129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document	**No. 1389**
S.P. 433	In Senate, March 26, 2019

An Act To Address Transparency, Accountability and Oversight of Pharmacy Benefit Managers

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator POULIOT of Kennebec.
Cosponsored by Representative BLIER of Buxton and
Senator: FOLEY of York, Representative: MORRIS of Turner.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §1711-E, sub-§1, ¶G, as amended by PL 2011, c. 443, §1, is further amended to read:

G. "Pharmacy ~~benefits~~ benefit manager" has the same meaning as in Title 24-A, section ~~1913~~ 1914, subsection 1, paragraph ~~A~~ G.

Sec. 2. 22 MRSA §1711-E, sub-§1, ¶I, as amended by PL 2007, c. 460, §1, is further amended to read:

I. "Prescription drug information intermediary" means a person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber. "Prescription drug information intermediary" includes, but is not limited to, a pharmacy ~~benefits~~ benefit manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.

Sec. 3. 22 MRSA §8702, sub-§8, as amended by PL 2009, c. 71, §5, is further amended to read:

8. Payor. "Payor" means a 3rd-party payor, 3rd-party administrator, Medicare health plan sponsor, pharmacy ~~benefits~~ benefit manager or nonlicensed carrier.

Sec. 4. 22 MRSA §8702, sub-§8-B, as amended by PL 2011, c. 443, §3, is further amended to read:

8-B. Pharmacy benefit manager. "Pharmacy ~~benefits~~ benefit manager" has the same meaning as in Title 24-A, section ~~1913~~ 1914, subsection 1, paragraph ~~A~~ G.

Sec. 5. 22 MRSA §8706, sub-§2, ¶C, as amended by PL 2007, c. 136, §5, is further amended to read:

C. The operations of the organization must be supported from 3 sources as provided in this paragraph:

(1) Fees collected pursuant to paragraphs A and B;

(2) Annual assessments of not less than $100 assessed against the following entities licensed under Titles 24 and 24-A: nonprofit hospital and medical service organizations, health insurance carriers and health maintenance organizations on the basis of the total annual health care premium; and 3rd-party administrators, carriers that provide only administrative services for a plan sponsor and pharmacy ~~benefits~~ benefit managers that process and pay claims on the basis of claims processed or paid for each plan sponsor. The assessments are to be determined on an annual basis by the board. Health care policies issued for specified disease, accident, injury, hospital indemnity, disability, long-term care or other limited benefit health insurance policies are not subject to assessment under this subparagraph. For purposes of this subparagraph, policies issued for dental services are not considered to be limited benefit health insurance policies.

The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (3); and

(3) Annual assessments of not less than $100 assessed by the organization against providers. The assessments are to be determined on an annual basis by the board. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (2).

The aggregate level of annual assessments under subparagraphs (2) and (3) must be an amount sufficient to meet the organization's expenditures authorized in the state budget established under Title 5, chapter 149. The annual assessment may not exceed $1,346,904 in fiscal year 2002-03. In subsequent fiscal years, the annual assessment may increase above $1,346,904 by an amount not to exceed 5% per fiscal year. The board may waive assessments otherwise due under subparagraphs (2) and (3) when a waiver is determined to be in the interests of the organization and the parties to be assessed.

Sec. 6. 24-A MRSA §601, sub-§28, as enacted by PL 2009, c. 581, §3, is amended to read:

28. Pharmacy benefit manager. Pharmacy ~~benefits~~ benefit manager registration fees may not exceed:

A. Original issuance fee, $100; and

B. Annual renewal fee, $100.

Sec. 7. 24-A MRSA §1913, as repealed and replaced by PL 2011, c. 443, §4, is repealed.

