For purposes of this section, “proprietary information”  
11 includes trade secrets and information on pricing, costs,  
12 revenues, taxes, market share, negotiating strategies, customers,  
13 and personnel held by a pharmacy benefits manager and used for  
14 its business purposes.



# CALIFORNIA STATE BOARD OF PHARMACY

## BILL ANALYSIS

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**BILL NUMBER: AB 78**

**VERSION: AMENDED JULY 6, 2005**

**AUTHOR: PAVLEY**

**SPONSOR: PAVLEY**

**RECOMMENDED POSITION: NO POSITION**

**SUBJECT: PHARMACY BENEFIT MANAGEMENT**

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### **Existing Law:**

Provides for the regulation of HMOs and the benefits they provide by the Department of Managed Health Care.

### **This Bill:**

- 1) Defines "labeler" as any person who repackages prescription drugs for later sale and who has a labeler code issued by the Food and Drug Administration (FDA). (H&S 150000 Added)
- 2) Defines "pharmacy benefits management" as the administration or management of prescription drug benefits including:
  - a. The procurement of prescription drugs at a negotiated rate for dispensing,
  - b. The processing of prescription drug claims,
  - c. The administration of payments related to prescription drug claims. (H&S 150000 Added)
- 3) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (H&S 150000 Added)
- 4) Exempts health care service plans or health insurers if they perform pharmacy benefits management directly, or through a subsidiary, exclusively for their enrollees or insureds. Also exempts the Department of Health Services (DHS), with respect to implementing a drug assistance program. (H&S 150000 Added)
- 5) Defines "purchaser" as any entity that enters into an agreement with a PBM for the provisions of pharmacy benefit management services. (H&S 150000 Added)
- 6) Defines "proprietary information" to include trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy PBM and used for its business purposes. (H&S 150002 Added)
- 7) Requires contracts entered into between a PBM and a purchaser to include:
  - a. A disclosure in writing of any fees to be charged fro drug utilization reports requested by the purchaser; and
  - b. The terms of confidentiality for any information received by the purchaser.

8) Requires a PBM to disclose to the purchaser the following, no less than once a year, and at the request of the purchaser, within 30 days of the request:

- a. The aggregate amount of all rebates that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.
- b. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.
- c. Any prescription drug utilization information related to the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.
- d. Any arrangements with prescribers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.
- e. Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

(H&S 150001 Added)

9) Allows a PBM not to disclose required information in H&S 150001 unless a purchaser agrees in writing to maintain the disclosed information confidential and proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of the confidentiality provision.

(H&S 150002 Added)

### **Comment:**

**1) Author's Intent.** According to the author, this bill is needed to create consumer protection guidelines that PBMs must meet when doing business with California clients such as CalPERS, large employers, health plans, and union trust funds. The author believes that creating a more transparent market will shine a light on an industry that discloses an inadequate amount of pricing and conflict of interest information and will enable clients to make informed decisions about the type of prescriptions and benefits they select on behalf of their enrollees. According to the author, this will allow clients to take full advantage of the free market by incentivizing PBMs to compete in a fair, transparent environment for California business.

**2) PBM Task Force.** The board convened a task force on PBM regulation in 2003. The task force conducted a thorough evaluation of PBM practices to determine whether establishing state regulation of PBMs was necessary. The task force was unable to identify a clear need for regulation of PBMs. The task force was unable to define an existing or potential consumer harm that could be remedied by the regulation of PBMs. The areas of greatest potential concern, as expressed by participants, were related to the business and contractual relationships between PBMs and their clients (health plans, employers, trust funds, etc.) that would be best resolved by those parties in their negotiations.

**3) State Legislation.** AB 1960 (Pavley 2004), Pharmacy Benefit Management, was introduced last session and passed through the Legislature. Governor vetoed the bill. In his veto message the Governor stated "this measure would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal Program and other purchasers, without providing any real consumer benefit. Studies, including one from the Federal Trade Commission, have shown that enactment of this legislation will limit competition and significantly increase the cost of prescription drugs."

