ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 320

STATE OF NEW JERSEY

212th LEGISLATURE

ADOPTED MAY 18, 2006

Sponsored by:
Assemblyman NEIL M. COHEN
District 20 (Union)
Assemblywoman LINDA R. GREENSTEIN
District 14 (Mercer and Middlesex)
Assemblyman ROBERT M. GORDON
District 38 (Bergen)

Co-Sponsored by:
Assemblymen Hackett, Conners, Chivukula and Vas

SYNOPSIS

Regulates pharmacy benefits management companies; makes an appropriation.

CURRENT VERSION OF TEXT

Substitute as adopted by the Assembly Financial Institutions and Insurance Committee.

(Sponsorship Updated As Of: 6/23/2006)

AN ACT concerning pharmacy benefits management companies and supplementing Title 17B of the New Jersey Statutes and Title 52 of the Revised Statutes and making an appropriation.

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

1. The Legislature finds and declares that:

a. Pharmacy benefits management companies administer prescription drug benefit plans on behalf of their clients, who include health insurance companies, self-insured employers, unions, Medicaid and Medicare plans, the federal government, and local and state governments;

b. Pharmacy benefits management companies manage approximately 70 percent of the more than three billion prescriptions dispensed annually in the United States, with three large pharmacy benefits management companies dominating the market and collectively earning a net income of $2 billion in 2005;

c. Pharmacy benefits management companies initially functioned primarily as third party administrators, involved in the processing and payment of prescription drug claims on behalf of their clients; however, as pharmacy benefits management companies have diversified their services to include the development and management of formularies, the management of prescription drug utilization, acting as negotiating intermediaries between drug manufacturers and their clients who pay for the drugs, and the provision of mail-order pharmacy services, an increasing portion of their activities are not regulated under federal law or the laws of this State or other states;

d. Recent federal and state litigation filed by the federal government, state governments, private corporations, pharmacists, health insurers, unions, and individuals against pharmacy benefits management companies has brought to light several questionable business practices, the common theme of which suggests that some pharmacy benefits management companies are not acting to maximize the savings to their clients or taking into serious consideration the health needs of the people who are obtaining prescription drugs under their prescription drug plan.

e. Specifically, most litigation involves one or more claims that pharmacy benefits management companies have: (1) engaged in unfair, deceptive, or fraudulent activities in which revenue paid by drug manufacturers to pharmacy benefits management companies, based on their clients' prescription drug benefits plan or clients' purchasing volumes, are not disclosed or transferred to clients; (2) instituted drug substitution policies that are aimed at maximizing earnings by pharmacy benefits management companies, rather than creating savings for clients and providing the best medical outcome

for persons receiving the prescriptions; and (3) mandating the use of mail-order services which has led to numerous allegations and investigations of fraud and, at a minimum, presents a conflict of interest for the companies in managing prescription drug benefits in the best financial interests of the clients while earning profits as actual dispensers of prescription drugs;

f. Many of these cases have been settled and have resulted in multi-million dollar fines and injunctions, one of the most recent cases being a settlement between the federal government and one of the three large, national pharmacy benefits management companies, resulting in a $137.5 million penalty and a five-year injunction against certain business practices;

g. In response to the exposure of such activities, at least eight states have acted to fill the gaps in the laws concerning the business practices of pharmacy benefits management companies and to bring more transparency to the companies' business practices and financial relationships, and at least 16 states are considering instituting similar measures;

h. To ensure that pharmacy benefits management companies are acting in the best interests of their clients and the persons who receive the prescription drug coverage, to help control the costs of prescription drug coverage for state and local governments, employers, unions, and individuals, and to ensure that people covered under prescription drug plans have access to the medication they need, the Legislature has therefore determined that it is in the public interest to apply regulatory oversight to the activities of pharmacy benefits management companies providing services in this State.

2. 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, who is the sponsor of the health benefits plan, 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.

“Formulary” means a list of prescription drugs that: have been evaluated for their safety and efficacy using the appropriate medical and scientific evidence by physicians and dentists authorized to write prescriptions, pharmacists, and other health care professionals; and will be covered, at defined benefit levels, by the purchaser pursuant to an agreement with the pharmacy benefits management company.