Sec. 8. 24-A MRSA §1914 is enacted to read:

§1914. Pharmacy benefit managers

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Aggregate retained rebate percentage" means the percentage of all rebates received from a pharmaceutical manufacturer or other entity by a pharmacy benefit manager for use of a prescription drug of the manufacturer or other entity that is not passed on to an insurer for whom the pharmacy benefit manager provides services. The percentage is calculated for each insurer for rebates in the prior calendar year as the total dollar amount of rebates received by the pharmacy benefit manager from all pharmaceutical manufacturers or other entities for the use of the manufacturers' or other entities' prescription drugs by covered persons of the insurer that was not passed through to the insurer divided by the total dollar amount of all rebates received by the pharmacy benefit manager from all pharmaceutical manufacturers or other entities for the use of the manufacturers' or other entities' prescription drugs by covered persons of the insurer.

B. "Covered person" means a policyholder, subscriber, enrollee or other individual who is participating in a health benefit plan or who otherwise receives health care services or reimbursement for health care services from an insurer.

C. "Department" means the Department of Health and Human Services.

D. "Health benefit plan" means a policy, contract, certificate or agreement offered or issued by an insurer to provide, deliver, arrange for, pay for or reimburse costs for health care services.

E. "Insurer" means an insurer under section 4, a self-insurance plan or other 3rd-party payor that contracts, offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse costs of health care services, including a health insurance company, a health maintenance organization, a hospital, a health services corporation or any other entity providing, paying for or reimbursing costs for a health insurance plan, health benefits or health care services.

F. "Pharmacy" has the same meaning as in Title 32, section 13702-A, subsection 24.

G. "Pharmacy benefit manager" means a person that, pursuant to a contract or under an employment relationship with an insurer, either directly or through an intermediary, manages the prescription drug coverage provided by the insurer, including the processing and payment of claims for prescription drugs, the performance of drug use review, the processing of prior authorization requests, the adjudication of appeals and grievances related to prescription drug coverage, contracting with network pharmacies and controlling the cost of prescription drugs.

2. Registration required. A pharmacy benefit manager conducting business in the State must be annually registered under this section. The department may issue a nontransferable registration to a pharmacy benefit manager if the department determines the pharmacy benefit manager possesses the necessary organization, expertise and financial integrity to manage an insurer's prescription drug coverage and may limit or restrict the registration, including the type of services that a pharmacy benefit manager may provide or the activities in which the pharmacy benefit manager may engage. A pharmacy benefit manager registered under this subsection shall maintain a registered agent and registered address in the State for purposes of accepting service of process. A pharmacy benefit manager who conducts business in the State without a valid registration under this subsection commits a civil violation for which a penalty of $5,000 per day of violation must be assessed.

3. Registration application. An application for registration under subsection 2 must require the following information:

A. The name of the pharmacy benefit manager;

B. The address, telephone number and other contact information of the pharmacy benefit manager;

C. The name and address of the pharmacy benefit manager's registered agent in the State;

D. The name and address of each person beneficially interested in the activities of the pharmacy benefit manager; and

E. The name and address of each person with management or control over the pharmacy benefit manager.

An applicant under this section shall pay the registration fee under section 601, subsection 28 upon submission of the application.

4. Registration term; suspension, revocation and probation. A registration issued under subsection 2 is valid for 3 years. The department may suspend, revoke or place on probation a registration issued under subsection 2 if:

A. The pharmacy benefit manager engages in fraudulent activity that constitutes a violation of state or federal law;

B. The department receives a consumer complaint that justifies action under this subsection to protect the safety and interests of a consumer;

C. The pharmacy benefit manager fails to pay the registration fee or violates any other rule of the department; or

D. The pharmacy benefit manager fails to comply with or violates a provision of this section.

5. Pharmacy benefit manager business practices. In addition to the provisions in section 4317, a pharmacy benefit manager shall comply with the following business practices.

A. A pharmacy benefit manager has a fiduciary duty to the insurer for which the pharmacy benefit manager performs services and shall discharge the duty in accordance with state and federal law.

B. A pharmacy benefit manager shall perform services with care, prudence, diligence and professionalism.

C. A pharmacy benefit manager shall notify in writing an insurer for which the pharmacy benefit manager performs services of any activity, policy or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest with the provisions of this chapter.

