

AMENDED IN ASSEMBLY APRIL 12, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1960**

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**Introduced by Assembly Members Pavley and Frommer  
(Coauthors: Assembly Members Chu, and Ridley-Thomas)**

February 12, 2004

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An act to add Article 8 (commencing with Section 4130) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 1960, as amended, Pavley. Pharmacy benefits management.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for the regulation and licensure of persons engaged in pharmacy practices relating to the furnishing of dangerous drugs, as defined. Under existing law, a violation of the provisions of the Pharmacy Law is a crime.

This bill would define the term “pharmacy benefits management” as ~~negotiating the purchase of dangerous drugs on behalf of specified entities and administering or managing the prescription drug benefit programs of those entities~~, *among other things, the procurement of prescription drugs at a negotiated rate for dispensation within this state*. The bill would also define the term “pharmacy benefits manager” as an entity that performs pharmacy benefits management. The bill would ~~impose on that entity a fiduciary duty to the person employing or contracting with the entity~~ *require pharmacy benefits managers to register with the California State Board of Pharmacy, and would require that board to set specified standards for the registration*

thereof. The bill would further require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers with regard to revenues and its drug formularies, upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

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. Article 8 (commencing with Section 4130) is  
2 added to Chapter 9 of Division 2 of the Business and Professions  
3 Code, to read:

4  
5 Article 8. Pharmacy Benefits Management  
6

7 ~~4130.—“Pharmacy benefits management” means negotiating~~  
8 ~~the purchase of dangerous drugs on behalf of an entity that~~  
9 ~~provides health care services, including a health care service plan~~  
10 ~~or a health insurer, or an entity that purchases those services and~~  
11 ~~administering or managing the prescription drug benefit program~~  
12 ~~provided or purchased by those entities. The administration or~~  
13 ~~management of a prescription drug benefit program includes all of~~  
14 ~~the following:~~

- 15 ~~(a) Providing mail pharmacy services.~~
- 16 ~~(b) Claims processing, managing a retail network, and paying~~  
17 ~~claims to a pharmacy for dangerous drugs dispensed to an enrollee~~  
18 ~~or insured.~~
- 19 ~~(c) Rebate contracting and administering the rebates.~~



1 ~~(d) Therapeutic intervention and generic substitution~~  
2 ~~programs.~~

3 ~~(e) Disease management programs.~~

4 ~~4131. A “pharmacy benefits manager” means an entity that~~  
5 ~~performs pharmacy benefits management and includes a person or~~  
6 ~~entity acting for a pharmacy benefits manager in a contractual or~~  
7 ~~employment relationship in the performance of pharmacy benefits~~  
8 ~~management.~~

9 ~~4132. A pharmacy benefits manager owes a fiduciary duty to~~  
10 ~~the person who contracts with, or employs, the pharmacy benefits~~  
11 ~~manager.~~

12 *4130. For purposes of this article, the following definitions*  
13 *shall apply:*

14 *(a) “Labeler” means any person who receives prescription*  
15 *drugs from a manufacturer or wholesaler and repackages those*  
16 *drugs for later retail sale and who has a labeler code from the*  
17 *federal Food and Drug Administration under Section 207.20 of*  
18 *Title 21 of the Code of Federal Regulations.*

19 *(b) “Pharmacy benefits management” is the procurement of*  
20 *prescription drugs at a negotiated rate for dispensation within this*  
21 *state, the administration or management of prescription drug*  
22 *benefits, or the provision of any of the following services with*  
23 *regard to the administration of the following pharmacy benefits:*

24 *(1) Mail service pharmacy.*

25 *(2) Claims processing, retail network management, and*  
26 *payment of claims to pharmacies for prescription drugs.*

27 *(3) Clinical formulary development and management services.*

28 *(4) Rebate contracting and administration.*

29 *(5) Certain patient compliance, therapeutic intervention, and*  
30 *generic substitution programs.*

31 *(6) Disease management programs involving prescription drug*  
32 *utilization.*

33 *(c) “Pharmacy benefits manager” is any person who performs*  
34 *pharmacy benefits management. The term does not include a*  
35 *health care service plan or health insurer if the health care service*  
36 *plan or health insurer offers or provides pharmacy benefits*  
37 *management services or administration through an affiliate,*  
38 *subsidiary, or other related entity, and if those services or*  
39 *administration are offered or provided only to enrollees,*  
40 *subscribers, or insureds who are also covered by health benefits*



1 offered or provided by that health care service plan or health  
2 insurer.