"Health benefits plan" means a benefits plan which pays hospital or medical expense benefits for covered services and prescription drug 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 automobile insurance issued pursuant to P.L.1972, c.70 (C.39:6A-1 et seq.), or hospital confinement indemnity coverage.

"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.

“Non-purchaser remuneration” means any remuneration or revenue received, directly or indirectly, by a pharmacy benefits management company from a pharmaceutical manufacturer, labeler, or any entity other than a purchaser, in which the payment of remuneration or revenue is in connection with a purchaser’s prescription drug benefits or a purchaser’s drug utilization. “Non-purchaser remuneration” shall include, but is not limited to: rebates; discounts; incentives; fees for the sale or provision of drug utilization data; fees for administrative or managerial services provided to any entity other than a purchaser; payments received in return for changing the benefits level of a drug on a purchaser’s formulary; payments received based on volume drug purchases by the purchaser; and any other remuneration or revenue received by a pharmacy benefits management company in connection with a purchaser’s prescription drug benefits or drug utilization, regardless of how that remuneration or revenue is categorized.

"Pharmacy benefits management services" means the provision of any of the following services on behalf of a purchaser: the procurement of prescription drugs at a negotiated rate for

dispensation within this State; the processing of prescription drug claims; the administration of payments related to prescription drug claims; or any other service performed on behalf of a purchaser as provided under this act.

"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 purchaser.

“Prescriber” means a physician, dentist, or other health care professional who is authorized to write prescriptions and who is the treating physician, dentist, or other health care professional that wrote a prescription for a covered person.

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

“Prescription drug benefits” means the benefits provided for prescription drugs and pharmacy services for covered services under a health benefits plan contract.

"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.

3. 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.

b. 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.

4. a. Any 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 14 of this act. Nothing in this section shall operate to impair any contract which was entered into before the effective date of this act.

b. A pharmacy benefits management company shall submit an application for a certificate on a 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 that may be posed by department staff;

(3) the proposed plan of operation for the pharmacy benefits management company, including the manner in which pharmacy benefits management services will be provided;

(4) a copy of the most recent financial statement audited by an independent certified public accountant; and

(5) such other information as the commissioner may require to ensure that the pharmacy benefits management company can and will comply with the provisions of this act.

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.

c. 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 pharmacy benefits management services in compliance with the provisions of this act;

(2) the pharmacy benefits management company will provide a complaint resolution mechanism to provide reasonable procedures for the resolution of complaints by pharmacists, prescribers, and covered persons;

(3) the pharmacy benefits management company is financially sound and may reasonably be expected to meet its obligations to purchasers and covered persons;

(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, which meet 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, prescribers, and covered persons.

d. 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 the purchaser and covered persons.

e. A certificate issued pursuant to this section shall be valid for three years from the date of issuance by the commissioner, and shall be renewed thereafter, upon notification by the pharmacy benefits management company of any changes in the information supplied under the certificate application pursuant to subsection b. of this section.

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

g. The provisions of this section shall not apply to a pharmacy benefits management company that is an affiliate of a carrier and provides pharmacy benefits management services solely to that carrier.

5. a. A pharmacy benefits management company shall file an annual statement for the preceding calendar year with the commissioner and the New Jersey State Board of Pharmacy by March 1. The statement shall be verified by at least two principal officers of the pharmacy benefits management company.

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

(1) a financial statement of the company with an actual or prospective financial position at a particular time, or results of operations, cash flow, or changes in financial position for a period of time, in conformity with generally accepted accounting principles or another comprehensive basis of accounting;

(2) the number of covered persons provided pharmacy benefits management services under all purchasers' health benefits plans as of the beginning of the calendar year and as of the end of the year;

(3) any conflicts of interest disclosed to the purchaser pursuant to section 9 of this act, any direct or indirect financial interests held by the pharmacy benefits management company with any pharmacy, pharmaceutical manufacturer, or labeler during the

preceding calendar year, and any direct or indirect financial interests held by any pharmacy, mail-order pharmacy, pharmaceutical manufacturer, or labeler with the pharmacy benefits management company;

(4) a copy of the certified audit report;

(5) any financial examination of the pharmacy benefits management company that is conducted pursuant to the laws of another state and certified by the regulatory agency of that state;

