

Assembly Bill No. 1960

Passed the Assembly August 25, 2004

Chief Clerk of the Assembly

Passed the Senate August 24, 2004

Secretary of the Senate

This bill was received by the Governor this _____ day of
_____, 2004, at _____ o'clock __M.

Private Secretary of the Governor



CHAPTER _____

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, Pavley. Pharmacy benefits management.

Existing law 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.

The people of the State of California do enact as follows:

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

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) “Labeler” means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the



federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) “Pharmacy benefits management” is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

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

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

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

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

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

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug



benefits specific to the purchaser. A therapeutic class shall include at least two drugs.

(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the purchaser. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

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

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

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

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

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

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A therapeutic class shall include at least two drugs.



(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

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

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

150003. (a) A pharmacy benefits manager shall provide the information described in Section 150001 no less frequently than on a quarterly basis.

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

150004. A pharmacy benefits manager may not execute a contract for the provision of pharmacy benefits management services that fails to address the following items:

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



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

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

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

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

(e) Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers that are related to the services to be provided to the purchaser.

(f) The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits manager meets the requirements of Sections 150005, 150006, and 150007.

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

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

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

150006. (a) Except as provided in subdivision (b), any request from a pharmacy benefits manager to a prescriber for authorization to substitute a medication shall include all of the following disclosures:

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

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



(3) The existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser.

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

(5) The circumstances and extent to which, if any, related health care costs arising from the medication substitution will be compensated.

(6) Any known differences in potential effects on a patient's health and safety, including side effects.

(b) A pharmacy benefits manager shall not be required to make the disclosures required by subdivision (a) under any of the following instances:

(1) The substitution is from a brand drug to a generic or chemical equivalent in accordance with applicable state law.

(2) The medication substitution is initiated for patient safety reasons.

(3) The currently prescribed medication is no longer available in the market.

(4) The substitution is initiated pursuant to a drug utilization review.

(5) The substitution is required for coverage reasons where the prescribed drug is not covered by the patient's formulary or plan.

(c) A pharmacy benefits manager shall record the name and title of the prescriber, or the person other than the prescriber, authorizing the medication substitution if the authorization is given verbally.

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

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

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

(3) Potential side effects of the medication substitution.

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



(5) The circumstances and the extent to which, if any, health care costs related to the medication substitution will be compensated.

(6) Notification that the patient may decline the medication substitution if the currently prescribed drug remains on the patient's formulary, and the patient is willing to pay any difference in the copayment amount.

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

(e) The pharmacy benefits manager shall cancel and reverse the medication substitution upon written or verbal instructions from a prescriber or the patient. The pharmacy benefits manager shall not be required to cancel and reverse the medication substitution if the prescribed drug is no longer on the purchaser's formulary or the patient is unwilling to pay a higher copayment or other cost associated with the prescribed drug.

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

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

150007. A pharmacy benefits manager shall monitor the health effects on patients of medication substitutions requested by the pharmacy benefits manager. The pharmacy benefits manager shall, on a quarterly basis, report to his or her Pharmacy and Therapeutics Committee the results of the monitoring. This report shall include all patient and prescriber communications received by the pharmacy benefits manager that concern the efficacy or health effects of the medication substitutions.

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



Approved _____, 2004

Governor

