

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 and ~~Frommer~~, *Chu, Frommer, and Ridley-Thomas*
(~~Coauthors: Assembly Members Chu, 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 provisions of~~ the Pharmacy Law is a crime.

This bill would define the term “pharmacy benefits management” as, ~~among other things~~, 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 ~~that the~~ 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, *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 ~~specify an additional requirement~~ *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 ~~the following pharmacy benefits~~
3 *pharmacy benefits including:*

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

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

29 (d) “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,*
37 *but 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, ~~on request, the amount of all~~
11 ~~rebate revenues and the nature, type, and amounts of all other~~
12 ~~revenues that the pharmacy benefits manager receives from each~~
13 ~~pharmaceutical manufacturer or labeler with whom the pharmacy~~
14 ~~benefits manager has a contract. The pharmacy benefits manager~~
15 ~~shall disclose in writing all of the following:~~

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

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

31 (3) Any prescription drug utilization information ~~requested by~~
32 ~~the purchaser. related to utilization by the purchaser's enrollees or~~
33 ~~aggregate utilization data that is not specific to an individual~~
34 ~~consumer, prescriber, or purchaser.~~

35 (4) *Records developed by the pharmacy and therapeutic*
36 *committee of the plan, or by others responsible for developing,*
37 *modifying, and overseeing formularies, including medical groups,*
38 *individual practice associations, and contracting pharmaceutical*
39 *benefits management companies, used to guide the drugs*



1 *prescribed for the enrollees of the plan, that fully describe the*
2 *reasoning behind formulary decisions.*

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

8 (b) A pharmacy benefits manager shall provide the information
9 described in paragraphs (1), (2), ~~and (3)~~ (3), (4), and (5) of
10 subdivision (a) within 30 days of receipt of the request. If
11 requested, the information shall be provided no less than once each
12 year.

13 (c) Except for utilization information, a pharmacy benefits
14 manager need not make the disclosures required in subdivision (a)
15 unless and until the purchaser or prospective purchaser agrees in
16 writing to maintain as confidential any information that the
17 pharmacy benefits manager reasonably considers proprietary.
18 That agreement may provide for equitable and legal remedies in
19 the event of a violation of the agreement. Proprietary information
20 includes trade secrets, and information on pricing, costs, revenues,
21 taxes, market share, negotiating strategies, customers and
22 personnel held by a pharmacy benefits manager and used for its
23 business purposes.

24 ~~(d) Every pharmacy benefits manager that maintains one or~~
25 ~~more drug formularies shall provide to members of the public,~~
26 ~~upon request, a copy of the most current list of prescription drugs~~
27 ~~on the formulary of the manager by major therapeutic category,~~
28 ~~with an indication of whether any drugs on the list are preferred~~
29 ~~over other listed drugs. If the pharmacy benefits manager~~
30 ~~maintains more than one formulary, the manager shall notify the~~
31 ~~requester that a choice of formulary lists is available.~~

32 ~~(e) A pharmacy benefits manager shall disclose the~~
33 ~~membership of any pharmacy and therapeutics committee, the~~
34 ~~credentials of committee members, and any relationships between~~
35 ~~committee members and drug manufacturers.~~

36 4133. A pharmacy benefits manager may not execute a
37 contract for the provision of pharmacy benefits management
38 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 that shall be passed on to the purchaser.

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

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

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

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

14 (f) Bulk purchase arrangements between *the* pharmacy
15 benefits ~~managers with~~ *manager's* mail-order pharmacies and
16 drug manufacturers *and labelers*.

17 (g) The process for development of formularies and
18 notification of changes to formularies, *and approval of those*
19 *changes by the purchaser*, provided that the pharmacy benefits
20 manager meets the requirements of Sections ~~4134 and~~ 4135 *and*
21 *4136*.

