

AMENDED IN ASSEMBLY MAY 20, 2004

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 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 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~~, *including specified information about the pharmacy benefit manager’s 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. *The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.*

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:



1 (a) “Labeler” means any person who receives prescription
2 drugs from a manufacturer or wholesaler and repackages those
3 drugs for later retail sale and who has a labeler code from the
4 federal Food and Drug Administration under Section 207.20 of
5 Title 21 of the Code of Federal Regulations.

6 (b) “Pharmacy benefits management” is the *administration or*
7 *management of prescription drug benefits. Pharmacy benefits*
8 *management includes the procurement of prescription drugs at a*
9 *negotiated rate for dispensation within this state, the*
10 ~~administration or management of prescription drug benefits, or the~~
11 ~~provision of any of the following services with regard to the~~
12 ~~administration of pharmacy benefits including:~~

- 13 ~~(1) Mail service pharmacy.~~
- 14 ~~(2) Claims processing, retail network management, and~~
15 ~~payment of claims to pharmacies for prescription drugs.~~
- 16 ~~(3) Clinical formulary development and management services.~~
- 17 ~~(4) Rebate contracting and administration.~~
- 18 ~~(5) Certain patient compliance, therapeutic intervention, and~~
19 ~~generic substitution programs.~~
- 20 ~~(6) Disease management programs involving prescription drug~~
21 ~~utilization. state, the processing of prescription drug claims, and~~
22 ~~the administration of payments related to prescription drug~~
23 ~~claims.~~

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

38 (d) “Prospective purchaser” is any person to whom a
39 pharmacy benefits manager offers to provide pharmacy benefit
40 management services.



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

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

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

7 ~~(1) Submit to the board, on an annual basis, an application on~~
8 ~~the form that the board provides. The application shall include, but~~
9 ~~shall not be limited to, all of the following items:~~

10 ~~(A) The name of the pharmacy benefits manager.~~

11 ~~(B) The address of the pharmacy benefits manager.~~

12 ~~(C) Contact information for the pharmacy benefits manager.~~

13 ~~(D) The number of individuals in California who receive~~
14 ~~services from the pharmacy benefits manager.~~

15 ~~(2) Submit the documents that the board requires.~~

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

17 ~~(e) The board shall register each applicant that meets the~~
18 ~~standards of this section, and shall maintain an updated list of~~
19 ~~registered pharmacy benefit managers.~~

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

21 ~~4132. (a) A pharmacy benefits manager shall disclose to the~~
22 ~~purchaser or prospective purchaser in writing all of the following:~~

23 ~~(1) The aggregate amount, and for a specified list of drugs, the~~
24 ~~specific amount, of all rebates and other retrospective utilization~~
25 ~~discounts received by the pharmacy benefits manager directly or~~
26 ~~indirectly from each pharmaceutical manufacturer or labeler that~~
27 ~~are earned in connection with prescription drug benefits managed~~
28 ~~by the pharmacy benefits manager related to the purchaser or~~
29 ~~prospective purchaser.~~

30 ~~(2) The nature, type, and amount of all other revenue received~~
31 ~~by the pharmacy benefits manager directly or indirectly from each~~
32 ~~pharmaceutical manufacturer or labeler related to the purchaser or~~
33 ~~prospective purchaser.~~

34 ~~(3)~~

35 *4131. A pharmacy benefits manager shall disclose to the*
36 *purchaser in writing all of the following:*

37 *(a) The aggregate amount, and for a specified list of*
38 *therapeutic classes, the specific amount, of all rebates and other*
39 *retrospective utilization discounts that the pharmacy benefits*
40 *manager receives, directly or indirectly, from pharmaceutical*



1 *manufacturers or labelers in connection with prescription drug*
2 *benefits related to the purchaser. A therapeutic class shall include*
3 *at least two drugs.*

4 (b) *The nature, type, and amount of all other revenue that the*
5 *pharmacy benefits manager receives, directly or indirectly, from*
6 *pharmaceutical manufacturers or labelers in connection with*
7 *prescription drug benefits related to the purchaser.*

8 (c) *Any prescription drug utilization information related to*
9 *utilization by the purchaser's enrollees or aggregate utilization*
10 *data that is not specific to an individual consumer, prescriber, or*
11 *purchaser.*

12 ~~(4) 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 ~~(5)~~

20 (d) *Any administrative or other fees charged by the pharmacy*
21 *benefits manager to the purchaser.*

22 (e) *The credentials of members of any pharmacy and*
23 *therapeutic committee and any direct or indirect financial*
24 *relationships between committee members and the*
25 *pharmaceutical industry.*

26 (f) *Any arrangements with prescribing providers, medical*
27 *groups, individual practice associations, pharmacists, or other*
28 *entities that are associated with activities of the pharmacy benefits*
29 *manager to encourage formulary compliance or otherwise manage*
30 *prescription drug benefits.*

31 ~~(b)~~

32 4132. *A pharmacy benefits manager shall disclose to a*
33 *prospective purchaser in writing all of the following:*

