

AMENDED IN SENATE JUNE 23, 2004

AMENDED IN SENATE JUNE 9, 2004

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
(Coauthors: Assembly Members Chan and 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~~ *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 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 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 and prospective purchasers, 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~~-no. State-mandated local program: ~~yes~~-no.

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 ~~SECTION 1. Division 113 (commencing with Section 150000)~~
- 4 ~~is added to the Health and Safety Code, to read:~~
- 5



1 ~~Article 8. Pharmacy Benefits Management~~

2
3 *DIVISION 113. PHARMACY BENEFITS MANAGEMENT*

4
5 ~~4130. For purposes of this article~~

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 includes the procurement of prescription drugs at a
16 negotiated rate for dispensation within this state, the processing of
17 prescription drug claims, and the administration of payments
18 related to prescription drug claims.

19 (c) “Pharmacy benefits manager” is any person who 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 provided
24 only to enrollees, subscribers, or insureds who are also covered by
25 health benefits offered or provided by that health care service plan
26 or health insurer, nor does the term include an affiliate, subsidiary,
27 or other related entity of the health care service plan or health
28 insurer that would otherwise qualify as a pharmacy benefits
29 manager, as long as the services offered or provided by the related
30 entity are offered or provided only to enrollees, subscribers, or
31 insureds who are also covered by the health benefits offered or
32 provided by that health care service plan or health insurer.

33 (d) “Prospective purchaser” is any person to whom a
34 pharmacy benefits manager offers to provide pharmacy benefit
35 management services.

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

39 ~~4131.~~

1 150001. A pharmacy benefits manager shall disclose to the
2 purchaser in writing all of the following:

3 (a) The aggregate amount of all rebates and other retrospective
4 utilization discounts that the pharmacy benefits manager receives,
5 directly or indirectly, from pharmaceutical manufacturers or
6 labelers in connection with prescription drug benefits specific to
7 the purchaser.

8 (b) For a specified list of therapeutic classes, the aggregate
9 amount for each therapeutic class of all rebates and other
10 retrospective utilization discounts that the pharmacy benefits
11 manager receives, directly or indirectly, from pharmaceutical
12 manufacturers or labelers in connection with prescription drug
13 benefits specific to the purchaser. A therapeutic class shall include
14 at least two drugs.

15 (c) The nature, type, and amount of all other revenue that the
16 pharmacy benefits manager receives, directly or indirectly, from
17 pharmaceutical manufacturers or labelers in connection with
18 prescription drug benefits related to the purchaser.

19 (d) Any prescription drug utilization information related to
20 utilization by the purchaser's enrollees or aggregate utilization
21 data that is not specific to an individual consumer, prescriber, or
22 purchaser.

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

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

30 ~~4132.~~

31 150002. A pharmacy benefits manager shall disclose to a
32 prospective purchaser in writing all of the following:

33 (a) The aggregate amount of all rebates and other retrospective
34 utilization discounts that the pharmacy benefits manager estimates
35 it will receive, directly or indirectly, from pharmaceutical
36 manufacturers or labelers in connection with prescription drug
37 benefits related to the prospective purchaser.

38 (b) For a specified list of therapeutic classes, the aggregate
39 amount for each therapeutic class of all rebates and other
40 retrospective utilization discounts that the pharmacy benefits



1 manager estimates it will receive, directly or indirectly, from
2 pharmaceutical manufacturers or labelers in connection with
3 prescription drug benefits specific to the prospective purchaser. A
4 therapeutic class shall include at least two drugs.

5 (c) The nature, type, and amount of all other revenue that the
6 pharmacy benefits manager estimates it will receive, directly or
7 indirectly, from pharmaceutical manufacturers or labelers in
8 connection with prescription drug benefits related to the
9 prospective purchaser.

10 (d) Any administrative or other fees charged by the pharmacy
11 benefits manager to the prospective purchaser.

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 manage
16 prescription drug benefits.

17 ~~4133.~~

18 *150003.* (a) A pharmacy benefits manager shall provide the
19 information described in Sections ~~4131 and 4132~~ *150001 and*
20 *150002* within 30 days of receipt of the request. If requested, the
21 information shall be provided no less than once each year.