(6) the number of complaints referred to and resolved under the company's complaint resolution mechanism that provides reasonable procedures for the resolution of complaints by pharmacists, prescribers, and covered persons; and

(7) other information relating to the operations of the pharmacy benefits management company as required by the commissioner. The commissioner may address any inquiries to the pharmacy benefits management company or its officers in relation to its condition or affairs, or any matter connected with its transactions, and the officers of the pharmacy benefits management company shall promptly reply in writing to all such inquiries.

b. The commissioner may extend the time prescribed for filing an annual statement or other reports required to be submitted with the annual statement for good cause shown by the pharmacy benefits management company; however, the commissioner shall not extend the time for filing annual statements beyond 60 days after March 1. Pursuant to section 14 of this act, the commissioner may suspend or revoke the certificate of any pharmacy benefits management company that fails to file its annual statement within the time prescribed by this section.

c. Any pharmacy benefits management company failing to make and file its annual statement in the form and within the time provided by this section shall be liable to a penalty of $100 for each day that failure continues, and, in addition thereto, pursuant section 14 of this act, the commissioner may revoke or suspend its certificate to do business in this State.

6. a. The commissioner or any of his examiners may conduct an examination of the assets and liabilities, method of conducting business and all other affairs of a pharmacy benefits management company as often as the commissioner in his sole discretion deems appropriate. In scheduling and determining the nature, scope and frequency of the examinations, the commissioner shall consider such matters as the results of financial statement analyses, changes in management or ownership, reports of independent certified public accountants, and other criteria as set forth by the commissioner through regulation.

b. When making an examination under this section, the commissioner may retain attorneys, appraisers, independent

certified public accountants, or other professionals and specialists as examiners, the cost of which shall be borne by the pharmacy benefits management company that is the subject of the examination.

c. The reasonable expenses of any examination conducted under this section shall be fixed and determined by the commissioner, and he shall collect them from the pharmacy benefits management company examined, which shall pay them on a presentation of an account of the expenses on such form as determined by the commissioner. If any company, after the examination, is adjudged insolvent by a court of competent jurisdiction, the expense of the examination, if unpaid, shall be ordered out of the assets of the pharmacy benefits management company.

7. Except for a pharmacy benefits management company that is an affiliate of a carrier and provides pharmacy benefits management services solely to that carrier, a pharmacy benefits management company shall be deemed to act in a fiduciary capacity on behalf of a purchaser and shall have all responsibility attendant to a fiduciary as established by law.

8. a. Pursuant to a written contract with a purchaser, a pharmacy benefits management company may engage in any activity disclosed in the proposed plan of operation required to be submitted with the application for certification and approved by the commissioner pursuant to section 4, any activity in accordance with regulations adopted by the commissioner, and any of the following activities:

(1) processing prescription drug claims and issuing payments to pharmacists for drugs dispensed to covered persons in accordance with the provisions of P.L.1999, c.154 (C.17B:30-23 et al.) and any other provision of the statutory law concerning the processing and payment of prescription drug claims as it applies to a pharmacy benefits management company as an agent of a carrier;

(2) providing mail-order pharmacy services for prescription drugs or any specialty prescription drugs to a covered person, provided that the covered person chooses to use the mail-order pharmacy service through an express written request submitted to the pharmacy benefits management company;

(3) developing a network of pharmacists to provide covered services to covered persons;

(4) developing an open incentive-based prescription drug formulary and providing pharmacy benefits management services using the formulary;

(5) soliciting for or receiving non-purchaser remuneration;

(6) developing and implementing disease management protocols to help contain prescription drug expenditures for chronic

conditions, including, but not limited to, asthma and diabetes, and to manage the care of covered persons with chronic conditions; and

(7) performing 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.).

b. A pharmacy benefits management company that receives any non-purchaser remuneration shall pass the remuneration to the purchaser in full, unless the purchaser has specifically agreed to terms written clearly and conspicuously in the contract that allow the pharmacy benefits management company to retain the remuneration in full or in part.

c. A pharmacy benefits management company that provides pharmacy benefits management services using a formulary agreed to by the purchaser shall make available to network pharmacists, prescribers, and covered persons, upon request, the most current version of the formulary.

d. A pharmacy benefits management company shall establish a complaint resolution mechanism to provide reasonable procedures for the resolution of complaints by pharmacists, prescribers, and covered persons.