**4) Other States:** Maine was the first state to pass a PBM disclosure law. Shortly after passage, the law was challenged in the courts by the Pharmaceutical Care Management Association. The lawsuit claimed that Maine's Unfair Prescription Drug Practices Act is preempted by federal law, would effect a regulatory taking of trade secrets and revenues, and violates due process, freedom of speech and the Commerce Clause of the Constitution.

States that rejected PBM disclosure laws in 2004 include California, Florida, Iowa, Kansas Maryland, Minnesota, Mississippi, New York, Vermont and Washington, the association said.

#### **5) Support / Opposition.**

Support: AFSCME

AIDS Healthcare Foundation  
California Alliance for Retired Americans  
California Labor Federation  
California Pharmacists Association  
California School Employees Association  
California Nurses Association  
CalPERS Board of Administration  
CALPIRG  
Consumers Union  
Gray Panthers  
Greenlining Institute  
Health Access  
Older Women's League of California  
Retired Public Employees Association  
SEIU

Opposition: America's Health Insurance Plans

California Chamber of Commerce  
Express Scripts, Inc  
Health Net  
Medco Health Solutions

#### **6) History.**

2005

July 6 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com.on JUD.  
June 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.  
June 23 From committee: Do pass, and re-refer to Com. on JUD. Re-referred. (Ayes 6. Noes 3.).  
June 9 Referred to Coms. on HEALTH and JUD.  
June 2 In Senate. Read first time. To Com. on RLS. for assignment.  
June 1 Read third time, passed, and to Senate. (Ayes 44. Noes 34. Page 2051.)  
Apr. 28 Read second time. To third reading.  
Apr. 27 From committee: Do pass. (Ayes 6. Noes 3.) (April 26).  
Apr. 19 Re-referred to Com. on B. & P.  
Apr. 18 Read second time and amended.  
Apr. 14 From committee: Amend, do pass as amended, and re-refer to Com. On B. & P. (Ayes 10. Noes 4.) (April 12).  
Apr. 6 Re-referred to Com. on HEALTH.  
Apr. 5 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. (Corrected January 10.)

**AB 78**

**AMENDED: April 18, 2005**

**SENATE HEALTH  
COMMITTEE ANALYSIS**  
Senator Deborah V. Ortiz, Chair

FISCAL: Judiciary/ NonFiscal  
8

CONSULTANT:  
Bohannon / ak

**SUBJECT**

Pharmacy benefits management

**SUMMARY**

This bill would require a contract between a pharmacy benefits manager (PBM) and a purchaser, as defined, to disclose any fees to be charged for drug utilization reports requested by the purchaser and to additionally specify the terms of confidentiality for specified proprietary information received by the purchaser upon annual disclosure by the PBM or at the request of the purchaser.

**ABSTRACT**

Existing law:

- 1.Provides for the regulation of health plans by the Department of Managed Health Care (DMHC) and for the regulation of health insurers by the California Department of Insurance (CDI).
- 2.Requires every plan that covers prescription drug benefits to provide notice in the evidence of coverage and disclosure form to enrollees regarding whether the plan uses a formulary.
- 3.Requires the notice to include an explanation of what a formulary is, how the plan determines which prescription drugs are included or excluded, and how often the plan reviews the content of the formulary.
- 4.Requires every plan that covers prescription drug benefits to provide to members of the public, upon request, information regarding whether a specific drug or drugs are on the plan's formulary. Requires notice of the opportunity to secure this information from the plan to be included in the evidence of coverage and disclosure form to enrollees.

5.Requires every plan to notify enrollees, and members of the public who request formulary information, that the presence of a drug on the formulary does not guarantee that an enrollee will be prescribed that drug by his or her prescribing provider for a particular medical condition.

6.Requires health plans that provide prescription drug benefits to maintain an expeditious process by which prescribing providers can obtain authorization for a medically necessary nonformulary prescription drug.

This bill:

1.Defines "labeler" to mean any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration.

