

AMENDED IN ASSEMBLY APRIL 22, 2004

AMENDED IN ASSEMBLY APRIL 15, 2004

AMENDED IN ASSEMBLY APRIL 12, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 1960

**Introduced by Assembly Members Pavley, Chu, Frommer, and
Ridley-Thomas
(Coauthor: Assembly Member Koretz)
(Coauthor: Senator Kuehl)**

February 12, 2004

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 Pharmacy Law is a crime.

This bill would define the term “pharmacy benefits management” as the procurement of prescription drugs at a negotiated rate for dispensation within this state, the management of prescription drug benefits, and the provision of specified services relating to pharmacy benefits. The bill would also define the term “pharmacy benefits manager” as an entity that performs pharmacy benefits management.

The bill would require pharmacy benefits managers to register with the California State Board of Pharmacy, and would require the board to set specified standards for registration. 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, and to make specified disclosures to the public 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 create additional requirements 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. For purposes of this article, the following definitions
8 shall apply:

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

14 (b) "Pharmacy benefits management" is the procurement of
15 prescription drugs at a negotiated rate for dispensation within this
16 state, the administration or management of prescription drug



1 benefits, or the provision of any of the following services with
2 regard to the administration of pharmacy benefits including:

- 3 (1) Mail service pharmacy.
- 4 (2) Claims processing, retail network management, and
5 payment of claims to pharmacies for prescription drugs.
- 6 (3) Clinical formulary development and management services.
- 7 (4) Rebate contracting and administration.
- 8 (5) Certain patient compliance, therapeutic intervention, and
9 generic substitution programs.
- 10 (6) Disease management programs involving prescription drug
11 utilization.

12 (c) “Pharmacy benefits manager” is any person who performs
13 pharmacy benefits management. The term does not include a
14 health care service plan or health insurer if the health care service
15 plan or health insurer offers or provides pharmacy benefits
16 management services and if those services are offered or provided
17 only to enrollees, subscribers, or insureds who are also covered by
18 health benefits offered or provided by that health care service plan
19 or health insurer, nor does the term include an affiliate, subsidiary,
20 or other related entity of the health care service plan or health
21 insurer that would otherwise qualify as a pharmacy benefits
22 manager, as long as the services offered or provided by the related
23 entity are offered or provided only to enrollees, subscribers, or
24 insureds who are also covered by the health benefits offered or
25 provided by that health care service plan or health insurer.

26 (d) *“Prospective purchaser” is any person to whom a*
27 *pharmacy benefits manager offers to provide pharmacy benefit*
28 *management services.*

29 (e) “Purchaser” is any person who enters into an agreement
30 with a pharmacy benefits manager for the provision of pharmacy
31 benefit management services.

32 4131. (a) A person may not engage in pharmacy benefits
33 management in the state unless the person registers with the board.

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

- 35 (1) Submit to the board, on an annual basis, an application on
36 the form that the board provides. The application shall include, but
37 shall not be limited to, all of the following items:
 - 38 (A) The name of the pharmacy benefits manager.
 - 39 (B) The address of the pharmacy benefits manager.
 - 40 (C) Contact information for the pharmacy benefits manager.



- 1 (D) The number of individuals in California who receive
2 services from the pharmacy benefits manager.
- 3 (2) Submit the documents that the board requires.
- 4 (3) Pay to the board a fee set by the board.
- 5 (c) The board shall register each applicant that meets the
6 standards of this section, and shall maintain an updated list of
7 registered pharmacy benefit managers.
- 8 (d) The board shall set standards for the denial of registration.
- 9 4132. (a) A pharmacy benefits manager shall disclose to the
10 purchaser or prospective purchaser in writing all of the following:
- 11 (1) The aggregate amount, and for a specified list of drugs, the
12 specific amount, of all rebates and other retrospective utilization
13 discounts received by the pharmacy benefits manager directly or
14 indirectly from each pharmaceutical manufacturer or labeler that
15 are earned in connection with prescription drug benefits managed
16 by the pharmacy benefits manager related to the purchaser or
17 prospective purchaser.
- 18 (2) The nature, type, and amount of all other revenue received
19 by the pharmacy benefits manager directly or indirectly from each
20 pharmaceutical manufacturer or labeler related to the purchaser or
21 prospective purchaser.
- 22 (3) Any prescription drug utilization information related to
23 utilization by the purchaser's enrollees or aggregate utilization
24 data that is not specific to an individual consumer, prescriber, or
25 purchaser.
- 26 (4) Records developed by the pharmacy and therapeutic
27 committee of the plan, or by others responsible for developing,
28 modifying, and overseeing formularies, including medical groups,
29 individual practice associations, and contracting pharmaceutical
30 benefits management companies, used to guide the drugs
31 prescribed for the enrollees of the plan, that fully describe the
32 reasoning behind formulary decisions.
- 33 (5) Any arrangements with prescribing providers, medical
34 groups, individual practice associations, pharmacists, or other
35 entities that are associated with activities of the pharmacy benefits
36 manager to encourage formulary compliance or otherwise manage
37 prescription drug benefits.
- 38 (b) A pharmacy benefits manager shall provide the information
39 described in paragraphs (1), (2), (3), (4), and (5) of subdivision (a)