9. a. A pharmacy benefits management company shall disclose to a purchaser upon execution of a contract for services, the following:

(1) any relationship between a pharmacy benefits management company and another entity that could be considered a conflict of interest for the pharmacy benefits management company in its requirement to act in a fiduciary capacity on behalf of the purchaser;

(2) any direct or indirect financial interests held by the pharmacy benefits management company with any pharmacy, mail-order pharmacy, pharmaceutical manufacturer, or labeler;

(3) any direct or indirect financial interests held by any pharmacy, mail-order pharmacy, pharmaceutical manufacturer, or labeler with the pharmacy benefits management company;

(4) the obligations of the pharmacy benefits management company and the purchaser, as set forth in the contract;

(5) a clear description of the products and services that will be delivered or performed pursuant to the contract;

(6) the costs to the purchaser for the products and services, including any administrative fees, that will be delivered or performed pursuant to the contract;

(7) the formulary developed by the pharmacy benefits management company and agreed to by the purchaser;

(8) if applicable, the availability of a voluntary mail-order service provided by the pharmacy benefits management company for prescription drugs or specialty prescription drugs, which shall be

available to a covered person who chooses to use the service through an express written request submitted to the pharmacy benefits management company;

(9) any arrangements with prescribers, medical associations, pharmacists, or other entities that are associated with the business practices of the pharmacy benefits management company to encourage formulary compliance or otherwise manage the prescription drug benefits on behalf of the purchaser;

(10) any circumstance in which the pharmacy benefits management company will request authorization from the purchaser to substitute a drug prescribed to a covered person with another drug, and a statement attesting that the pharmacy benefits management company will not represent to a covered person or the prescriber that the request for the drug substitution has been initiated by the purchaser; and

(11) the definition of the term "non-purchaser remuneration," which shall include, at a minimum, the definition of "non-purchaser remuneration" as provided in section 2 of this act, and a statement that the pharmacy benefits management company may solicit for or receive non-purchaser remuneration, and, as required by subsection b. of section 8 of this act, the pharmacy benefits management company is required by law to transfer to the purchaser any non-purchaser remuneration, unless the purchaser has specifically agreed to terms written clearly and conspicuously in the contract that allow the pharmacy benefits management company to retain the revenue in full or in part.

b. A pharmacy benefits management company shall disclose to a purchaser, on a quarterly basis:

(1) the aggregate drug utilization of and drug expenditures by the purchaser compiled to prevent the identification of any covered person or prescriber;

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

(3) the nature, type, and amount of non-purchaser renumeration that the pharmacy benefits management company received during the reporting period and the amount of the remuneration that will be transferred to the purchaser pursuant to the contract;

(4) the aggregate drug utilization of all purchasers under contract with the pharmacy benefits management company for that reporting period, compiled to prevent the identification of any covered person, prescriber, or purchaser; and

(5) any changes in the information required to be disclosed pursuant to subsection a. of this section.

c. A pharmacy benefits management company shall make the disclosures pursuant to this section 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 and may include, as parties to the agreement persons or entities with whom the purchaser contracts to provide consultation regarding pharmacy services.

d. Unless otherwise provided under the contract, this section shall not be construed to require a pharmacy benefits management company to disclose the purchase price or purchase discount of a particular prescription drug or an individual therapeutic class of drugs that was negotiated with a pharmaceutical manufacturer or labeler on behalf of the purchaser.

e. The provisions of this section shall not apply to a pharmacy benefits management company that is an affiliate of a carrier and provides pharmacy benefits management services solely to that carrier.