3 4131. (a) A person may not engage in pharmacy benefits  
4 management in the state unless the person registers with the board.

5 (b) An applicant for registration shall do all of the following:

6 (1) Submit to the board an application on the form that the  
7 board provides.

8 (2) Submit the documents that the board requires.

9 (3) Pay to the board a fee set by the board.

10 (c) The board shall register each applicant that meets the  
11 standards of this section.

12 (d) The board shall set standards for the denial of registration.

13 4132. (a) A pharmacy benefits manager shall disclose to the  
14 purchaser or prospective purchaser, on request, the amount of all  
15 rebate revenues and the nature, type, and amounts of all other  
16 revenues that the pharmacy benefits manager receives from each  
17 pharmaceutical manufacturer or labeler with whom the pharmacy  
18 benefits manager has a contract. The pharmacy benefits manager  
19 shall disclose in writing all of the following:

20 (1) The aggregate amount, and for a specified list of drugs, the  
21 specific amount, of all rebates and other retrospective utilization  
22 discounts received by the pharmacy benefits manager directly or  
23 indirectly from each pharmaceutical manufacturer or labeler that  
24 are earned in connection with the dispensing of prescription drugs  
25 to individuals benefiting from the pharmacy benefits manager  
26 services.

27 (2) The nature, type, and amount of all other revenue received  
28 by the pharmacy benefits manager directly or indirectly from each  
29 pharmaceutical manufacturer or labeler for any other products or  
30 services provided to the pharmaceutical manufacturer or labeler  
31 by the pharmacy benefits manager with respect to programs  
32 offered by the purchaser to individuals receiving the benefits of the  
33 manager.

34 (3) Any prescription drug utilization information requested by  
35 the purchaser.

36 (b) A pharmacy benefits manager shall provide the information  
37 described in paragraphs (1), (2), and (3) of subdivision (a) within  
38 30 days of receipt of the request. If requested, the information shall  
39 be provided no less than once each year.



1 (c) Except for utilization information, a pharmacy benefits  
2 manager need not make the disclosures required in subdivision (a)  
3 unless and until the purchaser or prospective purchaser agrees in  
4 writing to maintain as confidential any information that the  
5 pharmacy benefits manager reasonably considers proprietary.  
6 That agreement may provide for equitable and legal remedies in  
7 the event of a violation of the agreement. Proprietary information  
8 includes trade secrets, and information on pricing, costs, revenues,  
9 taxes, market share, negotiating strategies, customers and  
10 personnel held by a pharmacy benefits manager and used for its  
11 business purposes.

12 (d) Every pharmacy benefits manager that maintains one or  
13 more drug formularies shall provide to members of the public,  
14 upon request, a copy of the most current list of prescription drugs  
15 on the formulary of the manager by major therapeutic category,  
16 with an indication of whether any drugs on the list are preferred  
17 over other listed drugs. If the pharmacy benefits manager  
18 maintains more than one formulary, the manager shall notify the  
19 requester that a choice of formulary lists is available.

20 (e) A pharmacy benefits manager shall disclose the  
21 membership of any pharmacy and therapeutics committee, the  
22 credentials of committee members, and any relationships between  
23 committee members and drug manufacturers.

24 4133. A pharmacy benefits manager may not execute a  
25 contract for the provision of pharmacy benefits management  
26 services that fails to address the following items:

27 (a) The amount of the total revenues, rebates, and discounts  
28 identified in paragraphs (1) and (2) of subdivision (a) of Section  
29 4132 that shall be passed on to the purchaser.

30 (b) The disclosure or sale of enrollee utilization data by the  
31 pharmacy benefits manager to any person or entity other than the  
32 purchaser or prospective purchaser.

