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BULLETIN NO. 24-18

TO: **PHARMACY BENEFITS MANAGERS, PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS, HOSPITAL, MEDICAL AND HEALTH SERVICE CORPORATIONS, CERTIFIED AND LICENSED ORGANIZED DELIVERY SYSTEMS, AND INSURANCE COMPANIES AND HEALTH MAINTENANCE ORGANIZATIONS AUTHORIZED TO ISSUE HEALTH BENEFIT PLANS IN NEW JERSEY**

FROM: **JUSTIN ZIMMERMAN, COMMISSIONER**

RE: **CARRIER, PHARMACY BENEFITS MANAGER, AND PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION COMPLIANCE WITH P.L. 2023, c. 107, PHARMACY BENEFITS MANAGERS**

The purpose of this bulletin is to remind and provide guidance to carriers[1], pharmacy benefits managers[2] ("PBMs"), and pharmacy services administrative organizations[3] ("PSAOs") concerning requirements under P.L. 2023, c. 107 ("Act"). On July 10, 2023, Governor Murphy signed the Act which revised N.J.S.A. 17B:27F-1 to -10[4] to establish greater oversight of PBMs. The Act will be effective January 1, 2025. The Department of Banking and Insurance ("Department") is in the

[1] 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. N.J.S.A. 17B:27F-1.

[2] 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. N.J.S.A. 17B:27F-1.

[3] Pharmacy services administrative organization means an entity operating within the State that contracts with independent pharmacies to conduct business on their behalf with third-party payers. N.J.S.A. 17B:27F-1.

[4] Citations to the statute refer to the versions which take effect January 1, 2025, and not to the versions that are in effect until December 31, 2024.

process of promulgating regulations to effectuate the purposes of the Act. Prior to the promulgation of regulations, carriers, PBMs, and PSAOs must still comply with the Act.

Licensure of PBMs

Under N.J.S.A. 17B:27F-1.1, PBMs must be licensed to operate in New Jersey. Attached as Appendix A is a license application for PBMs that may also be found on the Department's website at: https://www.nj.gov/dobi/division_insurance/pharmacybenefitsmanagers/index.htm. This is a separate and distinct process from the required registration with the New Jersey Department of Law and Public Safety, Division of Consumer Affairs pursuant to P.L. 2023, c. 106 and N.J.A.C. 13:45K-1.1. Under N.J.S.A. 17B:27F-1.1h.(1), PBMs that completed a Notification of Organized Delivery System Anticipated Application pursuant to the Department's Bulletin 18-11 may continue to operate during the pendency of its application for licensure pursuant to this bulletin, but not later than December 31, 2026. These PBMs are encouraged to submit the required license application as soon as possible to ensure licensure before the expiration of the 24 months.

As of January 1, 2025, Certificates of compliance required by N.J.A.C. 11:4-62.5 are no longer required to be submitted to the Department.

The following standards will apply to the Department's review of applications for a PBM license:

- All necessary application information and documents have been filed;
- The persons responsible for conducting the applicant's affairs are competent, trustworthy and possess good reputations, and have appropriate experience, training and education;
- The applicant has demonstrated the ability to assure that its services will be performed in a manner which will ensure the efficient operation of its business, including appropriate financial controls;
- The standard contract forms to be used by the applicant are acceptable;
- The applicant has adequate financial arrangements with the carriers for which it will perform its services and adequate arrangements for complying with the Accounting Practices and Procedures Manual adopted by the National Association of Insurance Commissioners, and all applicable provisions of law;
- The compensation arrangements between the applicant and carriers clearly state whether the applicant assumes financial risk from the carriers and that the carriers will not admit receivables from the applicants, except to the extent allowed by the Accounting Practices and Procedures Manual adopted by the National Association of Insurance Commissioners, and all applicable provisions of law;
- The name used by the applicant to do business in this State does not so closely resemble the name of an insurer authorized to do business in this State or otherwise include such descriptive language as to be likely to mislead the public with respect to the nature of its business operations; and
- The applicant meets all requirements of N.J.S.A. 17B:27F-1 et seq. and demonstrates the ability to continue to meet all those requirements.

If the application for licensure is denied, the Department will notify the applicant in writing. The applicant may request a hearing by notice to the Commissioner no later than the 30th day following receipt of the notice of denial.

The following documents will be considered to be confidential: pending applications for a license; social security numbers and residential addresses provided in biographical affidavits submitted for consideration; the applicant's business plan and contracts; compensation formulas and fee schedules; and the applicant's audited financial statements.

