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Section 1. Authority and Purpose

This rule is adopted pursuant to 24-A M.R.S. §§ 212, 4348(8), and 4349(5), to establish licensing requirements for pharmacy benefits managers (PBMs), to ensure that savings generated from pharmaceutical rebates are passed on to consumers via reductions in premiums or other means, and to prohibit the use of spread pricing in state-regulated health plans, with the exception of MaineCare, until January 1, 2031.

Section 2. Applicability and Scope

This rule shall apply to all PBMs, as defined in 24-A M.R.S. §4347(17) and carriers, as defined in 24-A M.R.S. §4347(3), that contract with PBMs. For purposes of this rule, as set forth in 24-A M.R.S. §4347(3), the MaineCare program and the state employee health plan are considered carriers, but a multiple-employer welfare arrangement is not considered a carrier if it contracts with a third-party administrator to administer its benefit plan and does not contract separately with a PBM for its prescription drug benefits.

Section 3. Definitions

The definitions applicable to this rule are contained in 24-A M.R.S. §4347. In addition to those definitions, the following definitions apply:

1. **Pharmaceutical rebate.** “Pharmaceutical rebate” means a discount or other price concession that is paid by a manufacturer or third party directly or indirectly to a PBM or a pharmacy, other than a discount or price concession that is fully disclosed and reflected at the point of sale by incorporation into the ingredient cost paid by the carrier and the calculation of the enrollee’s cost sharing amount.

2. **Spread pricing.** “Spread pricing” means any amount charged or claimed by a PBM in excess of:
 - A. The ingredient cost, as defined by 24-A M.R.S. § 4347(11), for a dispensed prescription drug, plus
 - B. The dispensing fee, as defined by 24-A M.R.S. § 4347(7), paid directly or indirectly to any pharmacy or pharmacist on behalf of a health plan, less
 - C. Any pharmacy benefits management fee, as defined by 24-A M.R.S. § 4350-F(1)(A).

Section 4. Licensing Requirements

1. Initial Licensing

On or after January 1, 2020, any person acting or purporting to act as a PBM shall apply for a license on a form prescribed by the Superintendent. The application must contain the following:

A. Applicant Information

- (1) The name, principal business address, and telephone number of the applicant;
- (2) The name, address, and telephone number of the applicant’s agent for service of process located in Maine;
- (3) The name, address, telephone number of each officer and director of the applicant;
- (4) The name, address and telephone number of each person who owns 10% or more of the voting securities or equivalent ownership rights of the applicant; and
- (5) The state in which the applicant is domiciled;

B. Applicant Qualifications

The applicant must provide information by which the Superintendent can determine whether the applicant has the necessary organizational capability to supply the services sought to be offered. This information includes, but is not limited to:

- (1) Copies of the basic organizational documents of the applicant, such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents, including all amendments, bylaws, rules, regulations, and/or procedures regulating the internal conduct of the applicant;

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- (2) Biographical information for each officer and director of the applicant, including:
 - (a) His or her principal occupation and all offices and positions held during the past five years;
 - (b) Whether any such occupation, position, office, or employment required licensing by or registration with any federal, state, or municipal governmental agency, and if so, the current status of each such license or registration and an explanation of any surrender, revocation, suspension, or disciplinary proceedings in connection therewith; and
 - (c) Any conviction of crimes other than minor traffic violations.
 - (3) Whether the applicant has ever been refused a registration, license or certification to act as a provider of pharmacy benefits management services in any jurisdiction, or had such license, registration or certification suspended, revoked, or subject to disciplinary action in any jurisdiction. Disciplinary action includes, but is not limited to, the imposition of any fines or civil penalties and any reprimand, probation, or deferred prosecution agreement.
 - (4) Whether the applicant has ever had a business relationship with a carrier or other health benefit payer terminated due to alleged fraudulent, illegal, or dishonest activities in connection with the administration of pharmacy benefits management services. If the applicant has had such a relationship terminated, it must explain the circumstances surrounding the termination.
 - (5) Whether the applicant has ever been found liable in any lawsuit or arbitration proceeding involving allegations of fraudulent, illegal, or dishonest activities in connection with the administration of pharmacy benefits management services;
 - (6) Whether the applicant, or any company or organization controlling the operation of the applicant, has experienced any events resulting in unauthorized access to, disruption of, or misuse of its information system or stored information.
- C. The applicant must provide information by which the Superintendent can determine whether the applicant has the necessary expertise to supply the services sought to be offered. This information includes, but is not limited to:
- (1) A copy of the applicant's standard contract template used in this State for contracts with pharmacies or pharmacy services administrative organizations in the administration of pharmacy services.
 - (2) A current client list and a template copy of the client contract.

- (3) The number of projected enrollees or beneficiaries in this State to be serviced by the applicant during the upcoming year for all contracted entities. If applicable, provide the actual number of enrollees or beneficiaries serviced by the applicant for each entity during the previous calendar year.
- (4) The applicant's network service areas or proposed network service areas for each contracted carrier in Maine and the applicant's pharmacy network directory. All pharmacies that provide pharmaceuticals exclusively through the mail must be listed separately. The applicant must file with the Superintendent:
 - (a) A list of all pharmacies in the network, and indicate which dispense specialty drugs;
 - (b) The projected ratio of retail pharmacies to plan enrollees by county;
 - (c) Written standards for providing a retail pharmacy network that is sufficient in numbers and types of pharmacies to assure that prescriptions to covered persons, including specialty prescriptions, will be reasonably accessible without unreasonable delay. Standards must be reasonable for the community, the delivery system, and clinical safety; and
 - (d) A description of the applicant's plan for providing prescription drugs for rural and underserved populations.