10. a. A pharmacy benefits management company shall disclose to a prospective purchaser prior to the execution of a contract for services, the following:

(1) any relationship between a pharmacy benefits management company and another entity that could be considered a conflict of interest for the pharmacy benefits management company in its requirement to act in a fiduciary capacity on behalf of a purchaser;

(2) any direct or indirect financial interests held by the pharmacy benefits management company with any pharmacy, mail-order pharmacy, pharmaceutical manufacturer, or labeler;

(3) any direct or indirect financial interests held by any pharmacy, mail-order pharmacy, pharmaceutical manufacturer, or labeler with the pharmacy benefits management company;

(4) a clear description of the products and services that would be available to the prospective purchaser, and the costs to the purchaser for such products and services, including any administrative fees;

(5) examples of formularies developed by the pharmacy benefits management company for purchasers;

(6) the aggregate drug utilization of all purchasers under contract with the pharmacy benefits management company for the previous calendar year, compiled to prevent the identification of any covered person, prescriber, or purchaser;

(7) the availability of a voluntary mail-order service provided by the pharmacy benefits management company for prescription drugs or specialty prescription drugs, which shall be available to a covered person who chooses to use the service through an express written request submitted to the pharmacy benefits management company;

(8) any arrangements with prescribers, medical associations, pharmacists, or other entities that are associated with the business practices of the pharmacy benefits management company to

encourage formulary compliance or otherwise manage the prescription drug benefits on behalf of a purchaser;

(9) any circumstance in which the pharmacy benefits management company will request authorization from the purchaser to substitute a drug prescribed to a covered person with another drug, and a statement attesting that the pharmacy benefits management company will not represent to a covered person or the prescriber that the request for the drug substitution has been initiated by the purchaser;

(10) the definition of the term "non-purchaser remuneration," which shall include, at a minimum, the definition of "non-purchaser remuneration" as provided in section 2 of this act, and a statement that the pharmacy benefits management company may solicit for or receive non-purchaser remuneration, and, as required by subsection b. of section 8 of this act, the pharmacy benefits management company must transfer to the purchaser any non-purchaser remuneration, unless the purchaser has specifically agreed to terms written clearly and conspicuously in the contract that allow the pharmacy benefits management company to retain the revenue in full or in part; and

(11) the pharmacy benefits management company is required under this act to disclose to a purchaser on a quarterly basis the following information:

(a) the aggregate drug utilization of and drug expenditures by the purchaser compiled to prevent the identification of any covered person or prescriber;

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

(c) the nature, type, and amount of non-purchaser remuneration that the pharmacy benefits management company received during the reporting period and the amount of the remuneration that will be transferred to the purchaser pursuant to the contract; and

(d) the aggregate drug utilization of all purchasers under contract with the pharmacy benefits management company for that reporting period, compiled to prevent the identification of any covered person, prescriber, or purchaser.

b. A pharmacy benefits management company shall make the disclosures pursuant to this section 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 and may include as parties to the agreement persons or entities with whom the prospective purchaser contracts to provide consultation regarding pharmacy services.

c. This section shall not be construed to require a pharmacy benefits management company to disclose the purchase price or purchase discount of a particular prescription drug or an individual

therapeutic class of drugs that was negotiated with a pharmaceutical manufacturer or labeler on behalf of any purchaser.

11. A pharmacy benefits management company shall include in the certificate of coverage prepared for and delivered to covered persons by the carrier on or about the date of commencement of coverage under the health benefits plan a statement which:

a. Explains restrictions on prescription drug benefits under the health benefits plan;

b. Lists the network pharmacies included in a network with which the pharmacy benefits management company contracts;

c. Explains that mail-order pharmacy services are available for prescription drugs or specialty prescription drugs, and that the covered person must submit an express written request to the pharmacy benefits management company if he chooses to use the mail-order service;

d. Explains the circumstances and procedure by which the pharmacy benefits management company may initiate a request to substitute a drug prescribed to a covered person with another drug and the covered person's rights concerning drug substitutions. The pharmacy benefits management company shall not represent to the covered person that substitution requests are initiated by either the prescriber or the purchaser. At a minimum, this disclosure shall include: the circumstances in which the drug substitution may only be made with prior approval from the covered person's prescriber; the circumstances in which the covered person may refuse the drug substitution and how the covered person may make that refusal notification; that the covered person shall not be required to pay a higher copayment or other out-of-pocket expenses, unless the covered person refuses the drug substitution, and health care expenses that are incurred as a direct result of the drug substitution will be reimbursed to the covered person up to $200; and the information allowing the covered person to contact the pharmacy benefits management company to learn his rights, refuse a drug substitution, or request reimbursement for out-of-pocket expenses resulting from the substitution; and

e. Includes other information as the commissioner may require.

