HOUSE DOCKET, NO. 1764 FILED ON: 1/20/2011

HOUSE . . . . . No. 1521

The Commonwealth of Massachusetts

PRESENTED BY:

Jeffrey Sánchez

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to ensure transparency in prescription drug practices in the Commonwealth.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Jeffrey Sánchez	*15th Suffolk*	*2/4/2011*
Jason M. Lewis	*31st Middlesex*	*2/4/2011*
Bruce E. Tarr		*1/31/2011*
John W. Scibak	*2nd Hampshire*	*2/3/2011*

HOUSE DOCKET, NO. 1764 FILED ON: 1/20/2011

HOUSE . . . . . No. 1521

By Mr. Sánchez of Boston, a petition (accompanied by bill, House, No. 1521) of Jeffrey Sánchez and others for legislation to ensure transparency in prescription drug practices. Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An Act to ensure transparency in prescription drug practices in the Commonwealth.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Section 1. Purpose.

It is the intent of the legislature to ensure transparency in contracts and in prescription drug pricing, fair dealing between pharmacy benefit managers and their clients, and protection of consumers, including health plans and insurers by regulating the trade practices of pharmacy benefit managers in the commonwealth.

Section 2. Definitions. For the purposes of this chapter:

(a) "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to the health insurance laws of the commonwealth; a health program administered by the commonwealth in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the commonwealth that provides health coverage to covered individuals who are employed or reside in the commonwealth. "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 and 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) “Individual identifying information” means information which directly or indirectly identifies a prescriber or a patient, where the information is derived from or relates to a prescription for any prescribed product.

(e) "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).

(f) “Marketing” means any activity by a pharmacy benefit manager, alone or in collaboration with a company making or selling prescribed products, which is intended to influence prescribing or purchasing choices of the products, including but not limited to:

(1) advertising, publicizing, promoting or sharing information about a product;

(2) identifying individuals to receive a message promoting use of a particular product, including but not limited to an advertisement, brochure, or contact by a sales representative;

(3) planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document;

(4) evaluating or compensating sales representatives;

(5) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value;

(6) advertising or promoting prescribed products directly to patients, including through refill reminders or information about alternative products.

(g) "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within the commonwealth 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

(h) "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.

(i) “Prescribed product” includes a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.

Section 3. Registration of Pharmacy Benefit Managers.

(a) A pharmacy benefit manager shall not do business in the commonwealth without first registering with the board of registration in pharmacy on a form and in a manner prescribed by the board of registration in pharmacy.

(b) Each pharmacy benefit manager shall pay a registration fee of $3,000.00. Fees collected under this section shall fund the costs of registration by the board of registration in pharmacy and enforcement of this chapter by the attorney general’s office.

(c) Compliance with the requirements of this chapter is required for pharmacy benefit managers entering into contracts with a covered entity for pharmacy benefit management in the commonwealth.

Section 4. Fiduciary Duty.

(a) 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.

(b) 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.

(c) 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 section.

(d) Covered entities shall have the right to terminate contracts without cause.

(e) A pharmacy benefit manager shall provide notice to the covered entity of its rights under this chapter.

Section 5. Transparency.

(a) 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. The parties' contract shall specify which third-party entity's database the pharmacy benefits manager contractors must use when calculating the drug costs billed under the contract, the maximum allowable cost applicable to the covered entity, the methodology for calculating rebate amounts, and identify specialty drugs and the pricing mechanism for these drugs.

(b) 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-substitution programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

(c) A pharmacy benefits manager providing information under this section 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, except that disclosure may be made in a court filing, ordered by a court of the commonwealth for good cause shown, or made in a court filing under seal until otherwise ordered by a court.

(d) Nothing in this section limits the attorney general's authority under state law including, but not limited to, chapter 93A, to investigate violations of this section.

Section 6. Prescription Drug Substitutions and Formulary Management.

(a) The following provisions apply to the dispensation of a prescription drug substituted for a prescribed drug to a covered individual:

(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; and

(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 subsection (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.

(b) Pharmacy benefit managers shall notify a covered entity 10 days in advance of any changes to the entity's drug formulary or preferred drug list, except in case of emergency recall of a drug. Pharmacy benefit managers shall provide the covered entity an explanation for the changes, including but not limited to the medical and financial reasons for the addition, removal, or change in a drug on the formulary or preferred drug list.

Section 7. Sales Volume Discounts. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the commonwealth based on volume of sales for certain prescription drugs or classes or brands of drugs within the commonwealth shall pass that payment or benefit on in full to the covered entity.

Section 8. Privacy Protections.

(a) In addition to the disclosure and privacy provisions of the Health Insurance Portability and Accountability Act of 1996, a pharmacy benefit manager shall not knowingly disclose or use records containing individual identifying information for marketing a prescribed product to a patient or prescriber.

(b) This section shall not prevent a pharmacy benefit manager from disclosing individual identifying information to the identified individual as long as the information does not include protected information pertaining to any other person.

Section 9. Audits.

(a) Upon request, pharmacy benefit managers shall allow access by the covered entity, the covered entity's agent, or the state auditor to the pharmacy benefit managers and its contractors' facilities and all financial and contractual information necessary to conduct a complete and independent audit designed to verify costs and discounts associated with drug claims, pharmacy benefit manager contractor compliance with the contract requirements, and services provided by subcontractors, including, but not limited to:

(1) the drug prices and rebates received from a pharmaceutical manufacturer associated with all drugs dispensed to covered individuals of the covered entity in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract;

(2) the drug prices and rebates provided by the pharmacy benefit manager to the covered entity associated with all drugs dispensed to covered individuals in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract;

(3) all other fees charged or financial remuneration received by the pharmacy benefit manager associated with all drugs dispensed to covered individuals of the covered entity in both retail and mail order settings or resulting from any of the pharmacy benefit management functions defined in the contract, including rebates from pharmaceutical manufacturers; and

(4) the full benefits of the pricing arrangements and activities of the pharmacy benefit manager required by the contract.

(b) Every contract shall define the reporting requirements for audits that a pharmacy benefit manager contractors performs concerning the conduct of the pharmacy network,

including what information should be reported, how often audit results should be reported, and require the pharmacy benefit manager contractor to return recovered overpayments to the covered entity.

(c) All audits performed under this section shall comply with auditing standards to ensure the business processes and activities related to the audit objectives are reviewed and tested for compliance and reliability and that there is sufficient, appropriate evidence captured to support the audit's findings and conclusions.

(d) "Financial and contractual information" includes, but is not limited to, financial records, contracts, medical records, agreements, and relationships with subcontractors.

Section 10. Enforcement.

(a) In addition to any other remedy provided by law, a violation of this chapter shall be a violation of section 2 of chapter 93A as an unfair or deceptive act in trade or commerce and may be enforced by the attorney general acting on behalf of the commonwealth, or by an individual. All rights, authority, and remedies available to the attorney general and private parties to enforce the unfair trade practices act shall be available to enforce the provisions of this subchapter.

(b) Any person who knowingly fails to comply with the requirements of this chapter or rules adopted pursuant to this chapter shall be subject to a fine of not more than $50,000.00 per violation. Each failure to disclose shall constitute a violation. The office of the attorney general shall take necessary action to enforce payment of penalties assessed under this section.

Section 11. Rules. The board of registration in pharmacy shall make rules for the implementation of this chapter.

Section 12. Severability. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

Section 13. Application. This act applies to contracts executed or renewed on or after July 1, 2010. For purposes of this section, a contract executed pursuant to a memorandum of agreement executed prior to July 1, 2010 is deemed to have been executed prior to July 1, 2010 even if the contract was executed after that date