D. The applicant shall state whether it intends to provide PBM services for carriers offering health plans or benefits in Maine within the scope of this rule. Before providing services for carriers, the applicant must demonstrate to the satisfaction of the Superintendent its ability to comply with the requirements of 24-A M.R.S. §§ 4349 through 4350-D by providing the following information:

- (1) A description, including any relevant written procedures, of how the applicant intends to comply with the prohibition against requiring a covered person to make a payment at the point of sale that exceeds either: the applicable cost-sharing amount for the prescription drug; the amount the covered person would pay without using the health plan or any other source of prescription drug benefits or discounts; or the total amount the pharmacy will be reimbursed for the prescription, including the cost-sharing amount paid by the covered person.
- (2) A description of how the applicant intends to comply with the requirements of 24-A M.R.S. §4350, including: procedures for changes to the maximum allowable cost list; disclosure of allowable cost information; the applicant's appeals process; payment for drugs that are not on the maximum allowable cost list; ensuring that pharmacy providers' payments are not retroactively denied or reduced except for error or fraud; and standards and procedures for determination and payment of ingredient costs and dispensing fees.

- (3) If applicable, a description of how the applicant intends to comply with the requirement to use all rebates for the benefit of covered persons.
 - (4) Documentation verifying that the applicant has established a pharmacy and therapeutics committee and implemented appropriate procedures to address conflicts of interest and prohibited compensation arrangements for committee members.
- E. The applicant must provide information by which the Superintendent can determine the financial integrity of the applicant to supply the services sought to be offered. This information includes, but is not limited to:
- (1) A copy of the applicant's most recent annual audited financial statement.
 - (2) Information demonstrating that either:
 - (a) the applicant is currently licensed in good standing as a Third-Party Administrator;
 - (b) the applicant has a pending application for licensure as a Third-Party Administrator;
 - (c) the applicant does not handle claims or collect premium; or
 - (d) the applicant is exempt from licensure as a Third-Party Administrator.
 - (3) A description of the applicant's business plan.

2. **Renewal**

A PBM must renew its license every three years to continue to act as a PBM in this state. An applicant for renewal shall provide the same information as an applicant for initial licensing. To the extent that the information is already on file from a previous application, the applicant may incorporate that information by reference if it attests that there have been no changes since it was originally submitted.

Section 5. Oversight and Contracting Responsibilities

1. **Fiduciary Duty**

- A. A carrier that contracts with a PBM must ensure that the contract specifies that the PBM acts as the carrier's agent in administering the carrier's prescription drug benefits, and owes a fiduciary duty to the carrier that obligates the PBM to:
- (1) Act prudently and solely in the best interest of the carrier in its management of activities related to the carrier's prescription drug benefits;

- (2) Account for and disclose to the carrier all compensation that it receives so that the carrier may use it in compliance with subsection 2; and
- (3) Ensure compliance with all other requirements of this rule and other applicable law.

B. A carrier that contracts with a PBM shall file proof, satisfactory to the Superintendent, that the contract complies with this subsection. An image of a signed Agreement Concerning Fiduciary Obligations in a form specified by the Superintendent shall constitute sufficient proof of compliance. Proof of compliance shall be filed within 30 days after entering into a contractual relationship with a PBM, or within 30 days after the effective date of this rule for existing relationships. Contractual language filed in accordance with this paragraph may not be rescinded or amended without advance notice to the Superintendent.

2. **Compensation for the Benefit of Covered Persons**

All compensation remitted directly or indirectly by a pharmaceutical manufacturer, developer, or labeler to a carrier, or to a PBM under contract with a carrier, including but not limited to pharmaceutical rebates, must either be applied directly to reduce the covered person's out-of-pocket cost or used by the carrier in its plan design to reduce premiums.

3. **Covered Person's Right to Waive Coverage and Pay Cash**

A carrier, a PBM under contract with a carrier, or any other person acting on a carrier's behalf must allow a pharmacy provider to accept the provider's cash price from a covered person for a prescription drug, in lieu of filing a claim with the covered person's carrier, if the cash price is less than the covered person's cost sharing amount.

4. **Pharmacy Provider's Right to Provide Information**

A carrier, a PBM under contract with a carrier, or any other person acting on a carrier's behalf may not prevent or restrict a pharmacy provider from providing information required by law to a state or federal agency, a law enforcement agency, or the Superintendent.

5. **Spread Pricing Prohibited**

A carrier or PBM under contract with a carrier may not, either directly or indirectly through an intermediary, agent, or affiliate, engage in, facilitate, or enter into a contract with another person involving spread pricing in this State.

A. Annually, by December 31, each carrier providing pharmacy benefits in this State, and each PBM administering pharmacy benefits in this State on behalf of one or more carriers, shall submit a certification on a form prescribed by the Superintendent, signed by the chief executive officer or chief financial officer of the carrier or PBM, certifying that that it has fully complied with the requirements of this subsection throughout the calendar year concluding on the certification date.

- B. This subsection is effective January 1, 2026, and applies to all contracts entered into or renewed on or after that date. This subsection is repealed January 31, 2031. This subsection does not apply to the MaineCare program.

Section 6. Severability

If any section, term, or provision of this rule shall be deemed invalid for any reason, any remaining section, provision, or definition shall remain in full force and effect.

Section 7. Effective date

This rule is effective February 14, 2021.

The 2025 amendments are effective _____, 202_.

STATUTORY AUTHORITY:

24-A MRS §§ 4348(8), 4349(5)

EFFECTIVE DATE:

February 14, 2021 – filing 2021-037