SENATE, No. 2221

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED MARCH 7, 2022

Sponsored by: Senator VIN GOPAL District 11 (Monmouth)

SYNOPSIS

Establishes new transparency standards for business practices of pharmacy benefits managers and establishes new licensure requirements.

CURRENT VERSION OF TEXT

As introduced.



1	AN ACT concerning pharmacy benefits managers and licensing and
2	amending and supplementing P.L.2015, c.179.

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

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- 1. Section 1 of P.L.2015, c.179 (C.17B:27F-1) is amended to read as follows:
 - 1. As used in [this act] P.L.2015, c.179 (C.17B:27F-1 et seq.):

"Anticipated loss ratio" means the ratio of the present value of
the future benefits payments, including claim offsets after the point
of sale, to the present value of the future premiums of a policy form
over the entire period for which rates are computed to provide
health insurance coverage.

"Average wholesale price" means the average wholesale price of a prescription drug determined by a national drug pricing publisher selected by a carrier. The average wholesale price shall be identified using the national drug code published by the National Drug Code Directory within the United States Food and Drug Administration.

"Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

"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.

"Compensation" means any direct or indirect financial benefit, including, but not limited to, rebates, discounts, credits, fees, grants, chargebacks or other payments or benefits of any kind.

"Contracted pharmacy" means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

- a. the pharmacy benefits manager directly;
- b. a pharmacy services administration organization; or
- c. a pharmacy group purchasing organization.

"Cost-sharing amount" means the amount paid by a covered person as required under the covered person's health benefits plan for a prescription drug at the point of sale.

"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.

"Health benefits plan" means a benefits plan which pays hospital or medical expense benefits for covered services, or 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.

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

- 1 For the purposes of P.L.2015, c.179 (C.17B:27F-1), health benefits
- 2 plan shall not include the following plans, policies or contracts:
- 3 accident only, credit disability, long-term care, Medicare
- 4 supplement coverage; TRICARE supplement coverage, coverage
- 5 for Medicare services pursuant to a contract with the United States
- 6 government, the State Medicaid program established pursuant to
- 7 P.L.1968, c.413 (C.30:4D-1 et seq.), coverage arising out of a
- 8 worker's compensation or similar law, the State Health Benefits
- 9 Program, the School Employees' Health Benefits Program, or a self-
- 10 insured health benefits plan governed by the provisions of the
- 11 federal "Employee Retirement Income Security Act of 1974,"
- 12 29 U.S.C. s.1001 et seq., coverage under a policy of private
- passenger automobile insurance issued pursuant to P.L.1972, c.70
- 14 (C.39:6A-1 et seq.), or hospital confinement indemnity coverage.

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- "Mail order pharmacy" means a pharmacy, the principle business of which is to receive a prescription by mail, fax or electronic submission, and to dispense medication to a covered person using the United States Postal Service or other common or contract carrier service and that provides consultation with patients electronically rather than in person.
- "Maximum allowable cost" means the maximum amount a health insurer will pay for a generic drug or brand-name drug that has at least one generic alternative available.
- "Network pharmacy" means a licensed retail pharmacy or other pharmacy provider that contracts with a pharmacy benefits manager.
- "Pharmacy" means any place in the State, either physical or electronic, where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.
- "Pharmacy benefits manager" means a corporation, business, or other entity, or unit within a corporation, business, or other entity, that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan or other third-party payer, either directly or through an intermediary, administers prescription drug benefits on behalf of a purchaser.
- "Pharmacy benefits manager compensation" means the difference between: (1) the value of payments made by a carrier of a health benefits plan to its pharmacy benefits manager; and (2) the value of payments made by the pharmacy benefits manager to dispensing pharmacists for the provision of prescription drugs or pharmacy services with regard to pharmacy benefits covered by the health benefits plan.
- "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

1 claims; or the administration of payments related to prescription 2 drug claims.

"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.

"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 to covered persons.

(cf: P.L.2019, c.274, s.2)

- 2. (New section) a. A corporation, business, or other entity shall not act as a pharmacy benefits manager in this State without first obtaining a license from the department. An applicant for licensure as a pharmacy benefits manager shall provide to the department information that includes, but is not limited to, the following:
 - (1) the name of the applicant;
 - (2) the address and telephone number of the applicant;
- (3) the name and address of the applicant's agent for service of process in the State;
 - (4) the name and address of each person beneficially interested in the applicant; and
 - (5) the name and address of each person with management or control over the applicant.
 - b. A license issued pursuant to this section shall be valid for a period of two years and may be renewed at the end of the two-year period. The commissioner shall establish fees for a license issued or renewed pursuant to this section.
 - c. The department may issue a pharmacy benefits manager license to an applicant only if the department is satisfied that the applicant possesses the necessary organization, expertise, and financial integrity to supply the services sought to be offered.
 - d. The department may issue a pharmacy benefits manager license subject to restrictions or limitations, including the type of services that may be supplied or the activities in which the pharmacy benefits manager may engage.
- e. A license issued pursuant to this section shall not be transferable.
- f. (1) An applicant shall report any change to the information provided within the application for a pharmacy benefits manager license pursuant to subsection a. of this section to the department within 30 days of the change occurring.
- 46 (2) Failure to report a change pursuant to paragraph (1) of this 47 subsection shall result in a civil penalty of \$50, to be recovered with 48 costs by the department in a civil action by a summary proceeding

- pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).
- g. The department may suspend, revoke or place on probation a pharmacy benefits manager license if:
 - (1) the pharmacy benefits manager has engaged in fraudulent activity that constitutes a violation of State or federal law;
 - (2) the department has received consumer complaints that justify an action under this subsection to protect the safety and interests of consumers;
 - (3) the pharmacy benefits manager fails to pay the original issuance or renewal fee for the license; or
- 12 (4) the pharmacy benefits manager fails to comply with any 13 requirement set forth in P.L. , c. (C.) (pending before the 14 Legislature as this bill).
 - h. If a corporation, business, or other entity acts as a pharmacy benefits manager without obtaining a license pursuant to this section, the corporation, business, or other entity shall be subject to:
 - (1) a warning notice;

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- (2) an opportunity to cure the violation within 14 days following the issuance of the notice;
- 21 (3) a hearing before the commissioner within 70 days following 22 the issuance of the notice; and
 - (4) if the violation has not been cured pursuant to subsection a. of this section, a penalty of not less than \$5,000 or more than \$10,000.
- i. Notwithstanding the provisions of subsection a. of this section, a pharmacy benefits manager certified or licensed as an organized delivery system prior to the effective date of P.L., c. (C.) (pending before the Legislature as this bill), in accordance with P.L.1999, c.409 (C.17:48H-1 et seq.), may
- 31 continue to operate during the pendency of its application submitted
- pursuant to this section, but no more than 18 months after the effective date of this act.
- 34 j. All documents, materials, or other information, and copies
- thereof, in the possession or control of the department in the course of an application or investigation made pursuant to
- 37 P.L., c. (C.) (pending before the Legislature as this bill)
- 38 shall be confidential and privileged, and shall not be subject to
- 39 P.L.1963, c.73 (C.47:1A-1 et seq.), commonly known as the open
- 40 public records act, or be subject to subpoena or discovery. This
- 41 subsection shall only apply to disclosure of confidential documents
- by the department and shall not create any privilege in favor of any
- 43 other party.
- 44 k. Fees collected pursuant to this section shall be remitted to
- 45 the department. Civil penalties recovered pursuant to subsection f.
- of P.L., c. (C.) (pending before the Legislature as this bill)
- shall be deposited into the General Fund.

3. (New section) a. A carrier shall:

- (1) monitor all activities carried out on behalf of the carrier by a pharmacy benefits manager if the carrier contracts with a pharmacy benefits manager and is related to a carrier's prescription drug benefits; and
 - (2) ensure that all requirements of this section are met.
 - b. A carrier that contracts with a pharmacy benefits manager to perform any activities related to the carrier's prescription drug benefits shall ensure that, under the contract, the pharmacy benefits manager acts as the carrier's agent and owes a fiduciary duty to the carrier in the pharmacy benefits manager's activities related to the carrier's prescription drug benefits.
 - c. A carrier shall not enter into a contract or agreement, or allow a pharmacy benefits manager or any entity acting on the carrier's behalf to enter into a contract or agreement, that prohibits a pharmacy from:
 - (1) providing a covered person with the option of paying the pharmacy provider's cash price for the purchase of a prescription drug and not filing a claim with the covered person's carrier if the cash price is less than the covered person's cost-sharing amount; or
 - (2) providing information to a State or federal agency, law enforcement agency, or the department when such information is required by law.
 - d. A carrier or pharmacy benefits manager shall not require a covered person to make a payment at the point of sale for a covered prescription drug in an amount greater than:
 - (1) the applicable cost-sharing amount for the prescription drug; or
 - (2) the total amount the pharmacy will be reimbursed for the prescription drug from the pharmacy benefits manager or carrier, including the cost-sharing amount paid by a covered person, whichever is less.
 - e. A carrier shall provide a reasonably adequate retail pharmacy network for the provision of prescription drugs for its covered persons. A mail order pharmacy shall not be included in determining the adequacy of a retail pharmacy network.
 - 4. Section 2 of P.L.2015, c.179 (C.17B:27F-2) is amended to read as follows:
 - 2. Upon execution or renewal of each contract, or at such a time when there is any material change in the term of the contract, a pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a pharmacy services administrative organization, or between a pharmacy benefits manager and a contracted pharmacy:
- a. (1) include in the contract the sources utilized to determine multiple source generic drug pricing, brand drug pricing, and the wholesaler in the State of New Jersey where pharmacies may

acquire the product, including, but not limited to, the brand effective rate, generic effective rate, dispensing fee effective rate, maximum allowable cost or any other pricing formula for pharmacy reimbursement;