2.Defines "pharmacy benefits management" to mean the administration or management of prescription drug benefits including all of the following:

The procurement of prescription drugs at a negotiated rate for dispensation within this state;  
The processing of prescription drug claims; and,  
The administration of payments related to prescription drug claims.

1.Defines "PBM" to mean any entity that performs pharmacy benefits management excluding:

A health care service plan or health insurer if the plan or insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that plan or insurer; or,

An affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a PBM, as long as services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health service plan or health insurer.

1.Defines "purchaser" to mean any entity that enters into an agreement with a PBM for the provision of pharmacy benefit management services.

2.Requires the contract entered into between the PBM and the purchaser to include both of the following:

A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser; and,

The terms of confidentiality for any information received by the purchaser from the PBM.

1.Requires a PBM to provide all of the following information no less frequently than once each year and, at the request of the purchaser, within 30 days of receipt of the request by the purchaser:

The aggregate amount, for a list of drugs to be specified in the contract, of all rebates and other retrospective utilization discounts that the PBM receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving \_\_\_\_\_ under the purchaser's contract;

The nature, type, and amount of all revenue the PBM receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the PBM with respect to programs that the purchaser contracts with the PBM to provide;

Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser;

Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with the activities of the PBM to encourage formulary compliance or otherwise manage prescription drug benefits; and,

Any financial arrangements related to the provision of pharmacy benefits management for the purchaser that exist between the PBM and any brokers, consultants, consulting companies, or other intermediaries.

1.Provides that a PBM is not required to make the specified disclosures noted above unless and until the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information.

2.Allows the agreement to provide for equitable and legal remedies in the event of a violation of the confidentiality provision.

3.Allows the agreement to authorize the purchaser to disclose the confidential proprietary information to persons or entities with whom the purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

4. Includes as "proprietary information" trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a PBM and used for its business purposes.

## FISCAL IMPACT

## BACKGROUND AND DISCUSSION

### Purpose of bill

According to the author, AB 78 is needed to provide transparency in PBM contracting and will allow consumers to receive the full benefits of the rebates PBMs receive from pharmaceutical manufacturers. The author notes that the California Public Employees Retirement System (CalPERS) and other large employers in the state use PBMs to manage their prescription drug benefits. According to the author, since the late 1990's, PBMs have been investigated and sued by state governments, consumer and labor groups, the Federal Trade Commission, and U.S. Department of Justice. These investigations have targeted the refusal of PBMs to disclose the payments they receive from drug manufacturers and the practice of "drug switching" whereby PBMs steer customers toward more expensive drugs promoted by manufacturers. The author states that Maine and South Dakota have already enacted similar legislation and that numerous objective studies have highlighted the need for increased transparency within the PBM industry.

### PBMs

PBMs are independent specialty administrators focusing on administering pharmacy benefits and managing the purchasing, dispensing, and reimbursing of prescription drugs. According to the California Healthcare Foundation, about 45% of the U.S. population has pharmacy coverage provided directly by a PBM. PBMs offer health plans a variety of services including negotiating price discounts with retail pharmacies, negotiating rebates with drug manufacturers, and operating mail-order prescription services and administrative claims processing systems. PBMs also provide health plans with clinical services such as formulary development and management, prior authorization, and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication. In order to provide these services, PBMs operate with multiple stakeholders in a complex set of relationship involving health plans, enrollees, pharmacies, and pharmaceutical manufacturers.

### Major criticisms of PBMs

Conflicts of interest. Some PBMs are owned by drug manufacturers, pharmacy chains or insurance plans, and may additionally have undisclosed contracts with manufacturers to market or test their products.

Side deals and/or undisclosed payments and failure to pass savings along to consumers. Some PBMs negotiate additional discounts or rebates from drug manufacturers or pharmacies which they fail to pass on to consumers.

"Drug switching" to maximize rebate payments. Some PBMs have developed formularies that steer clients to higher-priced drugs and receive financial compensation for doing so. Additionally, some PBMs have been accused of substituting patient medication, without patient notification or authorization, for financial incentives.