12. a. A pharmacy benefits management company shall initiate a substitution for a prescribed drug for another drug only in accordance with the provisions of this section. The provisions of this section shall not apply when a pharmacy benefits management company initiates a drug substitution under the following circumstances:

(1) the drug substitution has been initiated for patient safety reasons;

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

(3) the prescribed drug is being substituted with a generic drug or chemical equivalent, in accordance with the provisions of a purchaser's contract or in compliance with State law, unless the prescriber objects to the drug substitution based on medically necessary reasons and the covered person is willing to pay any increase in co-payments or other out-of-pocket expenses for the originally prescribed drug.

b. A pharmacy benefits management company may initiate a substitution for a prescribed drug that is on the formulary with another drug that is on the formulary in accordance with the provisions of this subsection.

(1) A pharmacy benefits management company shall not initiate a drug substitution of a prescribed drug that is on the formulary with another prescribed drug that is on the formulary if:

(a) the drug substitution will result in the purchaser paying higher costs for the prescription drug benefit or paying any additional health care costs, on behalf of the covered person, that are incurred because health care services are performed in accordance with a treating health care provider's instructions as a direct result of the substitution of a prescribed drug with another drug, unless the pharmacy benefits management company agrees to reimburse the purchaser for those costs or the purchaser explicitly agrees at the time the request is submitted or in the contract for pharmacy benefits management services to pay for the higher costs;

(b) the prescriber refuses to authorize the drug substitution;

(c) the drug substitution will result in higher co-payments or any other out-of-pocket costs or any health care expenses that are incurred by the covered person because health care services are performed in accordance with a treating health care provider's instructions as a direct result of the substitution of a prescribed drug with another drug, unless the pharmacy benefits management company agrees to reimburse the covered person up to $200 for those expenses;

(d) the covered person refuses to accept the substitute drug and is willing to pay any increase in costs of co-payments or any other out-of-pocket expenses;

(e) the prescribed drug is a generic drug and the pharmacy benefits management company seeks authorization to substitute it for a brand name drug before it seeks authorization to substitute the prescribed generic drug with another generic drug, if available; or

(f) the pharmacy benefits management company seeks authorization to initiate a substitution for a particular prescription drug prescribed to a particular covered person, if in the preceding two years, the pharmacy benefits management company sought the identical authorization for the same substitution concerning the same covered person and the authorization was refused by the prescriber, even if the prescribers are different individuals.

(2) If a drug substitution is not prohibited pursuant to paragraph (1) of this subsection, unless otherwise provided for in a contract for pharmacy benefits management services, a pharmacy benefits management company shall obtain authorization from the purchaser to initiate a substitution for a prescribed drug that is on the formulary with another drug on the formulary. A pharmacy benefits management company shall disclose to the purchaser at the time of initiation of the substitution the following:

(a) the cost savings as a result of the substitution;

(b) any additional costs that will be incurred by the purchaser as a result of the substitution and the mechanism by which the pharmacy benefits management company will reimburse the purchaser for those costs, or, if applicable, a reiteration of the contract provision stating that the purchaser agreed to pay for any increase in costs arising out of a drug substitution;

(c) any non-purchaser remuneration the pharmacy benefits management company has received or will receive as a result of the substitution and how much, pursuant to the contract, the purchaser will receive; and

(d) the date on which the pharmacy benefits management company received approval from the prescriber to initiate the drug substitution.

(3) If a drug substitution is not prohibited pursuant to paragraph (1) of this subsection, a pharmacy benefits management company shall obtain authorization from the prescriber to initiate a substitution for a prescribed drug that is on the formulary with another drug on the formulary. A pharmacy benefits management company shall disclose to the prescriber the following:

(a) the basis for the substitution request;

(b) any circumstances in which the originally prescribed drug would be covered;

(c) any possible side effects of the drug substitution or of the substitute drug; and

(d) a toll-free telephone number dedicated solely for the purpose of allowing the prescriber to communicate with the pharmacy benefits management company and a pharmacist or a member of the body that developed the formulary to discuss the request.