- (2) update that pricing information every seven calendar days; and
- (3) establish a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable cost pricing lists, brand effective rate, generic effective rate, and dispensing fee effective rate, or any other pricing formulas for pharmacy reimbursement [; and].
 - b. Additionally, a pharmacy benefits manager shall:
- (1) [Maintain] maintain a procedure to eliminate drugs from the list of drugs subject to multiple source generic drug pricing and brand drug pricing, or modify maximum allowable cost rates, brand effective rate, generic effective rate, dispensing fee effective rate or any other applicable pricing formula in a timely fashion and make that procedure easily accessible to the pharmacy services administrative organizations or the pharmacies that they are contractually obligated with to provide that information according to the requirements of this section; and
- (2) provide a reasonable administrative appeal procedure, including a right to appeal in accordance with section 4 of P.L.2015, c.179 (C.17B:27F-4), to allow pharmacies with which the carrier or pharmacy benefits manager has a contract to challenge maximum allowable costs for a specified drug.
- 27 (cf: P.L.2019, c.274, s.3)

- 29 5. Section 3 of P.L.2015, c.179 (C.17B:27F-3) is amended to 30 read as follows:
 - 3. a. In order to place a particular prescription drug on a multiple source generic list, the pharmacy benefits manager shall, at a minimum, ensure that: A carrier, or a pharmacy benefits manager under contract with a carrier, shall use a single maximum allowable cost list to establish the maximum amount to be paid by a health benefits plan to a pharmacy provider for a generic drug or a brandname drug that has at least one generic equivalent available. A carrier, or a pharmacy benefits manager under contract with a carrier, shall use the same maximum allowable cost list for each pharmacy provider.
 - b. A maximum allowable cost may be set for a prescription drug, or a prescription drug may be allowed to continue on a maximum allowable cost list, only if:
- 44 (1) The drug is listed as therapeutically and pharmaceutically
 45 equivalent or "A," "B," "NR," or "NA" rated in the Food and Drug
 46 Administration's most recent version of the Approved Drug
 47 Products with Therapeutic Equivalence Evaluations, commonly
 48 known as the "Orange Book;" and

- (2) The drug is available for purchase without limitations by all pharmacies in the State from national or regional wholesalers and is not obsolete or temporarily unavailable.
- **[**b.**]** <u>c.</u> A pharmacy benefits manager shall not penalize a pharmacist or pharmacy on audit if the pharmacist or pharmacy performs a generic substitution pursuant to the "Prescription Drug Price and Quality Stabilization Act," P.L.1977, c.240 (C.24:6E-1 et seq.).
- 9 d. A carrier, or a pharmacy benefits manager under contract 10 with a carrier, shall use the average wholesale price to establish the 11 maximum payment for a brand-name drug for which a generic 12 equivalent is not available or a prescription drug not included on a 13 maximum allowable cost list. In order to use the average wholesale 14 price of a brand-name drug or prescription drug not included on a 15 maximum allowable cost list, a carrier, or a pharmacy benefits 16 manager under contract with a carrier, shall use only one national 17 drug pricing source during a calendar year, unless the original drug 18 pricing source is no longer available. A carrier, or a pharmacy 19 benefits manager under contract with a carrier, shall use the same 20 national drug pricing source for each pharmacy provider and 21 identify on its publicly accessible website the name of the national 22 drug pricing source used to determine the average wholesale price 23 of a prescription drug not included on the maximum allowable cost 24 list.
 - e. The amount paid by a carrier or a carrier's pharmacy benefits manager to a pharmacy provider under contract with the carrier or the carrier's pharmacy benefits manager for dispensing a prescription drug shall be the ingredient cost plus the dispensing fee less any cost-sharing amount paid by a covered person.

The ingredient cost shall not exceed the maximum allowable cost or average wholesale price, as applicable, and shall be disclosed by a carrier's pharmacy benefits manager to the carrier.

Only the pharmacy provider that dispensed the prescription drug shall retain the payment described in this subsection.

(cf: P.L.2015, c. 179, s.3)

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- 6. (New section) a. Compensation remitted by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, to a carrier or to a pharmacy benefits manager under contract with a carrier related to prescription drug benefits shall be:
- (1) remitted directly to the covered person at the point of sale to reduce the out-of-pocket cost to the covered person associated with a particular prescription drug; or
- (2) remitted to, and retained by, the carrier. Compensation remitted to the carrier shall be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons.

b. Beginning on March 1 next following the effective date of P.L., c. (C.) (pending before the Legislature as this bill), and annually thereafter, a carrier shall file with the department a report explaining how the carrier has complied with the provisions of this section. The report shall be written in a manner and form determined by the department.

