## Maine Bureau of Insurance PBM Application Requirements Checklist Updated 10/3/24

Pharmacy Benefit Managers MUST confirm/provide the following information with their application.

REQUIREMENT	REFERENCE	DESCRIPTION OF REQUIREMENT	CONFIRM LOCATION IN APPLICATION MUST EXPLAIN IF REQUIREMENT IS INAPPLICABLE
SECTION 1. APPLICA	NT INFORMAT	ΓΙΟΝ	
Basic information	24-A M.R.S. § 4348(1)(A),(B) Rule 210 § 4(1)(A)(1),(5)	Name, address, telephone number and state of domicile	
Service of Process Agent	24-A M.R.S. § 4348(1)(C) Rule 210 § 4(1)(A)(2)	Name and address of applicant's agent for service of process	
Interested persons	24-A M.R.S. § 4348(D) Rule 210 § 4(1)(A)(4)	Name and address of each person beneficially interested. (e.g. ownership of 10% or more)	
Management and Control	24-A M.R.S. § 4348(E) Rule 210 § 4(1) (A)(3)	Name and address of each officer and director.	
Licensing Fee	24-A M.R.S. § 4348(4); 24-A M.R.S. § 601(28-A)	Original issue fee is \$100; renewal fee is \$100 every three years.	

## SECTION 2. APPLICANT QUALIFICATIONS:

## A. Organization & Background

Organizational Documents	24-A M.R.S. §4348(2) Rule 210§4(1)(B)(1)	Articles of Incorporation, partnership agreement trust agreement or other applicable documents, including all amendments; bylaws, rules, regulations, and/or procedures regulating the internal conduct.	
Biographical Information	Rule 210§4(1)(B)(2)	For each officer and director this must include:  (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	

fr w se (6 co ar	awsuit 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.	
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B. Expertise			
Fiduciary Agreement	Rule 210 § 5(1)	A copy of signed Agreement Concerning Fiduciary Obligations (on the website) must be provided for each contracted carrier.	
List of All Current Clients and Contract Template	24-A M.R.S. § 4348(2) Rule 210 §4(1)(C)(2)	Provide a list of all current clients and a template copy of the client contract.  If any client contract provision deviates materially from the standard contract, provide a description of the material deviations.	

Maximum Allowable Cost	24-A M.R.S. §	A pharmacy benefits manager under contract with a carrier,	
Procedures	4350(1)	shall use a single maximum allowable cost list to establish	
Trocedures	\ /	the maximum amount to be paid by a health plan to a	
	Rule 210 84(1)(D)	pharmacy provider for a generic drug or a brand-name drug	
		that has at least one generic alternative 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.	
Changes To Maximum	24-A M.R.S. §	A carrier, or a pharmacy benefits manager under contract	
Allowable Cost List	4350(3)	with a carrier, shall establish a process for removing a	
Procedures	\ /	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.	
List of Prescription Drugs	24-A M.R.S. §	A maximum allowable cost may be set for a prescription	
	4350(2)	drug, or a prescription drug may be allowed to continue on	
		a maximum allowable cost list, only if that prescription	
		drug:	
		A) I (A) (D) (D)	
		A) 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	
		pricing reference, and	
		B) 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 manager.	
		promise in the promise of the manager.	

Disclosure in Contract	24-A M.R.S. § 4350(4) Rule 210 s. 4(1)(D)(2)	A description of allowable cost information that:  -Upon request, discloses the sources used to establish the maximum allowable costs;  -Provides a process for a pharmacy to readily obtain the maximum allowable payment available to that pharmacy under a maximum allowable cost list; and  -At least once every 7 business days, reviews and updates maximum allowable cost list information to reflect any modification of the maximum allowable payment available to a pharmacy under a maximum allowable cost list used.	
Contract Prohibitions	24-A M.R.S. § 4349(3)	The applicant may not enter into a contract or agreement that prohibits a pharmacy provider from:  A) 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  C) Providing information to a state or federal agency, law enforcement agency or the superintendent when such information is required by law.	

Excess Payments at Point of Sale Procedures	24-A M.R.S.§ 4349(4) Rule 210 § 4(1) (D)(1)	Provide 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.	
Pharmacy Payment Procedures	24-A M.R.S. § 4350(8) Rule 210 s. 4(1)(D)(2)	1) A description of methods to ensure that pharmacy providers' payments are not retroactively denied or reduced except for error or fraud; and 2) standards and procedures for determination and payment of ingredient costs and dispensing fees.  The amount paid by the applicant for dispensing a prescription drug must be the ingredient cost plus the dispensing fee less any cost-sharing amount paid by a covered person.  The ingredient cost may not exceed the maximum allowable cost or average wholesale price, as applicable, and must be disclosed by the carrier's pharmacy benefits manager to the carrier.  Only the pharmacy provider that dispensed the prescription drug may retain the payment described in this subsection. A pharmacy provider may not be denied payment or be subject to a reduced payment retroactively unless the original claim was submitted fraudulently or in error.	

