Draft: 3/17/2026

Adopted by the Executive Committee and Plenary Aug. 14, 2026
Adopted by the Market Regulation and Consumer Affairs (D) Committee March 25, 2026

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDANCE FOR REGULATORS

Maintained by the Pharmacy Benefit Management (D) Working Group of the Market Regulation and Consumer Affairs (D) Committee

The NAIC has prepared this publication to assist state insurance regulators that are considering licensure or regulation of pharmacy benefit managers (PBMs). It is not a model law and, as such, is not intended to represent a uniform standard for all state insurance regulators.

A regulator using these guidelines should refer to the laws adopted by their state when determining its requirements for licensure, registration, or regulation of pharmacy benefit managers.

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SECTION 1: INTRODUCTION

The purpose of this document is to serve as a guide for state insurance regulators that are considering pharmacy benefit manager licensure or regulation. It includes sample standards and criteria for the licensure of pharmacy benefit managers and their operations as defined in state law.

State insurance regulators may wish to license PBMs to:

(1) Promote, preserve, and protect the public health, safety and welfare; and

(2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act (15 U.S.C. §§ 1011 – 1015), as well as to ensure access and affordability in prescription drug benefits.

PBM licensing best practices include:

(1) Providing for powers and duties of the commissioner; and

(2) Prescribing enforcement standards and appeals processes for violations of state law.

The document includes the following sections:

1. Core licensing guidelines for PBMs – This section provides core licensing standards for licensing PBMs.
2. Illustrative operational requirements under license – This section goes beyond core licensing standards and addresses additional PBM operational requirements under the license for consideration. Some states have enacted or proposed laws establishing these operational standards. The examples provided here reflect standards that certain legislatures have adopted or considered as part of broader regulation tied to a PBM's license to operate in the state.
3. Additional policy resources - This section details additional NAIC resources for states that wish to consider further regulation of a PBM's operations or the pharmacy benefit, and a brief illustrative list of additional PBM regulations some states have proposed or enacted into law.

SECTION 2: CORE LICENSING GUIDELINES FOR PBMS

The following section reflects core licensing standards for states that wish to begin licensing pharmacy benefit managers (PBMs).

Definitions

States should ensure that key terms are clearly defined in state law when establishing licensing standards for PBMs. Definitions of terms such as covered person, health plan, health carrier, pharmacist, and pharmacy used in the licensure of PBMs should be consistent with their existing state laws or regulations to maintain uniformity and avoid introducing new interpretations of currently defined terms.

For new licensure standards, the only essential term to define is "pharmacy benefit manager," as all other terms necessary for licensing should already be addressed in a state's insurance or pharmacy statutes and regulations.

Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

A. (1) "Pharmacy benefit manager" means a person or entity that administers or processes prescription drug benefits on behalf of a health plan that is issued, delivered, or renewed in this state, is subject to state insurance regulation, and provides coverage to residents of this state, unless defined differently in state law.

(2) Pharmacy benefit manager does not include:

(a) A health care facility, pharmacist, or pharmacy licensed in this state;

(b) A health care professional licensed in this state;

(c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or

(d) A health carrier to the extent that it administers or processes prescription drug benefits exclusively for its enrollees.

Applicability & Scope

When establishing new standards, a state's statutes should clarify the applicability to PBMs currently operating in the state and to in-scope PBM-health plan contracts, as defined in state law, that are currently in-force.

For example, a state may determine that new rules apply to a PBM's in-scope operations for a contract with a health plan that is issued, renewed, recredentialed, amended or extended on or after the effective date of any regulatory changes as prescribed by the commissioner and provide that the commissioner will establish a timeline for compliance.

States should also clarify the applicability of licensing standards upon the date of license. For example, a state may consider, as a condition of licensure, any in-scope contract must comply with the state's licensing standards that relate to that contract upon issuance, renewal, recredentialing, or amendment, on or after the effective date of the PBM's license.

States should take care to provide that their licensing standards are not intended and should not be construed to conflict with existing relevant federal law.

Note: States should refer to state and federal law and consult the NAIC'S ERISA Handbook for additional, general guidelines.

Licensing Requirements

States should provide for the licensing process, including addressing the following items:

- License required – States should provide that a person may not establish or operate as a pharmacy benefit manager in this state for health plans subject to state insurance regulation without first obtaining a license from the commissioner.

- Commissioner authority to establish key requirements – States should permit the commissioner to adopt regulations establishing the licensing application and financial reporting requirements for pharmacy benefit managers.

- Key application materials – States should require a person applying for a pharmacy benefit manager license to submit an application for licensure in the form and manner prescribed by the commissioner. The state should specify key documents and forms to include in the application, such as:

  (1) Articles of Incorporation or other entity formation documents which contain stamps or certification of filing with the Secretary of State of the domicile state;

  (2) Organizational Chart detailing entity structure of officers;

  (3) Provide names, business and mailing address, email addresses and phone number for individuals responsible for regulatory compliance and complaints;

  (4) Certificate of Good Standing or other documentation verifying registration in the applying state;

(5) Completed Biographical Affidavit UCAA Form 11 or state form as prescribed by the commissioner for all officers and managing owners with more than 10% ownership in the entity;

(6) Surety Bond in the amount prescribed by the commissioner and all applicable state laws and regulations;

(7) Errors & Omissions Coverage in the amount prescribed by the commissioner and all applicable state laws and regulations;

(8) Audited Financials or other approved financial statement form approved by the commissioner showing financial viability;

(9) List of all affiliations of a health insurer, health care center, hospital service corporation, medical service corporation, sub-contractors with noted duties pursuant to agreements between parties, or fraternal benefit society licensed in the state of application attested to by an officer of the applying pharmacy benefit manager entity; and

(10) Any other state specific documents deemed necessary by the commissioner.