- 7. (New section) a. A carrier, or a pharmacy benefits manager under contract with a carrier, shall establish a pharmacy and therapeutics committee responsible for managing the formulary system.
- b. A carrier, or a pharmacy benefits manager under contract with a carrier, shall not allow a person with a conflict of interest to be a member of its pharmacy and therapeutics committee. A person shall not serve as a member of a pharmacy and therapeutics committee if the person:
- (1) is employed, or was employed within the preceding year, by a pharmaceutical manufacturer, developer, labeler, wholesaler, or distributor; or
- (2) receives compensation, or received compensation within the preceding year, from a pharmaceutical manufacturer, developer, labeler, wholesaler, or distributor.

- 8. (New section) a. A carrier shall maintain and have the ability to access all data related to the administration and provision of prescription drug benefits administered by a pharmacy benefits manager under the health benefits plan of the carrier, including, but not limited to:
- (1) the names, addresses, member identification numbers, protected health information and other personal information of covered persons; and
- (2) any contracts, documentation, and records, including transaction and pricing data and post point-of-sale information, related to the dispensing of prescription drugs to covered persons under the health benefits plan.
- b. A sale or transaction involving the transfer of any records, information or data described in subsection a. of this section shall comply with the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, and the federal Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, and any regulations adopted pursuant to those laws.
- c. A carrier may audit all transaction records related to the dispensing of prescription drugs to covered persons under a health benefits plan. A carrier may conduct audits at a location of its choosing and with an auditor of its choosing.
- d. A carrier shall maintain all records, information and data described in subsection a. of this section and all audit records

described in subsection c. of this section for a period of no less than five years.

e. Upon request, a carrier shall provide to the department any records, contracts, documents or data held by the carrier or the carrier's pharmacy benefits manager for inspection, examination or audit purposes.

- 9. (New section) a. If a carrier uses a pharmacy benefits manager to administer or manage the prescription drug benefits of covered persons, any pharmacy benefits manager compensation, for purposes of calculating a carrier's anticipated loss ratio or any loss ratio calculated as part of any applicable medical loss ratio filing or rate filing, shall:
- (1) constitute an administrative cost incurred by the carrier in connection with a health benefits plan; and
- (2) not constitute a benefit provided under a health benefits plan. A carrier shall claim only the amounts paid by the pharmacy benefits manager to a pharmacy or pharmacist as an incurred claim.
- b. Any rate filing submitted by a carrier with respect to a health benefits plan that provides coverage for prescription drugs or pharmacy services, that is administered or managed by a pharmacy benefits manager, shall include:
- (1) a memorandum prepared by a qualified actuary describing the calculation of the pharmacy benefits manager compensation; and
- (2) any records and supporting information as the department reasonably determines is necessary to confirm the calculation of the pharmacy benefits manager compensation.
- c. Upon request, a carrier shall provide any records to the department that relate to the calculation of the pharmacy benefits manager compensation.
- d. A pharmacy benefits manager shall provide any necessary documentation requested by a carrier that relates to pharmacy benefits manager compensation in order to comply with the requirements of this section.

 10. This act shall take effect on the first day of the seventh month next following the date of enactment, but the Commissioner of the Banking and Insurance may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of the act.

STATEMENT

This bill sets new transparency standards for the business practices of pharmacy benefits managers (PBM) and establishes new licensure requirements. The bill requires that PBMs apply for

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1 a license with the Department of Banking and Insurance every two 2 years and requires carriers to ensure that a PBM under contract with 3 the carrier owes a fiduciary duty to the carrier. PBMs applying for 4 a license with the department must notify the department of any 5 changes made to the application within 30 days of the change occurring, with a civil penalty of \$50 if the applicant fails to 6 7 comply. Any documents, material or information provided to the 8 department in relation to an application for a PBM license will be 9 confidential and privileged, and will not be subject to the Open 10 Public Records Act, a subpoena, or discovery. Carriers are to 11 maintain detailed records of transactions and submit annual 12 documentation showing that any compensation remitted by a manufacturer, developer, or labeler to a carrier or PBM was either 13 14 remitted directly to the covered person at the point of sale to reduce 15 out of pocket expenses or used to offset premium costs for future 16 plan years. Additionally, the bill mandates that carriers and PBMs 17 establish pharmacy and therapeutics committees that are free from 18 conflicts of interest and use one or more formularies. 19 purposes of calculating a carrier's anticipated loss ratio, PBM 20 compensation constitutes an administrative cost rather than a 21 benefit.