

Part 1 – An Act to Lower the Costs of Prescription Drugs Use of the Federal Public Health Service Act (340B)**Part 2 – An Act to Protect Against Unfair Prescription Drug Practices (PBMs)**

Part 1 – An Act to Lower the Costs of Prescription Drugs through the Use of the Federal Public Health Service Act**Section 1. Purposes**

The intent of the Legislature in enacting this Act is to reduce [State’s] prescription drug costs by ensuring maximum use of prescription drug pricing available through Section 340B of the federal Public Health Service Act.

Section 2. Working group and report

The [agency]¹ shall convene a working group to study and by November 1, 2010, provide a report to the [legislature’s committee(s) with jurisdiction over this Act] on the feasibility of providing discounted prescription drugs to [State’s] most vulnerable patient populations through the use of Section 340B of the federal Public Health Service Act, 42 United States Code, Section 256b (1999), referred to in this Resolve as "Section 340B." The working group shall include representatives of the following: 340B hospitals, the prison system, Medicaid, low-income non-profit advocacy organizations, a balanced and bi-partisan group of legislators from relevant health committees, and a representative of Federally Qualified Health Centers or related FQHC association. The working group, in concert with the [agency] shall work with other state agencies, representatives of state employees and representatives of health care providers and facilities in the State to provide the following information:

1. **Covered entities.**² A description of all health care providers and facilities in the State potentially eligible for designation as "covered entities" under Section 340B, including without limitation all hospitals eligible as disproportionate share hospitals; recipients of grants from the United States

¹ Each state should identify the agency within which the administration of this study fits most easily and is most capable of producing and ensuring a thorough and accurate process that meets the objectives of the Act. Options include the state department of health, or similar agency.

² H.R. 3590, [The Patient Protection and Affordable Care Act](#), the Senate health reform measure reported out by Senate Majority Leader Harry Reid on November, 18, 2009, includes language to expand the 340B program. The bill would extend 340B discounts to inpatient drugs and extend participation to “certain children’s hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers.” In addition to new auditing and reporting requirements of the program, the Senate bill requires the GAO to make recommendations to Congress for improving the 340B program within 18 months of the bill’s enactment.

Public Health Service; federally qualified health centers; federally qualified look-alikes; state-operated AIDS drug assistance programs; Ryan White CARE Act Title I, Title II and Title III programs; tuberculosis, black lung, family planning and sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; and clinics for homeless people.

2. **Potential applications and benefits.** A listing of potential applications of Section 340B and the potential benefits to public, private and 3rd-party payors for prescription drugs, including without limitation:
 - a. Application to inmates and employees in youth correctional facilities, county jails and state prisons;
 - b. Maximizing the use of Section 340B within state-funded managed care plans;
 - c. Including Section 340B providers in state bulk purchasing initiatives; and
 - d. Utilizing sole source contracts with Section 340B providers to furnish high-cost chronic care drugs;
3. **Section 340B discounts.** Discounts available through Section 340B contracts, including estimated costs savings to the State as a result of retail mark-up avoidance, negotiated sub-ceiling prices and coordination with the [state's Medicaid] program in order to minimize costs to the program and to other purchasers of prescription drugs; and
4. **Identification of resources.** The resources available to potential applicants for designation as covered entities for the application process, establishing a Section 340B program, restructuring the health care system or other methods of lowering the cost of prescription drugs. The resources must include state and federal agencies and private philanthropic grants to be used for the purposes of this section; and be it further

Section 3. Report out legislation.

The [legislature's committee(s) with jurisdiction over this Act] shall report out legislation to the current or next Legislative session regarding use in the State of Section 340B, restructuring the health care system or other methods of lowering the cost of prescription drugs.

Part 2 – An Act to Protect Against Unfair Prescription Drug Practices

Section 1. Purposes

The purpose of the Legislature in enacting Act are to reduce the state's spending on prescription drugs by requiring Pharmacy Benefit Managers (PBMs) to act as fiduciaries for their clients, to increase transparency of PBM practices, and to prevent fraud and deception and help market forces to work in the interest of lowering prices to end users of medicines. Under this Act, in addition to acting as fiduciaries for their clients, PBMs must disclose conflicts of interest, disgorge profits from self-dealing, and disclose to the covered entities certain of their financial arrangements with third parties. Violations of this law are violations of [State's] unfair trade practices or consumer protection laws, which generally provide for treble damages for violations and give authority to the Attorney General to bring actions on behalf of the state.

Pharmacy benefits managers and contracts for pharmacy benefits management shall and must comply with the requirements of this Act.

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 State insurance laws; a health program administered by the [health 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:
 - a. Mail service pharmacy;
 - b. Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
 - c. Clinical formulary development and management services;
 - d. Rebate contracting and administration;
 - e. Certain patient compliance, therapeutic intervention and generic substitution programs; and
 - f. 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.

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, except that disclosure may be made in a court filing under the State law governing deceptive trade practices or when authorized by that Act or ordered by a court of this State for good cause shown or made in a court filing under seal unless or until otherwise ordered by a court. Nothing in this paragraph limits the Attorney General's use of Civil Investigative Demand Authority (or similar authority) under the State law governing deceptive trade practices to investigate violations of this section.
- 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, except that disclosure may be made in a court filing under the State law governing deceptive trade practices or when authorized by that Act or ordered by a court of this State for good cause shown or made in a court filing under seal unless or until otherwise ordered by a court. Nothing in this paragraph limits the Attorney General's use of Civil Investigative Demand Authority (or similar authority) under the State law governing deceptive trade practices to investigate violations of this section.

Section 3. Registration

All pharmacy benefits managers operating in [State] shall register with the [agency with jurisdiction over insurance]. [Agency] shall assess all pharmacy benefits managers a reasonable annual fee to cover the costs of registration and this section.

Section 4. Annual certification

Any pharmacy benefits manager operating in [State] shall file annual certifications with [agency] to show that they are in compliance with the fiduciary, transparency, and other rules in this Act.

Section 5. Market conduct review and audit

[Agency] shall utilize its market conduct and audit authority to review pharmacy benefit managers' compliance with these rules. [Agency] shall have the authority to charge companies an annual fee proportional to the agency's cost associated with conducting the market conduct exam and audit. [Agency] shall carry out a market conduct exam (and audit) at least once every three years and report its findings to the [Legislature's committee with jurisdiction over this Act].³

Section 6. 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 7. Enforcement

- A. A violation of this section is a violation of the State law governing deceptive trade practices.⁴
- B. The superintendent of insurance (or similar authority) has authority under the insurance code to utilize any of the remedies under the insurance code to enforce this Act.

Section 8. Rulemaking

The [agency] may adopt rules as necessary to implement this Act.

³ Most state insurance commissioners can conduct a market conduct review to ensure insurance company compliance with state law. This Act would extend this authority to review of pharmacy benefit managers. The Senate health bill, H.R. 3590, includes transparency standards for any insurer and PBM in the new Exchange: "Sec. 6005. Pharmacy benefit managers transparency requirements. Requires a pharmacy benefit manager (PBM) or a health benefits plan that provides pharmacy benefits management services that contract with health plans under Medicare or the Exchange to report to the Secretary information regarding the generic dispensing rate: the rebates, discounts, or price concessions negotiated by the PBM and the payment difference between health plans and PBMs and the PBMs and pharmacies. All disclosed information would be confidential, except for certain specific purposes." This language leaves room for the need for state enforcement of the provisions of this model Act.

⁴ Under most state consumer protection and unfair trade practices laws there is injunctive relief and penalties and the ability of the state Attorney General to seek damages, as well as the option of a private right of action.

