PBM Fiduciary Duty and Disclosure Model Bill

Section 1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

(a) "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to *[Insert citation to appropriate statute]*; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.

(b) "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

(c) "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

(d) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 270.20 (1999).

(e) "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:

(1) Mail service pharmacy;
(2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
(3) Clinical formulary development and management services;
(4) Rebate contracting and administration;
(5) Certain patient compliance, therapeutic intervention and generic substitution programs; and
(6) Disease management programs.

(f) "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy.

[DRAFTING NOTE: You may wish to exempt from this definition in-house PBMs of health insurers or HMOs that work solely on managing pharmacy benefits for the enrollees of those insurers or HMOs. If you wish to do this, insert the following language after the last sentence in Section F. immediately above:

"Pharmacy benefits manager" does not include a health care service plan [DRAFTING NOTE: "health care service plan" is the term for HMO in California, insert your state's appropriate term here] 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.]

Section 2. Required practices. A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.

(a) A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

(b) A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subsection.

(c) A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, unless

ordered by a court of this State for good cause shown. Prior to making the disclosures required by this paragraph, a pharmacy benefits manager may require the covered entity to agree 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.

(d) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual the following provisions apply.

(1) If a pharmacy benefits manager makes a substitution in which the substitute drug costs more than the prescribed drug, the pharmacy benefits manager shall disclose to the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution.

(2) The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager either as a result of a prescription drug substitution under subparagraph (1) or as a result of the pharmacy benefits manager substituting a lower priced generic and therapeutically equivalent drug for a higher priced prescribed drug.

(e) A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity.

(f) A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees. A pharmacy benefits manager disclosing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and disclosed to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, unless ordered by a court of this State for good cause shown. Prior to making the disclosures required by this paragraph, a pharmacy benefits manager may require the covered entity to agree 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.

Section 3. Compliance. Compliance with the requirements of this section is required in all contracts for pharmacy benefits management entered into in this State or by a covered entity in this State.

Section 4. Enforcement. In addition to any other remedy provided by law, a covered entity aggrieved by a violation of this chapter or a rule adopted under this chapter may file an action in superior court for injunctive relief and an award of compensatory and punitive damages. The superior court shall award to the covered entity who prevails in an action under this section reasonable costs and attorney's fees.