Enrollees	Rule 210 §4(1)(C)	The number of projected enrollees or beneficiaries in this State to be serviced by the applicant on an annual basis for all contracted insurers. Also include the projected ratio of retail pharmacies to plan enrollees by county. If applicable, provide the number of enrollees or beneficiaries administered by the applicant for each insurer during the previous year.	
Network	24-A M.R.S. § 4349(5) Rule 210 § 4(1)(C)	A copy of the applicant's network service areas by county in this State for an insurer and the applicant's pharmacy directory list. Indicate which dispense specialty drugs Please list mail order pharmacies separately as they may not be included in determining the adequacy of a retail pharmacy network.  The information must include: -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 -A description of the applicant's plan for providing prescription drugs for rural and underserved populations.	
Appeals	24-A M.R.S. § 4350(5) Rule 210 §(4)(1)(D)(2)	The applicant must 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 carrier or pharmacy benefits manager has a contract to challenge maximum allowable costs for a specified drug.	

Resolution of Appeals Procedures	24-A M.R.S. § 4350(6) Rule 210 §(4)(1)(D)(2)	A description of procedures to respond to, investigate and resolve an appeal within 14 days after the receipt of the appeal.  A) If the appeal is upheld, the carrier or pharmacy benefits 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  B) If the appeal is denied, the carrier or pharmacy benefits 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.	
Prescription Drugs Not on Maximum Allowable Cost List Procedures/Description	24-A M.R.S. § 4350(7) Rule 210 §(4)(D)	A description of procedures for payment for drugs not on the maximum allowable cost list: The applicant must use the average wholesale price to establish the maximum payment for a brand-name drug for which a generic equivalent is not available or a prescription drug not included on a maximum allowable cost list. In order to use the average wholesale price of a brand-name drug or prescription drug not included on a maximum allowable cost list, a carrier, the applicant must use only one national drug pricing source during a calendar year, except that a carrier, or a pharmacy benefits manager under contract with a carrier, may use a different national drug pricing source if the original pricing source is no longer available. The applicant must use the same national drug pricing source for each pharmacy provider and identify on its publicly accessible website the name of the national drug pricing source used to determine the average wholesale price of a prescription drug not included on the maximum allowable cost list.	

Compensation	24-A M.R.S. § 4350-A	All 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 its prescription drug benefits must be:  A) 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  B) Remitted to, and retained by, the carrier.  Compensation remitted to the carrier must be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons.	
Pharmacy and Therapeutics Committee	24-A M.R.S. § 4350-B(1) Rule 210§4(1)(D)(4)	Evidence of establishment of a pharmacy and therapeutics committee. A carrier shall require its pharmacy and therapeutics committee or the pharmacy and therapeutics committee of the carrier's pharmacy benefits manager to use one or more formularies.	
Rebates	Rule 210§4(D)(3)	If applicable, provide a description of how the applicant intends to comply with the requirement to use all rebates for the benefit of covered persons.	

Procedures for Determining Conflicts of Interest for Committee  SECTION 3. FINANCIA	24- M.R.S. § 4350-B(2),(3) Rule 210 s. 4(1)(D)(4)	A pharmacy benefits manager may not allow a person with a conflict of interest, as described in paragraph A or B, to be a member of its pharmacy and therapeutics committee. A person may not serve as a member of a pharmacy and therapeutics committee if the person:  A) Is employed, or was employed within the preceding year, by a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor; or  B) Receives compensation, or received compensation within the preceding year, from a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.  The applicant shall prohibit its pharmacy and therapeutics committee or any member of the committee from receiving any compensation from a pharmaceutical manufacturer, developer, labeler, wholesaler or distributor.	
Audited Financial Statement	24-A M.R.S. § 4348(2) Rule 210 §4(1)(E)(1)	Applicant's most recent fiscal year-end audited financial statement	
Third Party Administrator License Information	24-A M.R.S. § 4348(2) Rule 210 §4(1)(E)(2)	The applicant must demonstrate 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.	
Business Plan	24-A M.R.S. § 4348(2) Rule 210	A description of the applicant's business plan and evidence that the applicant has the financial integrity to offer its proposed services.	

§4(1)(E)(3)	