



August 31st, 2020

Susan Tardiff  
Maine Bureau of Insurance  
34 State House Station  
Augusta, Maine 04333

**RE: Chapter 210 – Standards For Pharmacy Benefit Managers**

Dear Ms. Tardiff,

I am writing to provide the Pharmaceutical Care Management Association (PCMA) comments to the Maine Bureau of Insurance (BOI) proposed rules in Chapter 210 – Standards For Pharmacy Benefit Managers. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers.

We appreciate the opportunity to speak on the proposed rules and want to thank the Maine BOI for taking feedback from the industry on the application and rulemaking process. Below we outline where PCMA believes the proposed rulemaking goes beyond the statutory authority as well as share concerns on other aspects of the rules and offer the following comments for consideration. Additionally, we propose that the BOI consider the licensure requirements for third party administrators (TPAs) when looking at PBM licensure.

PCMA would first like to address the areas where we believe the proposed rules go beyond the statute.

Section 4 Licensing Requirements:

- 1B(3) requires the applicant to provide information on “[w]hether the applicant has ever been refused a registration, license or certification to act as a provider of PBM services in any jurisdiction, or had such license, registration, or certification suspended, revoked, or subject to disciplinary action in any jurisdiction.
  - PCMA requests that this be struck as this is not supported by language in Public Law, chapter 469. Additionally, it is not a common practice for a license to be denied based on fines, civil penalties, etc. in other jurisdictions.
- 1C(1) requests “[a] template copy of the client contract.” Contracts are confidential and contain proprietary information.
  - PCMA requests that this be struck as it is not authorized under the Public Law, chapter 469. Pursuant to the law, the carrier is responsible for its contracted PBMs activities and for ensuring all requirements of the chapter are met. Therefore, the BOI already has the ability and right to request information from PBMs regarding compliance with act.

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- As an alternative, we suggest the BOI allows PBMs to submit a contract certification/attestation similar to what is required under the TPA law (See Title 24-A M.R.S.A Chapter 18).
- 1C(4)(a) requests a list of all pharmacies in the network and indicate which dispense specialty drugs.
  - PCMA requests that the requirement to indicate which pharmacies dispense specialty drugs be removed because the PBMs do not know on any given day if a pharmacy dispenses specialty drugs. This is not authorized under the Public Law, chapter 469, which only requires the PBM to demonstrate an adequate number of pharmacies, not specific to the types of drugs they dispense. Any network adequacy requirements fall on the carrier to adhere to while PBM acts as the carrier's agent in fulfilling such requirements.
- 1C(4)(c) states “[w]ritten 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.”
  - PCMA requests that this be stricken as it potentially interferes with plan design, is inappropriate for determining network adequacy, and is outside of the scope of the Public Law, chapter 469. Further, any written standards for retail pharmacy would have to comply with the any willing pharmacy law already on the books. 24-A M.R.S.A. § 4317 states:  
*Notwithstanding section 2672, section 4307, subsection 3 and Title 32, chapter 117, subchapter 8,1 a carrier that provides coverage for prescription drugs as part of a health plan may not refuse to contract with a pharmacy provider that is qualified and is willing to meet the terms and conditions of the carrier's criteria for pharmacy participation as stipulated in the carrier's contractual agreement with its pharmacy providers. This subsection may not be construed to limit a carrier's ability to offer an enrollee incentives, including variations in premiums, deductibles, copayments or coinsurance or variations in the quantities of medications available to the enrollee, to encourage the use of certain preferred pharmacy providers as long as the carrier makes the terms applicable to the preferred pharmacy providers available to all pharmacy providers. For purposes of this subsection, a preferred pharmacy provider is any pharmacy willing to meet the specified terms, conditions and price that the carrier may require for its preferred pharmacy providers.*

#### Section 5 Oversight and Contracting Responsibilities:

- 1A(1)-1A(4) states “[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 prescriptions drug benefits, and owes a fiduciary duty to the carrier that obligates the PBM to:”
- PCMA believes the term fiduciary duty is a complicated legal term that should be defined by the contracting parties. The requirements listed in the regulations contain vague standards and terms, such as “adversely affecting a carrier's costs or expenses.” We believe this section is outside the scope of the law and addresses issues not contemplated by the law. Therefore, we suggest a simplified approach.

- PCMA requests that that 1A(1) to (4) be struck and replaced with “A carrier that contracts with a pharmacy benefits manager to perform any activities related to the carrier’s prescription drug benefits is responsible for ensuring 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 management of activities related to the carrier’s prescription drug benefits to exercise good faith and fair dealing in the performance of its contractual duties and notify the carrier in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents a conflict of interest.”

The following items are concerns that PCMA would like to offer comments for consideration.

### Section 3. Definitions:

- Defines “pharmaceutical rebate” as a discount or other price concession that is paid by a manufacturer or third party directly or indirectly to a PBM or a pharmacy that causes the PBM or pharmacy to pay less than retail or list price for a drug.
  - PCMA requests that this definition be stricken as does not reflect how the rebate process works and drug pricing works. PBMs do not pay “less than the list price” at the point of sale; rebates are paid retroactively based on utilization that has occurred in the past and ultimately reduce the net cost of the drug.
  - PCMA suggests replacing with “Pharmaceutical rebate means a formulary discount or concession attributable to the utilization of prescription drugs in the state of Maine, that is paid by a manufacturer to a pharmacy benefit manager after the pharmacy benefit manager processes a claim from a pharmacy.” This definition more accurately describes “pharmaceutical rebate” as the claim is processed by a pharmacy benefits manager with the manufacturer’s list price and then discounted later on.
  - PCMA requests that “spread pricing” be deleted from the definitions and by incorporation in Section 5 1A(4) since it is inappropriate to be included in fiduciary standards.

### Section 4 Licensing Requirements:

- 1B(6) states “[w]hether 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.” This language is too broad and we want specificity so PBMs are on notice as to what to report to the BOI.
  - PCMA requests that this be struck and replaced with “If the applicant, or any company or organization controlling the operation of the applicant, has experienced any data security breaches or HIPAA security breaches related to member data please attach all pertinent information regarding the breach on the application.”
- 1C(3) requests “[t]he 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.”
  - PCMA requests clarification on the “if applicable” piece. Does this mean if the PBM had beneficiaries in Maine during the previous year or something else?

- 1C(4)(b) requests the projected ratio of retail pharmacies to plan enrollees by county.
  - PCMA would like to know if this type of data is already being reported by the carriers in Maine. If so, this is duplicative and unnecessary.
- 1D(1) requests “[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.”
  - PCMA requests to add “including the cost-sharing amount paid by a covered person” in the rulemaking as it was included in the law.
- 1D(4) requests “[d]ocumentation 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.”
  - PCMA requests that this be struck and that the BOI look to the Centers for Medicare and Medicaid Services’ conflict of interest standards in the interpretation of the law.

Section 5 Oversight and Contracting Responsibilities:

- 1B requests an executed original of the form of Agreement Concerning Fiduciary Obligations specified by the Superintendent.
  - PCMA requests that this be struck as carriers are sophisticated purchasers capable of contracting with PBMs and therefore this is to be unnecessary.
- 3 states “[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.”
  - PCMA requests this be stricken as the law is clear that PBMs must charge the “lower of”, therefore this additional language is unnecessary.

We appreciate your consideration of our comments and are happy to answer any questions you have. Please contact me at 202-756-5727 if you have any questions.

Sincerely,



Sam Hallemeier  
Director, State Affairs