Refusal to be audited or release information on pricing structure, rebate deals and other fee structures. PBM negotiations are based on the internal disclosure of confidential proprietary information among manufacturers, pharmacies, and health plans, much of which can not be publicly disclosed. However, the PBM industry has long been criticized for not being forthcoming regarding the additional compensation or incentives they receive that may unduly influence their business decisions.

General Accounting Office (GAO) report on PBMs  
In January 2003, the GAO released a report entitled, "Federal Employees' Health Benefits: Effects of Using PBMs on Health Plans, Enrollees, and Pharmacies." The GAO's findings were generally positive stating that the PBMs reviewed produced savings for health plans by obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies, passing on certain manufacturer rebates to the plans, and operating drug utilization control programs. The GAO found that the average price PBMs obtained from retail pharmacies for 14 brand name drugs was about 18 percent below the average price paid by customers without third-party coverage.

Additionally, the report found that plan enrollees had wide access to retail pharmacies, coverage of most drugs, and benefited from cost savings generated by the PBMs. However, pharmacy associations reported that PBMs large market share leaves little leverage in negotiating with PBMs. The plans and PBMs reviewed provided technical comments and two independent reviewers stated the report was fair and balanced. In written response to the report, one pharmacy association expressed strong concerns that the report did not more broadly address economic relationships in the PBM industry. However, the GAO stated that relationships between PBMs and other entities for other plans were beyond the scope of the report.

Brief timeline of PBM related litigation  
2005

In May 2005, the U.S. Department of Education joined Arkansas, Florida, Tennessee, and Texas in a

whistleblower lawsuit alleging PBM Caremark avoided its obligation to reimburse Medicaid and other federal health insurance programs.

In April 2005, a U.S. District Court upheld Main's PBM legislation which was passed in 2003. The court stated: "This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best proposal among competing proposals from PBMs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs."

2004

On August 4, 2004, New York Attorney General Elliot Spitzer sued Express Scripts, Inc. alleging the company pocketed as much as \$100 million in drug rebates that should have gone to the state. The contract required the company to negotiate the lowest prices and return any rebates to the state, however Spitzer contends that Express Scripts called the rebates an administrative fee or similar term and kept them.

On April 26, 2004, Medco paid \$29 million to settle a federal lawsuit brought by 20 state Attorneys General, including California's Attorney General Bill Lockyer. The case involved the practice of "switching," in which PBMs receive a fee for substituting one medication for another, without a patient's knowledge or consent. The PBM switches were not made for medical reasons and instead resulted from deals that drug companies have with PBMs.

2003

In 2003, Medco paid \$42 million to settle a class-action lawsuit alleging that the company improperly promoted higher priced drugs promoted by its parent pharmaceutical company, rather than seeking the best price from alternative pharmaceutical companies.

In March 2003, the Prescription Access Litigation Project, in collaboration with the American Federation of State, County and Municipal Employees, brought suit against Medico, Caremark, Express Scripts, and Advance PCS, using California's unfair competition law, charging that they negotiated rebates from drug manufacturers and discounts from retail pharmacies, yet have not passed those savings onto healthcare plans and consumers.

Arguments in support

Supporters of the bill believe current law does nothing to ensure that a PBM is motivated to get the best drug prices for its clients. As such, they believe PBMs are serving the interests of drug manufacturers and themselves at the expense of their clients, including the state of California. Supporters believe AB 78 would provide PBM clients with accurate information about the discounts and incentives the PBM receives in connection with a given client's business. They insist that PBMs regularly receive rebates, discounts, and other financial incentives from drug manufacturers for steering consumers toward particular drugs. They argue that PBMs do not pass these "kickbacks" on to consumers and further, do not disclose to their clients that such deals exist. They insist that within such a dynamic, PBMs have an incentive to steer consumers toward those drugs that create the largest "spread," which are often the highest-priced drugs on the market. Additionally, supporters of the bill have grave concerns regarding how much the PBM industry is contributing to the high costs of prescription drugs and believe AB 78 would require better standards on a largely unregulated and growing industry.