Completed PBM license applications shall be sent to: pharmacyfilings@dobi.nj.gov

Questions regarding PBM licensing may also be addressed to: pharmacyfilings@dobi.nj.gov

Registration of PSAOs

Under N.J.S.A. 17B:27F-1.1, PSAOs must be registered to operate in New Jersey. Attached as Appendix B is a registration application for PSAOs that may also be found on the Department's website at: https://www.nj.gov/dobi/division_insurance/pharmacybenefitsmanagers/index.htm. This is a separate and distinct process from the required registration with the New Jersey Department of Law and Public Safety, Division of Consumer Affairs pursuant to P.L. 2023, c. 106 and N.J.A.C. 13:45K-1.1.

All PSAO registrations completed and submitted by March 31, 2025 will be reviewed by the Department and issued with an effective date of January 1, 2025, if complete. PSAO registration completed and submitted after March 31, 2025 will be effective on the date deemed complete by the Department.

The following standards will apply to the Department's review of applications for a PSAO registration:

- All necessary application information and documents have been filed;
- The persons responsible for conducting the applicant's affairs are competent, trustworthy and possess good reputations, and have appropriate experience, training and education;
- The applicant has demonstrated the ability to assure that its services will be performed in a manner which will ensure the efficient operation of its business;
- Any compensation arrangements between the registrant and carriers do not result in the assumption of financial risk by the applicant;
- The name used by the applicant to do business in this State does not so closely resemble the name of an insurer authorized to do business in this State or otherwise include such descriptive language as to be likely to mislead the public with respect to the nature of its business operations; and
- The applicant meets all requirements of N.J.S.A. 17B:27F-1 et seq. and demonstrates the ability to continue to meet all those requirements.

If the application for registration is denied, the Department will notify the applicant in writing. The applicant may request a hearing by notice to the Commissioner no later than the 30th day following receipt of the notice of denial.

The following documents will be considered to be confidential: pending applications for registration; social security numbers and residential addresses provided in biographical affidavits

submitted for consideration; the applicant's business plan and contracts; compensation arrangements; and the applicant's financial statements.

Completed PSAO registrations shall be sent to: pharmacyfilings@dobi.nj.gov

Questions regarding PSAO registrations may also be addressed to: pharmacyfilings@dobi.nj.gov

PBM and PSAO Contracts/PBM and Pharmacy Contracts

Pursuant to N.J.S.A. 17B:27F-2, when a contract between a PBM and a PSAO, or a PBM and a contracted pharmacy is executed or renewed, or when there is a material change in the contract, a PBM shall:

- include in the contract the sources utilized to determine multiple source generic drug pricing, brand drug pricing, and the wholesaler in the State 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;
- update that pricing information every seven calendar days;
- establish a reasonable process by which contracted pharmacies have a method to access relevant maximum allowable cost pricing lists, brand effective date, generic effective rate, and dispensing fee effective rate, or any other pricing formulas for pharmacy reimbursement;
- maintain a procedure for eliminating 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 PSAOs or the pharmacies that they are contractually obligated to provide that information; and
- provide an internal appeal mechanism for any disputes raised by carriers or pharmacies, regardless of whether the carrier or PBM has a contract to challenge maximum allowable costs for a specific drug. Any dispute regarding the determination of an internal appeal may be referred to arbitration. The Department is in the process of contracting with an arbitration organization. As information is available, it may be found on the Department's website at: https://www.nj.gov/dobi/division_insurance/pharmacybenefitsmanagers/index.htm

Requirements Imposed on PBMs, Generally

The Act imposes the following requirements on PBMs:

- PBMs must disclose any activity, policy, contract, or arrangement that directly or indirectly creates a conflict of interest with the carrier or health benefits plan in writing. N.J.S.A. 17B:27F-9.1f.