34 (a) *The aggregate amount, and for a specified list of*
35 *therapeutic classes, the specific amount, of all rebates and other*
36 *retrospective utilization discounts that the pharmacy benefits*
37 *manager estimates it will receive, directly or indirectly, from*
38 *pharmaceutical manufacturers or labelers in connection with*
39 *prescription drug benefits related to the prospective purchaser. A*
40 *therapeutic class shall include at least two drugs.*



1 (b) *The nature, type, and amount of all other revenue that the*
2 *pharmacy benefits manager estimates it will receive, directly or*
3 *indirectly, from pharmaceutical manufacturers or labelers in*
4 *connection with prescription drug benefits related to the*
5 *prospective purchaser.*

6 (c) *Any administrative or other fees charged by the pharmacy*
7 *benefits manager to the prospective purchaser.*

8 (d) *The credentials of members of any pharmacy and*
9 *therapeutic committee and any direct or indirect financial*
10 *relationships between committee members and the*
11 *pharmaceutical industry.*

12 (e) *Any arrangements with prescribing providers, medical*
13 *groups, individual practice associations, pharmacists, or other*
14 *entities that are associated with activities of the pharmacy benefits*
15 *manager to encourage formulary compliance or otherwise*
16 *manage prescription drug benefits.*

17 4133. (a) A pharmacy benefits manager shall provide the
18 information described in ~~paragraphs (1), (2), (3), (4), and (5) of~~
19 ~~subdivision (a) Sections 4131 and 4132~~ within 30 days of receipt
20 of the request. If requested, the information shall be provided no
21 less than once each year.

22 ~~(e)~~

23 (b) Except for utilization information, a pharmacy benefits
24 manager need not make the disclosures required in ~~subdivision (a)~~
25 ~~Sections 4131 and 4132~~ unless and until the purchaser or
26 prospective purchaser agrees in writing to maintain as confidential
27 any information that the pharmacy benefits manager reasonably
28 considers proprietary. That agreement may provide for equitable
29 and legal remedies in the event of a violation of the agreement.
30 *That agreement may also include persons or entities with whom the*
31 *purchaser or prospective purchaser contracts to provide*
32 *consultation regarding pharmacy services. Proprietary*
33 *information includes trade secrets, and information on pricing,*
34 *costs, revenues, taxes, market share, negotiating strategies,*
35 *customers and personnel held by a pharmacy benefits manager and*
36 *used for its business purposes.*

37 ~~4133.~~

38 4134. A pharmacy benefits manager may not execute a
39 contract for the provision of pharmacy benefits management
40 services that fails to address the following items:



1 (a) The amount of the total revenues, rebates, and discounts
2 identified in ~~paragraphs (1) and (2) of subdivision (a) of Section~~
3 ~~4132 subdivisions (a) and (b) of Section 4131 and subdivisions (a)~~
4 ~~and (b) of Section 4132~~ that shall be passed on to the purchaser.

5 (b) The disclosure or sale of enrollee utilization data by the
6 pharmacy benefits manager to any person or entity other than the
7 purchaser ~~or prospective purchaser.~~

8 (c) Any administrative or other fees charged by the pharmacy
9 benefits manager to the purchaser ~~or prospective purchaser.~~

10 ~~(d) Factors that trigger an audit of the contract for pharmacy~~
11 ~~benefits management services.~~

12 *(d) Conditions under which an audit will be conducted of the*
13 *contract for pharmacy benefits management services, who will*
14 *conduct the audit, and who will pay for the audit.*

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

18 ~~(f) Bulk purchase arrangements between the pharmacy benefits~~
19 ~~manager's mail order pharmacies and drug manufacturers and~~
20 ~~labelers.~~

21 ~~(g)~~

22 (f) The process for development of formularies and notification
23 of changes to formularies, and approval of those changes by the
24 purchaser, provided that the pharmacy benefits manager meets the
25 requirements of Sections 4135 and 4136.

26 ~~4134. A pharmacy benefits manager shall disclose to~~
27 ~~members of the public, upon request, the following information:~~

28 ~~(a) A copy of the most current list of prescription drugs on the~~
29 ~~formulary of the pharmacy benefits manager by major therapeutic~~
30 ~~category, with an indication of whether any drugs on the list are~~
31 ~~preferred over other listed drugs. If the pharmacy benefits~~
32 ~~manager maintains more than one formulary, the manager shall~~
33 ~~notify the requester that a choice of formulary lists is available.~~

34 ~~(b) The membership of any pharmacy and therapeutics~~
35 ~~committee, the credentials of committee members, and any direct~~
36 ~~or indirect financial relationships between committee members~~
37 ~~and drug manufacturers.~~

38 ~~4135. A pharmacy benefits manager may not limit or exclude~~
39 ~~coverage for a drug for an enrollee if the drug previously had been~~
40 ~~approved for coverage by the pharmacy benefits manager for a~~