33 (c) Any administrative or other fees charged by the pharmacy  
34 benefits manager to the purchaser or prospective purchaser.

35 (d) Factors that trigger an audit of the contract for pharmacy  
36 benefits management services.

37 (e) Any revenues, rebates, or discounts received by the  
38 pharmacy benefits manager directly or indirectly from entities  
39 other than manufacturers and labelers.



1 (f) Bulk purchase arrangements between pharmacy benefits  
2 managers with mail-order pharmacies and drug manufacturers.

3 (g) The process for development of formularies and  
4 notification of changes to formularies, provided that the pharmacy  
5 benefits manager meets the requirements of Sections 4134 and  
6 4135.

7 4134. A pharmacy benefits manager may not limit or exclude  
8 coverage for a drug for an enrollee if the drug previously had been  
9 approved for coverage by the pharmacy benefits manager for a  
10 medical condition of the individual consumer and the prescribing  
11 provider continues to prescribe the drug for the medical condition,  
12 provided that the drug is appropriately prescribed and is  
13 considered safe and effective for treating the consumer's medical  
14 condition. Nothing in this section shall preclude the prescribing  
15 provider from prescribing another drug covered by the manager  
16 that is medically appropriate for the consumer, nor shall this  
17 section be construed to prohibit generic drug substitutions as  
18 authorized by Section 4073. For purposes of this section, a  
19 prescribing provider shall include a provider authorized to write  
20 a prescription to treat a medical condition of a consumer pursuant  
21 to subdivision (a) of Section 4059.

22 4135. (a) A pharmacy benefits manager shall maintain an  
23 expeditious process by which prescribing providers may obtain  
24 authorization for a medically necessary nonformulary  
25 prescription drug. On or before July 1, 2005, every pharmacy  
26 benefits manager shall make public on request a description of its  
27 process, including timelines, for responding to authorization  
28 requests for nonformulary drugs. Each pharmacy benefits  
29 manager shall provide a written description of its most current  
30 process, including timelines, to each purchaser and, on request, to  
31 prescribing providers. For purposes of this section, a prescribing  
32 provider shall include a provider authorized to write a prescription  
33 to treat a medical condition of an enrollee pursuant to subdivision  
34 (a) of Section 4040.

35 (b) Any pharmacy benefits manager that disapproves a request  
36 made pursuant to subdivision (a) by a prescribing provider to  
37 obtain authorization for a nonformulary drug shall provide the  
38 reasons for the disapproval in a notice provided to the purchaser.

39 (c) The process described in subdivision (a) by which  
40 prescribing providers may obtain authorization for medically



1 *necessary nonformulary drugs does not apply to a nonformulary*  
2 *drug that has been prescribed for an enrollee in conformity with*  
3 *Section 4134.*

4 *(d) Every pharmacy benefits manager shall maintain all of the*  
5 *following information, which shall be made available to the*  
6 *purchaser or the public upon request:*

7 *(1) The complete drug formulary or formularies of the plan, if*  
8 *the plan maintains a formulary, including a list of the prescription*  
9 *drugs on the formulary of the plan by major therapeutic category*  
10 *with an indication of whether any drugs are preferred over other*  
11 *drugs.*

12 *(2) Records developed by the pharmacy and therapeutic*  
13 *committee of the plan, or by others responsible for developing,*  
14 *modifying, and overseeing formularies, including medical groups,*  
15 *individual practice associations, and contracting pharmaceutical*  
16 *benefits management companies, used to guide the drugs*  
17 *prescribed for the enrollees of the plan, that fully describe the*  
18 *reasoning behind formulary decisions.*

19 *(3) Any arrangements with prescribing providers, medical*  
20 *groups, individual practice associations, pharmacists, or other*  
21 *entities that are associated with activities of the pharmacy benefits*  
22 *manager to encourage formulary compliance or otherwise*  
23 *manage prescription drug benefits.*

24 *(e) Nonformulary prescription drugs shall include any drug for*  
25 *which an individual's copayment or out-of-pocket costs are*  
26 *different than the copayment for a formulary prescription drug,*  
27 *except as otherwise provided by law or regulation.*

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

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