- PBMs shall have the same duty to a covered person as the health benefits plan[5] or carrier for whom it is performing pharmacy benefits management services and must act as the carrier's agent in good faith and fair dealing with all parties. N.J.S.A. 17B:27F-3.1b, c.
- All funds received by the PBM, including any administrative fee or payment in relation to providing services, and funds received through spread pricing, shall be used or distributed only pursuant to the PBM's contract with the health benefits plan or carrier or applicable law. N.J.S.A. 17B:27F-3.1b.
- PBMs are prohibited from penalizing or restricting network pharmacies from: disclosing lower-cost drug options to covered persons; allowing covered persons to pay a cash price for a prescription if it is cheaper than the person's cost-sharing amount; providing required information to state or federal agencies or law enforcement when mandated by law; or applying a discounted price generated by a healthcare platform. N.J.S.A. 17B:27F-6b.
- PBMs must provide access to carriers and health benefits plans, including the State Health Benefits Program, the School Employees' Health Benefits Program, the State Medicaid program, and a self-insured health benefits plan governed by ERISA, to all data related to the administration of prescription drug benefits provided by a PBM, including personal information of covered persons and contractual documents and transaction data related to the dispensing of prescription drugs. N.J.S.A. 17B:27F-9.1a. Any sale or transaction involving the transfer of the data must comply with federal privacy laws**,** including the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH"). N.J.S.A. 17B:27F-9.1b.
- A PBM must provide any necessary documentation requested by a carrier that relates to PBM compensation. N.J.S.A. 17B:27F-3.4d.
- Upon request, a PBM must provide to the Department any records, contracts, documents or data it holds for inspection, examination or audit purposes. N.J.S.A. 17B:27F-9.1e.
- Carriers, or a PBM under contract with a carrier, must establish a pharmacy and therapeutics committee responsible for managing the formulary system. N.J.S.A. 17B:27F-3.3a. A person with a conflict of interest cannot be a member of the pharmacy and therapeutics committee. N.J.S.A. 17B:27F-3.3b.

Requirements Imposed on Carriers, Generally

The Act imposes the following requirements on carriers:

- A carrier must monitor the PBM's activities carried out on behalf of the carrier related to the carrier's prescription drug benefits and is responsible for ensuring compliance. N.J.S.A. 17B:27F-3.1a.
- A carrier must provide a reasonably adequate retail pharmacy network for the provision of prescription medication for its covered persons. N.J.S.A. 17B:27F-3.1e.
- A carrier must maintain records, information and data related to the administration and provision of prescription drug benefits administered by a PBM as set forth in N.J.S.A.

[5] For the purposes of N.J.S.A. 17B:27F-3.1, "health benefits plan" includes the State Health Benefits Plan, the School Employees' Health Benefits Plan, the State Medicaid program, or a self-insured health benefits plan governed by the Employee Retirement Income Security Act of 1974 ("ERISA.")

17B:27F-9.1a and audit records described in N.J.S.A. 17B:27F-9.1c for no less than five years. N.J.S.A. 17B:27F-9.1d.

- Carriers and health benefits plans have the right to audit all transaction records related to prescription drug dispensing. Audits can be performed at any location and with any auditor of their choice. N.J.S.A. 17B:27F-9.1c. Carriers are required to maintain data and audit records for at least five years. N.J.S.A. 17B:27F-9.1d. Upon request, carriers must provide the Department with any records, documents, or data it holds for inspection or audit. N.J.S.A. 17B:27F-9.1e.
- Beginning March 1, 2025 and annually thereafter, carriers shall file with the Department a report explaining how the carrier has complied with the provisions of N.J.S.A. 17B:27F-3.2b, which concerns compensation remitted by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, to a carrier or to a PBM. The required report, N.J.S.A. 17B:27F-3.2 Reporting Template for Carriers – Use of Compensation Received from Pharmaceutical Manufacturers, Developers, and Labelers, may be found on the Department's website at: https://nj.gov/dobi/division_insurance/lifehealthmain.html.
- Carriers, or a PBM under contract with a carrier, must establish a pharmacy and therapeutics committee responsible for managing the formulary system. N.J.S.A. 17B:27F-3.3a. A person with a conflict of interest cannot be a member of the pharmacy and therapeutics committee. N.J.S.A. 17B:27F-3.3b.

Further, the Department reminds all carriers that they must comply with Statement of Statutory Accounting Principles No. 84, including but not limited to pharmaceutical rebates that have not been collected within 90 days of the invoice date or confirmation date shall be nonadmitted. Furthermore, if accrued pharmaceutical rebate receivables are not invoiced or confirmed in writing in accordance with the contract provisions, the accrual shall be nonadmitted.

Point of Sale Payments

PBMs, in connection with any contract or arrangement with a private health insurer, prescription benefit plan, or the State Health Benefits Program or School Employees' Health Benefits Program, are prohibited from requiring covered persons to pay more at the point of sale for prescription drugs. The amount a person must pay for a deductible, coinsurance, or copayment cannot exceed the limits set by N.J.S.A. 17B:27F-3.1. N.J.S.A. 17B:27F-6a.

Pursuant to N.J.S.A. 17B:27F-3.1, a covered person is not required to pay more than the lesser of two amounts at the point of sale when purchasing a covered prescription drug. These amounts are: the applicable cost-sharing amount for the prescription drug; or the amount the covered person would pay if they purchased the prescription drug without using their health insurance. N.J.S.A. 17B:27F-3.1d.

