ASSEMBLY, No. 4279

STATE OF NEW JERSEY

216th LEGISLATURE

INTRODUCED MARCH 16, 2015

Sponsored by:
Assemblyman JOSEPH A. LAGANA
District 38 (Bergen and Passaic)
Assemblyman CRAIG J. COUGHLIN
District 19 (Middlesex)
Assemblywoman PAMELA R. LAMPITT
District 6 (Burlington and Camden)
Assemblyman RAJ MUKHERJI
District 33 (Hudson)

SYNOPSIS
Regulates pharmacy benefits management companies.

CURRENT VERSION OF TEXT
As introduced.

(Sponsorship Updated As Of: 6/2/2015)

AN ACT concerning pharmacy benefits management companies and supplementing Title 17B of the New Jersey Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Carrier" means an insurance company, health service corporation, hospital service corporation, medical service corporation or health maintenance organization authorized to issue health benefits plans in this State.

"Commissioner" means the Commissioner of Banking and Insurance.

"Covered person" means a person on whose behalf a carrier or other entity is obligated to pay benefits pursuant to a health benefits plan.

"Department" means the Department of Banking and Insurance.

"Drug" means a drug or device as defined in R.S.24:1-1.

"Drug utilization review" means a system for monitoring the prescribing, dispensing and consumption of prescription drugs under a health benefits plan according to specified guidelines, in order to recommend or determine whether, or to what extent, a prescription drug that is given or proposed to be given to a covered person should or will be reimbursed, covered, paid for or otherwise provided under the health benefits plan, and which system may include both retrospective and prospective review.

"Health benefits plan" means a benefits plan which pays hospital and medical expense benefits for covered services and is delivered or issued for delivery in this State by or through a carrier or any other sponsor, including, but not limited to a carrier, self-insured employer or union. For the purposes of this act, health benefits plan shall not include the following plans, policies or contracts: accident only, credit disability, long-term care, Medicare supplement coverage, CHAMPUS supplement coverage, coverage for Medicare services pursuant to a contract with the United States government, coverage arising out of a worker's compensation or similar law, coverage under a policy of private passenger, personal injury protection insurance issued pursuant to P.L.1972, c.70 (C.39:6A-1 et seq.) or hospital confinement indemnity coverage.

"Health care practitioner" means a physician, dentist or other health care professional authorized to write prescriptions.

"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, Code of Federal Regulations.

"Pharmacy benefits management services" means any of the following: the procurement of prescription drugs at a negotiated

rate for dispensation within this State, the processing of prescription drug claims or the administration of payments related to prescription drug claims.

"Pharmacy benefits management company" means a corporation, business or other entity, or unit within a corporation, business or other entity, that administers prescription drug benefits on behalf of a health benefits plan sponsor with the objective of providing high-quality pharmaceutical care at the lowest possible cost, but does not include a pharmacy benefits management company operated by a health maintenance organization solely for the benefit of its enrollees.

"Prescription" means a prescription as defined in section 5 of P.L.1977, c.240 (C.24:6E-4).

"Prospective purchaser" means any sponsor of a health benefits plan to whom a pharmacy benefits management company offers to provide pharmacy benefits management services.

"Purchaser" means any sponsor of a health benefits plan who enters into an agreement with a pharmacy benefits management company for the provision of pharmacy benefits management services.

2. a. After the effective date of this act, no person, corporation, partnership or other entity shall operate a pharmacy benefits management company in this State except in accordance with the provisions of this act. A pharmacy benefits management company which is operated by a health maintenance organization solely for the benefits of its enrollees is exempted from the provisions of this act.

b. A pharmacy benefits management company operating in this State on the effective date of this act shall submit an application for a certificate to the commissioner no later than nine months after the effective date of this act. The pharmacy benefits management company may continue to operate during the pendency of its application, but in no case longer than 18 months after the effective date of this act. If the application is denied, the applicant shall then be treated as a pharmacy benefits management company whose certificate has been revoked pursuant to section 12 of this act. Nothing in this subsection shall operate to impair any contract which was entered into before the effective date of this act.

c. Any person providing pharmacy benefits management services on behalf of a purchaser located in this State in a manner substantially provided for in this act shall be presumed to be subject to the provisions of this act unless the person is otherwise regulated under State law.

3. a. A pharmacy benefits management company shall submit an application for a certificate on the form, and in the manner, prescribed by the commissioner. The application shall be signed

under oath by the chief executive officer of the pharmacy benefits management company or by a legal representative of the pharmacy benefits management company, and shall include the following:

(1) the name, address, telephone number and normal business hours of the pharmacy benefits management company;

(2) the name, address and telephone number of a person who is employed by, or otherwise represents, the pharmacy benefits management company and who is available to answer questions concerning the application which may be posed by department staff;

(3) the proposed plan of operation for the pharmacy benefits management company, including the mechanism by which the pharmacy benefits management company will provide pharmacy benefits management services; and

(4) such other information as the commissioner may require to ensure that the pharmacy benefits management company can and will comply with the requirements for certification.