A pharmacy benefits management company shall record the name and title of the prescriber or the prescriber's representative who authorized or refused to authorize the substitution request.

(4) A pharmacy benefits management company shall cancel the drug substitution request if the covered person refuses the drug substitution and agrees to pay any increase in co-payments or other out-of-pocket costs for the originally prescribed drug.

A pharmacy benefits management company shall disclose to a covered person his rights concerning a drug substitution request in the certificate of coverage delivered to covered persons pursuant to

section 11 of this act. In addition, a pharmacy benefits management company shall make available a toll-free telephone number by which a covered person may obtain information as to his rights concerning the drug substitution and may refuse to accept the substitute drug if he agrees to pay for any higher copayments or other out-of-pocket costs for the originally prescribed drug.

If a covered person contacts the pharmacy benefits management company concerning a drug substitution, the pharmacy benefits management company shall explain to the covered person: his rights concerning the drug substitution; the circumstances in which the originally prescribed drug would be covered; the name of the substituted drug and any side effects that the substitution or the substituted drug may have; and how the covered person may receive reimbursement up to $200 for any health care expenses he incurs as a direct result of the substitution of a prescribed drug with another drug. The pharmacy benefits management company shall not represent to the covered person that the substitution request was initiated by either the prescriber or the purchaser.

A pharmacy benefits management company shall make available to a covered person a reimbursement form by which a covered person may seek reimbursement for any health care expenses that are a direct result of the drug substitution.

c. A pharmacy benefits management company required to maintain a toll-free telephone number pursuant to this section shall make staff available to answer inquiries made through that number during normal business hours for a minimum of eight hours per day, Monday through Friday.

13. a. A pharmacy benefits management company shall not sell or exchange for revenue or remuneration of any kind prescription drug utilization information that directly or indirectly identifies any covered person, unless the sale or exchange is expressly permitted under the "Health Insurance Portability and Accountability Act of 1996," Pub.L.104-191 and meets any requirements set forth under this act.

b. 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-13).

14. a. The commissioner may deny, revoke or suspend, after notice and a hearing, a certificate issued to a pharmacy benefits management company 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 has violated 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.) and shall be appropriated to the department to effectuate the purposes of this act.

15. 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.

16. There shall be appropriated annually from the General Fund to the Department of Banking and Insurance such sums as are deemed necessary to effectuate the purposes of this act.

17. a. The State Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of this act that provides hospital or medical expense benefits and prescription drug and pharmacy services benefits, in which the prescription drug and pharmacy services benefits are administered by a pharmacy benefits management company pursuant to a contract with a carrier, shall contain a provision requiring the carrier to disclose any non-purchaser remuneration it received from the pharmacy benefits management company that is attributable to prescription drug benefits, pharmacy services benefits, and prescription drug utilization of covered persons under the contract.

The carrier shall be required to disclose the amount of the non-purchaser remuneration it received up to the time of the disclosure within the contract year. The carrier shall disclose the information required pursuant to this section to the commission 90 days prior to the expiration date of the contract.

b. As used in this section:

“Non-purchaser remuneration” means any remuneration or revenue received, directly or indirectly, by a pharmacy benefits management company from a pharmaceutical manufacturer, labeler, or any entity other than a purchaser, in which the payment of remuneration or revenue is in connection with a purchaser’s prescription drug benefits or a purchaser’s drug utilization. “Non-purchaser remuneration” shall include, but is not limited to: rebates; discounts; incentives; fees for the sale or provision of drug utilization data; fees for administrative or managerial services

provided to any entity other than a purchaser; payments received in return for changing the benefits level of a drug on a purchaser's formulary; payments received based on volume drug purchases by the purchaser; and any other remuneration or revenue received by a pharmacy benefits management company in connection with a purchaser's prescription drug benefits or drug utilization, regardless of how that remuneration or revenue is categorized.

"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 purchaser and is regulated pursuant to P.L. , c. (C.) (pending before the Legislature as this bill).

18. The provisions of this act shall be deemed to be severable and if any phrase, clause, sentence or provision of this act is declared to be unconstitutional or the applicability thereof to any person is held invalid the remainder of this act shall not thereby be deemed to be unconstitutional or invalid.

19. This act shall take effect immediately.