Moreover, compensation from pharmaceutical manufacturers to carriers or PBMs under contract with a carrier, must be paid to the covered person at the point of sale, or remitted to the carrier who must apply it to offset the premium. N.J.S.A. 17B:27F-3.2a

PBM Compensation – Carrier Loss Ratio Calculations

If a carrier uses a PBM to manage prescription drug benefits, when calculating a carrier's anticipated loss ratio or any loss ratio calculated as part of any applicable medical loss ratio filing or rate filing, the PBM's compensation is considered an administrative cost, not a benefit provided under the health benefits plan and the carrier can only claim amounts paid by the PBM to pharmacies or pharmacists as incurred claims. N.J.S.A. 17B:27F-3.4a. Any rate filing by a carrier for a health benefits plan that includes prescription drug coverage managed by a PBM must include a memorandum from a qualified actuary explaining how PBM compensation was calculated and any necessary records and supporting information as determined by the Department to verify the calculation of PBM compensation. N.J.S.A. 17B:27F-3.4b. Upon request, a carrier shall provide any records to the Department that relate to the calculation of the PBM and PSAO compensation. N.J.S.A. 17B:27F-3.4c. A PBM and PSAO shall provide any necessary documentation requested by a carrier that relates to PBM compensation. N.J.S.A. 17B:27F-3.4d.

Prior to the promulgation of regulations, carriers should comply with the Act as set forth above, including filings in the individual market, small group market, and the large group market. The Department will update its regulations related to loss ratio calculations, including N.J.A.C. 11:20-7 (loss ratio and refund reporting requirements, individual health benefit plans) and N.J.A.C. 11:21-7A (loss ratio reports, small employer health benefit plans), as needed.

Maximum Allowable Cost

Carriers and PBMs under a contract with a carrier, must 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 brand-name drug that has at least one generic equivalent available. The same maximum allowable cost list must be used for each pharmacy provider. N.J.S.A. 17B:27F-3a. A prescription drug can be on the maximum allowable cost list if the conditions under N.J.S.A. 17B:27F-3b are met.

Pharmacists or pharmacies cannot be penalized if they perform a generic substitution. N.J.S.A. 17B:27F-3c. For brand-name drugs without a generic equivalent, or a prescription drug not included on a maximum allowable cost list, carriers or PBMs must use the average wholesale price to establish the maximum payment. N.J.S.A. 17B:27F-3d. Only one national drug pricing source can be used during a calendar year, unless the original drug pricing source is no longer available. N.J.S.A. 17B:27F-3d. The same national drug pricing source must be used for each pharmacy provider and be identified on the carrier's, or its PBM's, publicly accessible website. N.J.S.A. 17B:27F-3d.

Payments to a Pharmacy for Dispensing Prescription Drugs

The formula for determining the amount paid by a carrier or a carrier's PBM to a pharmacy for dispensing a prescription drug is the ingredient cost plus the dispensing fee less any cost-sharing amount paid by a covered person. N.J.S.A. 17B:27F-3e. The ingredient cost shall not exceed the maximum allowable cost or average wholesale price, as applicable, and shall be disclosed by a

carrier's PBM to the carrier. N.J.S.A. 17B:27F-3e. The pharmacy provider that dispensed the drug shall retain the payment. N.J.S.A. 17B:27F-3e.

Violations and Penalties

Pursuant to the Act, a PBM that violates the Act and entities that act as a PBM or PSAO without obtaining a license or registration can be fined $5,000 for the first violation and $10,000 for each subsequent violation; or the aggregate gross receipts attributable to all violations, whichever is greater. N.J.S.A. 17B:27F-10a; N.J.S.A. 17B:27F-1.1g. A PBM may also be required to make restitution and pay compensatory damages to any person injured by the violation. N.J.S.A. 17B:27F-10b.

PBMs and PSAOs may also have their license or registration suspended, revoked or placed on probation for engaging in fraudulent activity or any activity that constitutes a violation of State or federal law; if the Department receives consumer complaints that justify an action to protect the safety and interests of consumers; failing to pay the original issuance or renewal fee for the license or registration; or failing to comply with any requirement set forth in the Act. N.J.S.A. 17B:27F-1.1f. Carriers that violate the Act are subject to penalties as provided by law.

December 31, 2024
Date

Justin Zimmerman
Commissioner

jd PBM and carrier duties bulletin/Bulletins