D. A pharmacy benefit manager may not enter into a contract with a pharmacy or pharmacist that prohibits or penalizes a pharmacy or pharmacist for disclosure of information to a covered person regarding:

(1) The cost of a prescription medication to the covered person; or

(2) The availability of a therapeutically equivalent alternative medication or an alternative method of purchasing the prescription medication, including paying a cash price that is less than the cost of the prescription under the covered person's health benefit plan.

E. A pharmacy benefit manager may not require a pharmacy or other provider accreditation or certification that is inconsistent with, more stringent than or in addition to the requirements of the Maine Board of Pharmacy or other state or federal authority.

F. A pharmacy benefit manager or an insurer for which the pharmacy benefit manager performs services may not require a covered person to make a payment at the point of sale for a covered prescription medication in any amount greater than the lesser of:

(1) The applicable copayment for the prescription medication;

(2) The allowable claim amount for the prescription medication;

(3) The amount a covered person would pay for the prescription medication without using a health benefit plan or any other source of prescription medication benefits or discounts; and

(4) The amount the pharmacy would be reimbursed for the prescription drug from the pharmacy benefit manager or the insurer for which the pharmacy benefit manager performs services.

G. A pharmacy benefit manager or an insurer for which the pharmacy benefit manager performs services may not penalize, require or provide a financial incentive, including a variation in premium, deductible, copayment or coinsurance, to a covered person as an incentive to use a specific retail, mail order or other pharmacy provider in which the pharmacy benefit manager or covered person's insurer has an ownership interest or that has an ownership interest in the pharmacy benefit manager or the covered person's insurer.

6. Report. On or before June 1st of each year, a registered pharmacy benefit manager shall submit a report containing data from the prior calendar year to the department that contains the following:

A. The aggregate amount of all rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers for all insurers for which the pharmacy benefit manager provided services and the amount of rebates received from each insurer;

B. The aggregate administrative fees that the pharmacy benefit manager received from all insurers for which the pharmacy benefit manager provided services and the amount of administrative fees received from each insurer;

C. The aggregate retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers and that did not pass through to an insurer;

D. The aggregate retained rebate percentage; and

E. The highest, lowest and mean aggregate retained rebate percentage for each insurer and for all insurers for which the pharmacy benefit manager provided services.

A pharmacy benefit manager may designate information required under this subsection as a trade secret as defined in Title 10, section 1542, subsection 4 that may be disclosed only by court order upon a determination of good cause shown. Within 60 days of receipt, the department shall publish a report under this subsection on the department's publicly accessible website in a manner that does not violate Title 10, chapter 302. A pharmacy benefit manager that violates this subsection commits a civil violation for which a penalty of not more than $1,000 per day of violation may be assessed.

7. Rules. The department shall adopt rules to carry out the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 9. 24-A MRSA §4317, sub-§§4 and 5, as enacted by PL 2011, c. 443, §6, are amended to read:

4. Participation in contracts. A pharmacy ~~benefits~~ benefit manager may not require a pharmacist or pharmacy to participate in one network in order to participate in another network. The pharmacy ~~benefits~~ benefit manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in one network solely because the pharmacist or pharmacy declined to participate in another network managed by the pharmacy ~~benefits~~ benefit manager.

5. Prohibition. The written contract between a carrier and a pharmacy ~~benefits~~ benefit manager may not provide that the pharmacist or pharmacy is responsible for the actions of the insurer or a pharmacy ~~benefits~~ benefit manager.

Sec. 10. 24-A MRSA §4317, sub-§6, as amended by PL 2011, c. 691, Pt. A, §23, is further amended to read:

6. Pharmacy benefit manager duties. All contracts must provide that, when the pharmacy ~~benefits~~ benefit manager receives payment for the services of a pharmacist or pharmacy, the pharmacy ~~benefits~~ benefit manager shall distribute the funds in accordance with the time frames provided in this subchapter.