22 4134. *A pharmacy benefits manager shall disclose to*
23 *members of the public, upon request, the following information:*

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

30 (b) *The membership of any pharmacy and therapeutics*
31 *committee, the credentials of committee members, and any direct*
32 *or indirect financial relationships between committee members*
33 *and drug manufacturers.*

34 4135. A pharmacy benefits manager may not limit or exclude
35 coverage for a drug for an enrollee if the drug previously had been
36 approved for coverage by the pharmacy benefits manager for a
37 medical condition of the individual consumer and the prescribing
38 provider continues to prescribe the drug for the medical condition,
39 provided that the drug is appropriately prescribed and is
40 considered safe and effective for treating the consumer's medical



1 condition. Nothing in this section shall preclude the prescribing
2 provider from prescribing another drug covered by the *pharmacy*
3 *benefits* manager that is medically appropriate for the consumer,
4 nor shall this section be construed to prohibit generic drug
5 substitutions as authorized by Section 4073. For purposes of this
6 section, a prescribing provider shall include a provider authorized
7 to write a prescription to treat a medical condition of a consumer
8 pursuant to subdivision (a) of Section 4059.

9 ~~4135.~~

10 ~~4136.~~ (a) A pharmacy benefits manager shall maintain an
11 expeditious process by which prescribing providers may obtain
12 authorization for a medically necessary nonformulary prescription
13 drug. On or before July 1, 2005, every pharmacy benefits manager
14 shall make public on request a description of its process, including
15 timelines, for responding to authorization requests for
16 nonformulary drugs. Each pharmacy benefits manager shall
17 provide a written description of its most current process, including
18 timelines, to each purchaser and, on request, to prescribing
19 providers. For purposes of this section, a prescribing provider shall
20 include a provider authorized to write a prescription to treat a
21 medical condition of an enrollee pursuant to subdivision (a) of
22 Section 4040.

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

27 (c) The process described in subdivision (a) by which
28 prescribing providers may obtain authorization for medically
29 necessary nonformulary drugs does not apply to a nonformulary
30 drug that has been prescribed for an enrollee in conformity with
31 Section ~~4134~~ 4135.

32 ~~(d) Every pharmacy benefits manager shall maintain all of the~~
33 ~~following information, which shall be made available to the~~
34 ~~purchaser or the public upon request:~~

35 ~~(1) The complete drug formulary or formularies of the plan, if~~
36 ~~the plan maintains a formulary, including a list of the prescription~~
37 ~~drugs on the formulary of the plan by major therapeutic category~~
38 ~~with an indication of whether any drugs are preferred over other~~
39 ~~drugs.~~



1 ~~(2) Records developed by the pharmacy and therapeutic~~
 2 ~~committee of the plan, or by others responsible for developing,~~
 3 ~~modifying, and overseeing formularies, including medical groups,~~
 4 ~~individual practice associations, and contracting pharmaceutical~~
 5 ~~benefits management companies, used to guide the drugs~~
 6 ~~prescribed for the enrollees of the plan, that fully describe the~~
 7 ~~reasoning behind formulary decisions.~~

8 ~~(3) Any arrangements with prescribing providers, medical~~
 9 ~~groups, individual practice associations, pharmacists, or other~~
 10 ~~entities that are associated with activities of the pharmacy benefits~~
 11 ~~manager to encourage formulary compliance or otherwise manage~~
 12 ~~prescription drug benefits.~~

13 ~~(e)~~
 14 ~~(d) Nonformulary prescription drugs shall include any drug for~~
 15 ~~which an individual's copayment or out-of-pocket costs are~~
 16 ~~different than the copayment for a formulary prescription drug,~~
 17 ~~except as otherwise provided by law or regulation.~~

18 SEC. 2. No reimbursement is required by this act pursuant to
 19 Section 6 of Article XIII B of the California Constitution because
 20 the only costs that may be incurred by a local agency or school
 21 district will be incurred because this act creates a new crime or
 22 infraction, eliminates a crime or infraction, or changes the penalty
 23 for a crime or infraction, within the meaning of Section 17556 of
 24 the Government Code, or changes the definition of a crime within
 25 the meaning of Section 6 of Article XIII B of the California
 26 Constitution.