22 (b) Except for utilization information, a pharmacy benefits
23 manager need not make the disclosures required in Sections ~~4131~~
24 ~~and 4132~~ *150001 and 150002* unless and until the purchaser or
25 prospective purchaser agrees in writing to maintain as confidential
26 any proprietary information. That agreement may provide for
27 equitable and legal remedies in the event of a violation of the
28 agreement. That agreement may also include persons or entities
29 with whom the purchaser or prospective purchaser contracts to
30 provide consultation regarding pharmacy services. Proprietary
31 information includes trade secrets, and information on pricing,
32 costs, revenues, taxes, market share, negotiating strategies,
33 customers and personnel held by a pharmacy benefits manager and
34 used for its business purposes.

35 ~~4134.~~

36 *150004.* 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:

39 (a) The amount of the total revenues, rebates, and discounts
40 identified in subdivisions (a), (b), and (c) of Section ~~4131~~ *150001*



1 and subdivisions (a), (b), and (c) of Section ~~4132~~ 150002 that shall
2 be passed on to the purchaser.

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

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

8 (d) Conditions under which an audit will be conducted of the
9 contract for pharmacy benefits management services, who will
10 conduct the audit, and who will pay for the audit.

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) The process for development of formularies and
15 notification of changes to formularies, and approval of those
16 changes by the purchaser, provided that the pharmacy benefits
17 manager meets the requirements of Sections ~~4135, 4136, and~~
18 ~~4137.~~

19 ~~4135, 150005, 150006, and 150007.~~

20 (g) *Whether there is a difference between the price paid to a*
21 *retail pharmacy and the amount that will be billed to the purchaser*
22 *for prescription drugs.*

23 150005. (a) All members of a pharmacy and therapeutics
24 committee for a pharmacy benefits manager shall be physicians,
25 pharmacists, or other health care professionals, and a majority of
26 committee members shall not be employed by the pharmacy
27 benefits manager.

28 (b) A pharmacy and therapeutics committee member shall not
29 be an officer, employee, director, or agent of, or any person who
30 has financial interest in, other than ownership of stock from open
31 market purchases of less than a nominal amount of the outstanding
32 stock of, pharmaceutical companies.

33 ~~4136.~~

34 150006. A pharmacy benefits manager shall report not less
35 than quarterly to the pharmacy and therapeutics committee which
36 shall monitor the health effects of medication substitutions on the
37 health of the patients, including identifying information from
38 patients and prescribers concerning the efficacy or health effects
39 of medication substitution.

40 ~~4137.~~



1 150007. (a) A pharmacy benefits manager shall not
2 substitute a medication for another currently prescribed
3 medication without first obtaining express verifiable authorization
4 from the prescriber of the currently prescribed drug except in the
5 following instances:

6 (1) As provided in Sections 4052.5 and 4073 *of the Business*
7 *and Professions Code*.

8 (2) If the medication substitution is initiated for patient safety
9 reasons.

10 (3) If the currently prescribed medication is no longer available
11 in the market.

12 (4) If initiated pursuant to a drug utilization review.

13 (5) If required for coverage reasons where the prescribed drug
14 is not covered by the individual's formulary or plan.

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

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

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

21 (3) The existence of any additional payments received by the
22 pharmacy benefits manager not reflected in the cost savings to the
23 purchaser.

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

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

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

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

33 (c) The pharmacy benefits manager shall not substitute a
34 medication for a currently prescribed medication unless the
35 pharmacy benefits manager communicates with the patient to
36 provide that patient or their representative the following
37 information:

38 (1) The proposed medication and the currently prescribed
39 medication.



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

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

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

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

10 (6) The existence of any additional payments received by the
11 pharmacy benefits manager not reflected in the cost savings to the
12 purchaser.

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

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

17 (d) Unless a prescribed drug is no longer on the purchaser's
18 formulary or the individual is unwilling to pay any higher
19 applicable copayment or other costs, the pharmacy benefits
20 manager shall cancel and reverse the medication substitution upon
21 written or verbal instructions from a prescriber or the individual.

22 (1) The pharmacy benefits manager shall maintain a toll-free
23 telephone number during normal business hours for a minimum of
24 eight hours per day Monday through Friday for prescribers and
25 patients.

26 (2) The pharmacy benefits manager shall not charge the
27 individual any additional copayments or fees related to the
28 replacement medication.

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.~~



- 1 *150008. All disclosures made pursuant to this division shall*
- 2 *comply with the privacy standards of the federal Health Insurance*
- 3 *Portability and Accountability Act.*

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