Sec. 11. 24-A MRSA §4317, sub-§§7 to 9, as enacted by PL 2011, c. 443, §6, are amended to read:

7. Complaints, grievances and appeals. A pharmacy ~~benefits~~ benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy solely as a result of the pharmacist's or pharmacy's filing of a complaint, grievance or appeal. This subsection is not intended to restrict the pharmacy's and pharmacy ~~benefits~~ benefit manager's ability to enter into agreements that allow for mutual termination without cause.

8. Denial or limitation of benefits. A ~~pharmacy's benefits~~ pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy for expressing disagreement with a carrier's decision to deny or limit benefits to an enrollee or because the pharmacist or pharmacy assists the enrollee to seek reconsideration of the carrier's decision or because the pharmacist or pharmacy discusses alternative medications.

9. Written notice required. At least 60 days before a ~~pharmacy's benefits~~ pharmacy benefit manager terminates a pharmacy's or pharmacist's participation in the pharmacy ~~benefits~~ benefit manager's plan or network, the pharmacy ~~benefits~~ benefit manager shall give the pharmacy or pharmacist a written explanation of the reason for the termination, unless the termination is based on:

A. The loss of the pharmacy's license or the pharmacist's license to practice pharmacy or cancellation of professional liability insurance; or

B. A finding of fraud.

At least 60 days before a pharmacy or pharmacist terminates its participation in a pharmacy ~~benefits~~ benefit manager's plan or network, the pharmacy or pharmacist shall give the pharmacy ~~benefits~~ benefit manager a written explanation of the reason for the termination.

Sec. 12. 24-A MRSA §4317, sub-§10, as amended by PL 2013, c. 71, §1, is further amended to read:

10. Audits. Notwithstanding any other provision of law, when an on-site audit of the records of a pharmacy is conducted by a pharmacy ~~benefits~~ benefit manager, the audit must be conducted in accordance with the following criteria.

A. A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, unless the projected overpayment or denial is a part of a settlement agreed to by the pharmacy or pharmacist.

B. The auditor may not use extrapolation in calculating recoupments or penalties.

C. Any audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist.

D. Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

E. This subsection does not apply to any audit, review or investigation that is initiated based on or involves suspected or alleged fraud, willful misrepresentation or abuse.

F. Prior to an audit, the entity conducting an audit shall give the pharmacy 10 days' advance written notice of the audit and the range of prescription numbers and the range of dates included in the audit.

G. A pharmacy has the right to request mediation by a private mediator, agreed upon by the pharmacy and the pharmacy ~~benefits~~ benefit manager, to resolve any disagreements. A request for mediation does not waive any existing rights of appeal available to a pharmacy under this subsection or subsection 11.

H. The requirements of section 4303, subsection 10 apply to claims audited under this subsection.

Sec. 13. 24-A MRSA §4317, sub-§11, as enacted by PL 2011, c. 443, §6, is amended to read:

11. Audit information and reports. A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit under subsection 10. A pharmacy must be allowed at least 30 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit. A final audit report must be delivered to the pharmacy within 90 days after receipt of the preliminary audit report or final appeal, whichever is later. A charge-back, recoupment or other penalty

may not be assessed until the appeal process provided by the pharmacy ~~benefits~~ benefit manager has been exhausted and the final report issued. Except as provided by state or federal law, audit information may not be shared. Auditors may have access only to previous audit reports on a particular pharmacy conducted by that same entity.

Sec. 14. 24-A MRSA §4317, sub-§12, as enacted by PL 2015, c. 450, §1, is amended to read:

12. Maximum allowable cost. This subsection governs the maximum allowable cost for a prescription drug as determined by a pharmacy ~~benefits~~ benefit manager.

A. As used in this subsection, "maximum allowable cost" means the maximum amount that a pharmacy ~~benefits~~ benefit manager pays toward the cost of a prescription drug.

B. A pharmacy ~~benefits~~ benefit manager may set a maximum allowable cost for a prescription drug, or allow a prescription drug to continue on a maximum allowable cost list, only if that prescription drug:

(1) Is rated as "A" or "B" in the most recent version of the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as "the Orange Book," or an equivalent rating from a successor publication, or is rated as "NR" or "NA" or a similar rating by a nationally recognized pricing reference; and

(2) Is not obsolete and is generally available for purchase in this State from a national or regional wholesale distributor by pharmacies having a contract with the pharmacy ~~benefits~~ benefit manager.