If there is a material change in any of the information included in the application subsequent to its initial submission, including a change subsequent to the issuance or renewal of the certificate, the pharmacy benefits management company shall inform the commissioner of the change on a form, and in a manner, prescribed by the commissioner.

b. The commissioner shall issue a certificate of authority to a pharmacy benefits management company if, in the determination of the commissioner, the application demonstrates that:

(1) the pharmacy benefits management company will provide high-quality pharmacy benefits management services in a cost-effective manner which ensures adequate availability and accessibility of pharmacy benefits services to covered persons;

(2) the pharmacy benefits management company will provide a continuous quality of pharmaceutical care assurance and improvement program, a drug utilization review program which meets standards adopted by the commissioner, and a complaint resolution mechanism to provide reasonable procedures for the resolution of complaints by pharmacists, health care practitioners and covered persons;

(3) the pharmacy benefits management company is financially sound and may reasonably be expected to meet any obligations to persons covered under a purchaser's health benefits plan;

(4) the pharmacy benefits management company has a procedure to establish and maintain a uniform system of cost accounting approved by the commissioner and a uniform system of reporting and auditing, meeting the requirements of the commissioner; and

(5) the pharmacy benefits management company has adopted procedures to ensure compliance with all State and federal laws governing the confidentiality of its records with respect to pharmacists, health care practitioners and covered persons.

c. If an application is rejected by the commissioner, the commissioner shall specify in what respect it fails to comply with the requirements for certification. When the certificate of a pharmacy benefits management company is revoked, the company shall proceed, immediately following the effective date of the order of revocation, to pay all outstanding pharmacy benefits claims of covered persons and shall conduct no further business except as may be essential to the orderly conclusion of the affairs of the company. The commissioner may permit such further operation of the company as the commissioner may find to be in the best interest of covered persons to obtain pharmaceutical services.

d. A certificate issued pursuant to subsection b. of this section shall be valid for three years from the date of issuance by the commissioner, and shall be renewed thereafter, upon payment of the renewal fee by the pharmacy benefits management company, if the company meets the standards for recertification prescribed by the commissioner.

e. The commissioner shall establish uniform application and renewal fees for the certificate, the amount of which shall be no greater than is reasonably necessary to enable the department to carry out the provisions of this act.

4. a. Any pharmacy benefits management company that enters into a contract with a pharmacy or pharmacist to provide pharmacy benefits management services in this State after the effective date of this act shall file the contract with the commissioner 30 days prior to the execution of the contract. The contract shall be deemed approved unless the commissioner disapproves the contract within 30 days after filing with the commissioner. Disapproval shall be in writing, stating the reasons therefor, and a copy thereof shall be delivered to the pharmacy benefits management company. The commissioner shall promulgate regulations establishing criteria for the approval and disapproval of pharmacy benefits management contracts.

b. A pharmacy benefits management company shall file a statement with the commissioner annually by March 1. The statement shall be verified by at least two principal officers and shall cover the preceding calendar year. Each pharmacy benefits management company shall also send a copy of the statement to the New Jersey State Board of Pharmacy.

The statement shall be on a form prescribed by the commissioner and shall include:

(1) a financial statement of the company, including its balance sheet and income statement for the preceding year;

(2) the number of covered persons enrolled during the year, the number of covered persons enrolled as of the end of the year and the number of enrollments terminated during the year; and

(3) other information relating to the operations of the pharmacy benefits management company as required by the commissioner pursuant to this act.

c. If the pharmacy benefits management company is audited annually by an independent certified public accountant, a copy of the certified audit report shall be filed annually with the commissioner by June 30.

d. The commissioner may extend the time prescribed for any pharmacy benefits management company for filing annual statements or other reports or exhibits of any kind for good cause shown; however, the commissioner shall not extend the time for filing annual statements beyond 60 days after the time prescribed by subsection b. of this section. Pursuant to section 12 of this act, the commissioner may suspend or revoke the certificate of any pharmacy benefits management company which fails to file its annual statement within the time prescribed by this section.

5. a. In lieu of or in addition to making a financial examination of a pharmacy benefits management company pursuant to section 4 of this act, the commissioner may accept the report of a financial examination of any other person responsible for the pharmacy benefits management company under the laws of another state certified by the insurance supervisory official, similar regulatory agency or state health commissioner of that state.

b. The commissioner shall coordinate financial examinations of a pharmacy benefits management company that provides pharmacy benefits management services for purchasers in this State to ensure an appropriate level of regulatory oversight and avoid any undue duplication of effort or regulation. The pharmacy benefits management company being examined shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund that shall provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this act.