1 ~~medical condition of the individual consumer and the prescribing~~
2 ~~provider continues to prescribe the drug for the medical condition,~~
3 ~~provided that the drug is appropriately prescribed and is~~
4 ~~considered safe and effective for treating the consumer's medical~~
5 ~~condition. Nothing in this section shall preclude the prescribing~~
6 ~~provider from prescribing another drug covered by the pharmacy~~
7 ~~benefits manager that is medically appropriate for the consumer,~~
8 ~~nor shall this section be construed to prohibit generic drug~~
9 ~~substitutions as authorized by Section 4073. For purposes of this~~
10 ~~section, a prescribing provider shall include a provider authorized~~
11 ~~to write a prescription to treat a medical condition of a consumer~~
12 ~~pursuant to subdivision (a) of Section 4059.~~

13 ~~4136. (a) A pharmacy benefits manager shall maintain an~~
14 ~~expeditious process by which prescribing providers may obtain~~
15 ~~authorization for a medically necessary nonformulary prescription~~
16 ~~drug. On or before July 1, 2005, every pharmacy benefits manager~~
17 ~~shall make public on request a description of its process, including~~
18 ~~timelines, for responding to authorization requests for~~
19 ~~nonformulary drugs. Each pharmacy benefits manager shall~~
20 ~~provide a written description of its most current process, including~~
21 ~~timelines, to each purchaser and, on request, to prescribing~~
22 ~~providers. For purposes of this section, a prescribing provider shall~~
23 ~~include a provider authorized to write a prescription to treat a~~
24 ~~medical condition of an enrollee pursuant to subdivision (a) of~~
25 ~~Section 4040.~~

26 ~~(b) Any pharmacy benefits manager that disapproves a request~~
27 ~~made pursuant to subdivision (a) by a prescribing provider to~~
28 ~~obtain authorization for a nonformulary drug shall provide the~~
29 ~~reasons for the disapproval in a notice provided to the purchaser.~~

30 ~~(c) The process described in subdivision (a) by which~~
31 ~~prescribing providers may obtain authorization for medically~~
32 ~~necessary nonformulary drugs does not apply to a nonformulary~~
33 ~~drug that has been prescribed for an enrollee in conformity with~~
34 ~~Section 4135.~~

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

39 ~~4135. All members of a pharmacy and therapeutics committee~~
40 ~~for a pharmacy benefits manager shall be physicians,~~



1 pharmacists, or other health care professionals, and a majority of
2 committee members shall be actively practicing and not employed
3 by the pharmacy benefits manager.

4 4136. A pharmacy benefits manager shall report not less than
5 quarterly to the pharmacy and therapeutics committee which shall
6 monitor the health effects of medication substitutions on the health
7 of the patients, including identifying information from patients and
8 prescribers concerning the efficacy or health effects of medication
9 substitution.

10 4137. (a) A pharmacy benefits manager shall not substitute
11 a medication for another currently prescribed medication without
12 first obtaining express verifiable authorization from the prescriber
13 of the currently prescribed drug except in the following instances:

14 (1) As provided in Sections 4052.5 and 4073.

15 (2) If the medication substitution is initiated for patient safety
16 reasons.

17 (3) If the currently prescribed medication is no longer
18 available in the market.

19 (b) The request for authorization to the prescriber shall include
20 all of the following:

21 (1) The cost savings for the purchaser, if any, that are a result
22 of the medication substitution.

23 (2) The difference, if any, in copayments or other out-of-pocket
24 costs paid by the patient in order to obtain the medication.

25 (3) The existence of any additional payments received by the
26 pharmacy benefits manager not reflected in the cost savings to the
27 purchaser.

28 (4) The circumstances, if any, under which the currently
29 prescribed medication will be covered.

30 (5) The circumstances and extent to which, if any, related
31 health care costs arising from the change in medications will be
32 compensated.

33 (6) Any known differences in potential effects on patient health
34 and safety, including side-effects.

35 (7) The name and title of the individual authorizing the change
36 if the authorization by the provider is given verbally.

37 (c) The pharmacy benefits manager shall not substitute a
38 medication for a currently prescribed medication unless the
39 pharmacy benefits manager communicates with the patient to



1 provide that patient or their representative the following
2 information:

3 (1) The proposed medication and the currently prescribed
4 medication.

5 (2) The difference in copayments or other out-of-pocket costs
6 paid by the patient, if any.

7 (3) Any known differences in potential effects on patient health
8 and safety, including side-effects, if any.

9 (4) The circumstances, if any, under which the currently
10 prescribed medication will be covered.

11 (5) The cost savings for the purchaser, taking into account all
12 discounts, rebates, or other payments that lower the cost of the
13 medication to the purchaser.

14 (6) The existence of any additional payments received by the
15 pharmacy benefits manager not reflected in the cost savings to the
16 purchaser.

17 (7) A toll-free telephone number to communicate with the
18 pharmacy benefits manager.

19 (8) The circumstances and the extent to which, if any, related
20 health care costs will be compensated

21 (d) If either the prescriber or the patient instructs the pharmacy
22 benefits manager to reverse or cease the substitution and if the
23 currently prescribed medication remains on the formulary, the
24 pharmacy benefits manager shall assure that the patient does not
25 incur any additional copayments or other costs other than what the
26 patient would have incurred without the substitution. The
27 pharmacy benefits manager shall maintain a toll-free telephone
28 number that is known to prescribers and patients.

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