#### Arguments in opposition

Opponents of bill insist that AB 78 unnecessarily and inappropriately intrudes on private-sector transactions between sophisticated entities that have access to expert consultants to assist them in negotiating the best deal to meet their needs. They believe AB 78 will ultimately increase prescription drug costs for California employers and consumers by severely compromising the ability of PBMs to negotiate discounts with drug manufacturers. Additionally, opponents of the bill object to what they view as a "one-size-fits-all" approach with respect to private PBM contracts. They insist that such requirements should not be dictated by the state, but should be negotiated between parties in general, but even more so when the parties are sophisticated, as is the case in PBM negotiations. They additionally assert that imposing specific contract requirements in law for the PBM industry and the large providers and employers with whom they contract would set a bad precedent for other industries. While they acknowledge that the bill recognizes and provides a legal remedy in the event that proprietary information is inappropriately disclosed, they maintain that in such an event, the damage would have already been done.

#### Prior legislation

AB 1960 (Pavley, 2004) would have required PBMs to disclose to purchasers or prospective purchasers information pertaining to rebates, discounts and other financial information and additionally would have required certain provisions to be included in contracts between a PBM and a purchaser. AB 1960 also would have established conflict of interest standards for members of

the PBM pharmacy and therapeutics committee and would have required PBMs to meet certain conditions prior to switching a patient from one drug to another. This measure was vetoed by the Governor on the grounds that the bill would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal program and other purchasers, without providing any real consumer benefit.

Clarifying amendment

Clarifying/ technical amendment the author may wish to consider:

On page 3, line 18, after "receiving" insert "services"

PRIOR ACTIONS

Assembly Floor: 44 - 34 Pass  
Assembly Bus. & Prof.: 6 - 3 Do Pass  
Assembly Health: 10 - 4 Do Pass

POSITIONS

Support: AFSCME  
AIDS Healthcare Foundation  
California Alliance for Retired Americans  
California Labor Federation  
California Pharmacists Association  
California School Employees Association  
California Nurses Association  
CalPERS Board of Administration  
CALPIRG  
Consumers Union  
Gray Panthers  
Greenlining Institute  
Health Access  
Older Women's League of California  
Retired Public Employees Association  
SEIU

Oppose: America's Health Insurance Plans  
California Chamber of Commerce  
Express Scripts, Inc  
Health Net  
Medco Health Solutions



**MEETING SUMMARY**  
**LEGISLATION AND REGULATION COMMITTEE**  
**DATE: JULY 13, 2005**  
**LOCATION: DEPARTMENT OF CONSUMER AFFAIRS**  
400 R STREET, SUITE 4070  
SACRAMENTO, CA 95814  
9:30 A.M. – 12:00 P.M

**BOARD MEMBERS PRESENT:**

JOHN JONES, CHAIR  
KENETH SCHELL

**BOARD STAFF PRESENT:**

PATRICIA HARRIS  
VIRGINIA HEROLD  
JAN PEREZ

The meeting was convened at 9:30 a.m.

**Legislation**

The committee was provided with a list of bills and bill analysis, which it reviewed. Based on new information and discussions at the meeting, the committee either took positions or changed its recommended positions on the following bills: AB 21, AB 657, SB 401, SB 644, SB 798, SCR 49. Based on public comments at the end of the meeting, the committee directed staff to add AB 77 to its watch list.

The bills the committee discussed and the positions the committee recommended are as follows:

**AB 595 (Negrete McLeod) Pharmacy: Compounding Of Prescription Drugs**  
This bill is sponsored by the board to define "compounding" and to provide direction for regulations that will follow later this year. The board approved draft legislation at its January 2005 meeting.