1 within 30 days of receipt of the request. If requested, the
2 information shall be provided no less than once each year.

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

14 4133. A pharmacy benefits manager may not execute a
15 contract for the provision of pharmacy benefits management
16 services that fails to address the following items:

17 (a) The amount of the total revenues, rebates, and discounts
18 identified in paragraphs (1) and (2) of subdivision (a) of Section
19 4132 that shall be passed on to the purchaser.

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

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

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

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

30 (f) Bulk purchase arrangements between the pharmacy benefits
31 manager's mail-order pharmacies and drug manufacturers and
32 labelers.

33 (g) The process for development of formularies and
34 notification of changes to formularies, and approval of those
35 changes by the purchaser, provided that the pharmacy benefits
36 manager meets the requirements of Sections 4135 and 4136.

37 4134. A pharmacy benefits manager shall disclose to
38 members of the public, upon request, the following information:

39 (a) A copy of the most current list of prescription drugs on the
40 formulary of the pharmacy benefits manager by major therapeutic



1 category, with an indication of whether any drugs on the list are
2 preferred over other listed drugs. If the pharmacy benefits
3 manager maintains more than one formulary, the manager shall
4 notify the requester that a choice of formulary lists is available.

5 (b) The membership of any pharmacy and therapeutics
6 committee, the credentials of committee members, and any direct
7 or indirect financial relationships between committee members
8 and drug manufacturers.

9 4135. A pharmacy benefits manager may not limit or exclude
10 coverage for a drug for an enrollee if the drug previously had been
11 approved for coverage by the pharmacy benefits manager for a
12 medical condition of the individual consumer and the prescribing
13 provider continues to prescribe the drug for the medical condition,
14 provided that the drug is appropriately prescribed and is
15 considered safe and effective for treating the consumer's medical
16 condition. Nothing in this section shall preclude the prescribing
17 provider from prescribing another drug covered by the pharmacy
18 benefits manager that is medically appropriate for the consumer,
19 nor shall this section be construed to prohibit generic drug
20 substitutions as authorized by Section 4073. For purposes of this
21 section, a prescribing provider shall include a provider authorized
22 to write a prescription to treat a medical condition of a consumer
23 pursuant to subdivision (a) of Section 4059.

24 4136. (a) A pharmacy benefits manager shall maintain an
25 expeditious process by which prescribing providers may obtain
26 authorization for a medically necessary nonformulary prescription
27 drug. On or before July 1, 2005, every pharmacy benefits manager
28 shall make public on request a description of its process, including
29 timelines, for responding to authorization requests for
30 nonformulary drugs. Each pharmacy benefits manager shall
31 provide a written description of its most current process, including
32 timelines, to each purchaser and, on request, to prescribing
33 providers. For purposes of this section, a prescribing provider shall
34 include a provider authorized to write a prescription to treat a
35 medical condition of an enrollee pursuant to subdivision (a) of
36 Section 4040.

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



1 (c) The process described in subdivision (a) by which
2 prescribing providers may obtain authorization for medically
3 necessary nonformulary drugs does not apply to a nonformulary
4 drug that has been prescribed for an enrollee in conformity with
5 Section 4135.

6 (d) Nonformulary prescription drugs shall include any drug for
7 which an individual's copayment or out-of-pocket costs are
8 different than the copayment for a formulary prescription drug,
9 except as otherwise provided by law or regulation.

10 SEC. 2. No reimbursement is required by this act pursuant to
11 Section 6 of Article XIII B of the California Constitution because
12 the only costs that may be incurred by a local agency or school
13 district will be incurred because this act creates a new crime or
14 infraction, eliminates a crime or infraction, or changes the penalty
15 for a crime or infraction, within the meaning of Section 17556 of
16 the Government Code, or changes the definition of a crime within
17 the meaning of Section 6 of Article XIII B of the California
18 Constitution.