6. A pharmacy benefits management company may engage in any of the following activities, and in such other activities as the commissioner deems appropriate, in accordance with regulations adopted by the commissioner:

a. process prescription drug claims and issue payments to pharmacists for drugs dispensed to persons covered under a purchaser's health benefits plan;

b. provide mail-order pharmacy services to persons covered under a purchaser's health benefits plan;

c. contract with a network of pharmacists to obtain discounted prescription drug prices and dispensing fees for persons covered under a purchaser's health benefits plan;

d. develop and open, incentive-based or closed prescription drug formulary and make changes in the formulary;

e. negotiate with pharmaceutical manufacturers to obtain rebates on prescription drug prices for the purchaser;

f. develop disease management protocols to help contain prescription drug expenditures for chronic conditions, including, but not limited to, asthma and diabetes, and manage the care of persons with chronic conditions who are covered under a purchaser's health benefits; and

g. perform drug utilization review under the direction of a registered pharmacist within the meaning of the "New Jersey Pharmacy Practice Act," P.L.2003, c.280 (C.45:14-40 et seq.) and in accordance with section 10 of this act.

7. A pharmacy benefits management company shall provide to each covered person under a purchaser's health benefits plan a notice written in easily understandable language which: explains restrictions on covered pharmaceutical services under the plan; lists the pharmacies included in a network with which the pharmacy benefits management company contracts; and includes other information as the commissioner may require.

8. a. A pharmacy benefits management company shall disclose to a purchaser in writing the following:

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

(2) a list of therapeutic classes of drugs specified by the commissioner, the aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits management company 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;

(3) the nature, type and amount of any other revenue that the pharmacy benefits management company receives, directly or indirectly, from pharmaceutical manufactures or labelers in connection with prescription drug benefits related to the purchaser, except that no pharmacy benefits management company shall 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 a mail order pharmacy of the pharmacy benefits management company;

(4) any revenues, rebates or discounts received by the pharmacy benefits management company directly or indirectly from entities

other than manufacturers and labelers that are related to the services provided to the purchaser;

(5) the aggregate drug utilization of all purchasers compiled to prevent identifying any covered person, health care practitioner or purchaser;

(6) any administrative or other fees charged by the pharmacy benefits management company to the purchaser; and

(7) any arrangements with prescribing health care practitioners, medical groups, individual practice associations, pharmacists or other entities that are associated with business practices of the pharmacy benefits management company to encourage formulary compliance or otherwise manage prescription drug benefits.

b. A pharmacy benefits management company shall disclose the information required in subsection a. of this section no less frequently than on a quarterly basis and upon receiving a written agreement from the purchaser that it will keep the information confidential. 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 contracts to provide consultation regarding pharmacy services.

9. a. A pharmacy benefits management company shall disclose to a prospective purchaser in writing the following:

(1) the aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits management company 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 management company;

(2) a list of therapeutic classes of drugs specified by the commissioner, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits management company 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 management company. A therapeutic class shall include at least two drugs;

(3) the nature, type and amount of all other revenues that the pharmacy benefits management company 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 management company;

(4) any revenues, rebates or discounts received by the pharmacy benefits management company, directly or indirectly, from entities

other than manufacturers and labelers that are related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits management company;

(5) any administrative or other fees charged by the pharmacy benefits management company to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits management company; and

(6) any arrangement with health care practitioners, medical groups, individual practice associations, pharmacists or other entities that associate with the pharmacy benefits management company to encourage formulary compliance or otherwise manage prescription drug benefits for the prospective purchaser.

b. A pharmacy benefits management company shall disclose the information required in subsection a. of this section upon request from the prospective purchaser and upon receiving a written agreement from the prospective purchaser that it will keep the information confidential. 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 prospective purchaser contracts to provide consultation regarding pharmacy services.

10. a. Except as provided in subsection b. of this section, if a pharmacy benefits management company requests authorization of a health care practitioner to substitute a drug prescribed to a covered person, the pharmacy benefits management company shall disclose to the health care practitioner and the purchaser the following:

(1) any cost savings for the purchaser that are a result of the drug substitution;

(2) any difference in copayments or other out-of-pocket costs paid by the covered person in order to obtain the substitute drug;

(3) the existence of any additional payments received by the pharmacy benefits management company from any other entity that would be received upon approval of the drug substitution;

(4) any circumstance under which the currently prescribed drug will be covered;

(5) the extent to which related health care costs arising from the drug substitution will be compensated to the purchaser or covered person by the pharmacy benefits management company; and

(6) any known differences in potential effects on a covered person's health and safety, including any side effects.

b. No pharmacy benefits management company shall be required to disclose the information listed in subsection a. to a purchaser or health care practitioner under any of the following circumstances:

(1) the substitution is from a brand drug to a generic or chemical equivalent in accordance with applicable State law;

(2) the drug substitution is initiated for patient safety reasons;

(3) the currently prescribed drug is no longer available in the market; or

(4) the substitution is required for coverage reasons in which the prescribed drug is not covered under the covered person's formulary or health benefits plan.

c. A pharmacy benefits management company shall record the name and title of the health care practitioner, or the person other than the health care practitioner, authorizing the drug substitution if the authorization is given verbally.

d. No pharmacy benefits management company shall substitute a drug for a currently prescribed drug unless the pharmacy benefits management company communicates with the covered person to provide that covered person or his designated representative the following information:

(1) the proposed drug and the currently prescribed medication;

(2) the difference in copayments or any out-of-pocket costs paid by the covered person;

(3) potential side effects of the drug substitution;

(4) the circumstances under which the currently prescribed drug will be covered;

(5) the extent to which health care costs related to the drug substitution will be compensated to the purchaser or covered person by the pharmacy benefits management company;

(6) notification that the covered person may decline the drug substitution if the currently prescribed drug remains on the covered person's formulary, and the covered person is willing to pay any difference in the copayment amount; and

(7) a toll-free telephone number to communicate with the pharmacy benefits management company.

e. A pharmacy benefits management company shall cancel and reverse the drug substitution upon written or verbal instructions from a health care practitioner or the covered person. No pharmacy benefits management company shall be required to cancel and reverse the drug substitution if the prescribed drug is no longer on the purchaser's formulary or the covered person is unwilling to pay a higher copayment or other cost associated with the prescribed drug.

f. A pharmacy benefits management company shall maintain a toll-free telephone number during normal business hours for a minimum of eight hours per day, Monday through Friday for health care practitioner and covered person inquiries.

g. No pharmacy benefits management company shall charge a covered person any additional copayments or fees if the health care practitioner and covered person agree to the drug subsitution.

11. All disclosures made pursuant to this act shall be made in accordance with section 2713 of the "Health Insurance Portability

and Accountability Act of 1996," Pub.L.104-191 (42 U.S.C. s.300gg-300gg-9).

12. a. The commissioner may deny, revoke or suspend, after notice and a hearing, a certificate issued pursuant to this act for a violation of the provisions of this act or the rules and regulations adopted pursuant thereto. The commissioner shall provide for an appropriate and timely right of appeal for the pharmacy benefits management company.

b. If, after notice and opportunity to be heard, the commissioner finds that a pharmacy benefits management company violates a provision of this act, the pharmacy benefits management company shall be liable for a civil penalty of not less than $250 and not more than $10,000 for each day that the pharmacy benefits management company is in violation of this act. The penalty shall be collected by the commissioner in the name of the State in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

13. The commissioner, in consultation with the New Jersey State Board of Pharmacy, shall adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), to effectuate the purposes of this act.

14. This act shall take effect on the 180th day after the date of enactment, but the commissioner may take such anticipatory action in advance as shall be necessary for the implementation of the act.

STATEMENT

This bill provides for the regulation of the activities of pharmacy benefits management companies, companies which manage prescription drug benefits for sponsors of health care plans in this State.

Under the bill, pharmacy benefits management companies, or PBM's, must be certified by the Department of Banking and Insurance. Certification is intended to ensure that PBM's in this State are capable of providing high-quality pharmaceutical benefits to covered persons. Accordingly, this bill defines the business activities that a certified PBM is authorized to conduct in this State.

The bill requires that certain disclosures be made to covered persons concerning their pharmacy benefits coverage. In addition, it requires PBM's to make certain disclosures to sponsors of health benefits plans who purchase pharmacy benefits management services or who are considering purchasing the management services. Among other pieces of information, the bill requires a PBM to disclose to a purchaser any revenues, rebates or discounts

related to the purchaser's contract that a PBM receives from a pharmaceutical manufacturer, labeler or other entity. Prior to disclosing any information, PBM's may obtain a written agreement from purchasers or prospective purchasers that the information disclosed to them will remain confidential. This provision is in response to the situation in which certain PBM's are obtaining discounts from pharamaceutical manufacturers but not passing those discounts on to the purchaser.

To protect patient safety, this bill requires a PBM to make certain disclosures to health care practitioners, covered persons, and purchasers if that PBM seeks authorization to substitute a drug prescribed by a health care practitioner to a covered person. It also defines the circumstances in which a prescribed drug may be substituted for another.

The Commissioner of Banking and Insurance is authorized to deny, suspend or revoke the certification of any PBM in the State. The commissioner is also authorized to assess a penalty of not less than $250 and not more than $10,000 for each day a PBM is in violation of any provision of this act.