**Recommended Position: Support**

**Version: 5/26/05**

**SB 1111 (B&P Committee) Omnibus Bill**

**Recommended Position: Support**

**Version: 5/11/05**

**AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Nonresident Wholesaler License Surety Bond**  
**Recommended Position: Support**  
**Version: 4/19/05**

**SB 734 (Torlakson) Controlled Substances**  
**Recommended Position: Oppose Unless Amend**  
**Version: 4/18/05**

**AB 21 (Levine) Pharmacists: Practice Requirements**  
**Recommended Position: Oppose**  
**Version: 6/15/05**

**SB 644 (Ortiz) Dispensing Prescription Drugs And Devices**  
**Recommended Position:**  
**Version: 7/5/05**

**AB 283 (Koretz) Pseudoephedrine: Retail Sale**  
**Recommended Position: No Position**  
**Version: 5/26/05**

**SB 152 (Speier) Pseudoephedrine**  
**Recommended Position: Oppose**  
**Version: 4/18/05**

**AB 446 (NEGRETE MCLEOD) Settlement Agreements (Gag Clauses)**  
**Recommended Position: Support**  
**Version: 3/30/05**

**SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services**  
**Recommended Position: Support**  
**Version: 3/29/05**

**AB 896 (Matthews) Clinical laboratories**  
**Recommended Position: Support**  
**Version: Introduced**

**AB 657 (Karnette) Pharmacies: Prescription Containers: Labels**  
**Recommended Position: Support**  
**Version: 6/21/05**

**AB 225 (Negrete McLeod) Electronic Prescription Information**  
**Recommended Position: Support if Amended**  
**Version: 4/7/05**

**AB 522 (Plescia)** Automated drug delivery system  
**Recommended Position: Support if Amended**  
**Version: 6/23/05**

**SB 401 (Ortiz)** Medical information: Pharmacies: Marketing  
**Recommended Position: Oppose Unless Amend**  
**Version: 6/15/05**

**SCR 49 (Speier)** Medication Errors Panel  
**This is a new bill introduced on June 15, 2005**  
**Recommended Position: Support**  
**Version: 6/30/05**

**SB 798 (Simitian)** Prescription Drugs: Collection And Distribution Program  
**Recommended Position: Oppose Unless Amend**  
**Version: 6/21/05**

**SB 380 (Alquist)** Drugs: Adverse Event Reporting  
**Recommended Position:**  
**Version: 6/21/05**

**AB 71 (Chan)** Pharmaceuticals: Adverse Drug Reactions: Office of California Drug Safety  
**Recommended Position:**  
**Version: 6/23/05**

**AB 72 (Frommer)** Prescription Drugs: Clinical Trials  
**Recommended Position:**  
**Version: 5/26/05**

**SB 19 (Ortiz)** California Rx Program  
**Recommended Position:**  
**Version: 4/18/05**

**AB 73 (Frommer)** Prescription Drugs: Importation: Procurement  
**Recommended Position:**  
**Version: 3/17/05**

**AB 74 (Gordon)** California Rx Prescription Drug Hotline  
**Recommended Position:**  
**Version: 6/23/05**

**AB 75 (Frommer)** Pharmaceutical Assistance Program  
**Recommended Position:**  
**Version: 5/26/05**

**AB 76 (Frommer) Office of Pharmaceutical Purchasing**  
**Recommended Position:**  
**Version: 7/05/05**

**AB 77 (Frommer) Medi-Cal: Clinics: Reimbursement**  
**Recommended Position:**  
**Version: 6/23/05**

**AB 78 (Pavley) Pharmacy Benefits Management**  
**Recommended Position:**  
**Version: 7/6/05**

### **Regulations Update**

The committee was informed that the omnibus group of regulations approved by the board in January 2005 is currently undergoing Department of Finance Review. It is anticipated that the regulations will be approved by the Office of Administrative Law and will take effect by late summer 2005.

The committee was informed that an informational hearing regarding the posting of intern pharmacist addresses on the Board's web site will be held at the Board meeting in San Diego on July 20, 2005.

### **Proposed Initiative Update**

The committee discussed two ballot initiatives (Proposition 78, Prescription Drug Discounts Initiative Statute, Proposition 79, Prescription Drug Discounts State Negotiated Rebates) that will be on the November 8, 2005 ballot. The Committee chose not to take a position on either proposition at this time.

### **Adjournment**

The committee adjourned at 12:00 p.m.