C. A pharmacy ~~benefits~~ benefit manager shall establish a process for removing a prescription drug from a maximum allowable cost list or modifying a maximum allowable cost for a prescription drug in a timely manner to remain consistent with changes to such costs and the availability of the drug in the national marketplace.

D. With regard to a pharmacy with which the pharmacy ~~benefits~~ benefit manager has entered into a contract, a pharmacy ~~benefits~~ benefit manager shall:

(1) Upon request, disclose the sources used to establish the maximum allowable costs used by the pharmacy ~~benefits~~ benefit manager;

(2) Provide a process for a pharmacy to readily obtain the maximum allowable reimbursement available to that pharmacy under a maximum allowable cost list; and

(3) At least once every 7 business days, review and update maximum allowable cost list information to reflect any modification of the maximum allowable reimbursement available to a pharmacy under a maximum allowable cost list used by the pharmacy ~~benefits~~ benefit manager.

E. A pharmacy ~~benefits~~ benefit manager shall provide a reasonable administrative appeal procedure, including a right to appeal that is limited to 14 days following the initial claim, to allow pharmacies with which the pharmacy ~~benefits~~ benefit manager has a contract to challenge maximum allowable costs for a specified drug.

F. The pharmacy ~~benefits~~ benefit manager shall respond to, investigate and resolve an appeal under paragraph E within 14 days after the receipt of the appeal. The pharmacy ~~benefits~~ benefit manager shall respond to an appeal as follows:

(1) If the appeal is upheld, the pharmacy ~~benefits~~ benefit manager shall make the appropriate adjustment in the maximum allowable cost and permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question; or

(2) If the appeal is denied, the pharmacy ~~benefits~~ benefit manager shall provide the challenging pharmacy or pharmacist the national drug code from national or regional wholesalers of a comparable prescription drug that may be purchased at or below the maximum allowable cost.

G. The requirements of this subsection apply to contracts between a pharmacy and a pharmacy ~~benefits~~ benefit manager executed or renewed on or after September 1, 2016.

Sec. 15. 24-A MRSA §4317, sub-§13, as enacted by PL 2017, c. 44, §1, is amended to read:

13. Prohibition on excessive copayments or charges; disclosure not penalized. A carrier or pharmacy ~~benefits~~ benefit manager may not impose on an enrollee a copayment or other charge that exceeds the claim cost of a prescription drug. If information related to an enrollee's out-of-pocket cost or the clinical efficacy of a prescription drug or alternative medication is available to a pharmacy provider, a carrier or pharmacy ~~benefits~~ benefit manager may not penalize a pharmacy provider for providing that information to an enrollee.

SUMMARY

This bill requires that pharmacy benefit managers, which are entities that manage an insurer's prescription drug coverage, be registered by the Department of Health and Human Services. It sets standards for registration including:

1. Allowing the department to revoke, suspend or place on probation a pharmacy benefit manager's registration for fraudulent activities, to protect the safety and interest of a consumer or if the pharmacy benefit manager violates state law;

2. Setting out required pharmacy benefit manager business practices, including:

A. Placing a fiduciary duty on the managers with respect to the insurers who are the managers' clients;

B. Prohibiting the manager from entering into a contract that prohibits a pharmacy or pharmacist from recommending a lower cost or alternative prescription medication than the medication under a covered person's prescription drug plan;

C. Prohibiting the manager from requiring accreditation or certification for a pharmacy inconsistent with, more stringent than or in addition to those required by the Maine Board of Pharmacy and other state and federal authorities;

D. Limiting the amount of payment required by a covered person for a prescription drug at the point of sale; and

E. Prohibiting conflicts of interest; and

3. Requiring an annual report from a pharmacy benefit manager that details the rebates received by the pharmacy benefit manager from pharmaceutical manufacturers for use of the manufacturers' prescription drugs and the disposition of those rebates.