- Non-refundable application fee – States should specify that a person submitting an application for a pharmacy benefit manager license shall include with the application a non-refundable application fee as prescribed by the commissioner and applicable state laws and regulations.

  Note: States should consider setting the licensing fee to reflect the median PBM licensing fee across states when adjusted to exclude outliers. States may wish to consider the most updated information reflecting the median fee, including an NAIC compilation of state licensing fees, if available.

- Authority to deny a license – States should authorize the commissioner to refuse to issue or renew a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible or of good personal and business reputation or has been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction. States should specify written advance notice requirements should the commissioner elect to refuse to issue or renew a license.

- Renewal requirements – States should provide for renewal requirements, including:

  (1) Validity – States should specify that, unless surrendered, suspended or revoked by the commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager continues to do business in the state and remains in compliance with the provisions of the state's statutes and any applicable rules and regulations, including the payment of an annual/biennial/triennial license renewal fee as prescribed by applicable state laws and regulations and completion of a renewal application on a form prescribed by the commissioner.

  (2) Timing for renewal – States should specify when such renewal fee and application must be received. For example, a state may specify that they must be received by the commissioner on or before the designated renewal date or the anniversary of the effective date of the pharmacy benefit manager's initial or most recent license as prescribed by the commissioner and applicable state laws and regulations.

(3) Key application materials – The state should specify what materials should be included in the renewal application. For example, states may wish to specify that the renewal application must include:

(a) Audited financials or other financial statement form approved by the commissioner showing financial solvency as determined by the commissioner; and

(b) Proof of continuation of previously submitted bonds or newly executed surety and error and omissions bonds.

- Requirements After Inactivation of License – States should clarify the requirements that apply to a PBM after its license becomes inactive, including whether the PBM must maintain surety and E&O bonds for a defined period of time and what, if any, reporting requirements may continue to apply for a limited time. For example, states may use language such as the following:

(1) The pharmacy benefit manager shall maintain surety and errors and omissions bonds for a period of at least one year immediately following the surrender, non-renewal or revocation of the license.

(2) All data calls and reporting may be required for the months the pharmacy benefit manager was actively licensed and conducting business in the state.

Proof of Network Adequacy Requirements and Reporting.

Note: States should consider their existing network adequacy laws when establishing PBM network adequacy or other standards.

While many states impose network adequacy standards on health insurance issuers contracting with PBMs to ensure prescription drug access, states may also wish to establish standards for a PBM's own pharmacy networks that are in-scope to promote reasonable patient access. If a state elects to apply network adequacy requirements directly to PBMs, it may consider language such as the following:

(a) A pharmacy benefit manager's network shall be reasonably adequate, shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence and shall not be comprised only of mail order pharmacy benefits but have a mix of mail order and physical stores in this state.

(b) A pharmacy benefit manager shall provide a network report describing the pharmacy benefit manager's network and the mix of mail-order to physical stores in this state in a time and manner required as prescribed by the commissioner. A pharmacy benefit manager's network shall include a detailed description of any separate, sub-networks for specialty drugs.

(c) Failure to provide a timely report or meet the network adequacy standards provided in subparagraph (a) of this paragraph may result in the suspension, revocation, or denial of a pharmacy benefit manager's license by the commissioner.

Note: States may also consider adding a waiver provision for applicants and licensees unable to meet the network adequacy requirements under this subsection.

Enforcement

States should provide for enforcement of licensing requirements, including addressing the following items:

- Commissioner enforcement authority – States should specify that the commissioner must enforce compliance with all applicable laws and regulations of the state, unless this is already addressed generally in state insurance law.

- Regulatory Examinations – If state statutes do not already provide general authority, states should provide for the commissioner's authority to examine a licensed PBM's relevant books and records to determine compliance with state law and clearly specify when such information or data is not subject to public disclosure. For example, states may use language such as the following:

  (1) The commissioner may examine or audit the relevant books and records of a licensed pharmacy benefit manager for a health plan subject to state insurance regulation to determine compliance with all state laws and regulations.

  (2) All pharmacy benefit managers licensed in this state shall provide to the commissioner or their designee convenient and free access, at all reasonable office hours, to all books and records directly relating to compliance with the PBM laws and regulations of the state.

  (3) The cost of the examination shall be the responsibility of the pharmacy benefit manager. It can be considered that if the examination was the result of a complaint filed and it is determined that the complaint was not justified, the commissioner can consider not requiring payment from the pharmacy benefit manager.

  (4) The information or data acquired during an examination under paragraph (1) is:

    (a) Considered proprietary and confidential;

    (b) Not subject to the [Freedom of Information Act] of this state;

    (c) Not subject to subpoena; and

    (d) Not subject to discovery or admissible in evidence in any private civil action.

- Use of examination materials – States should specify that the commissioner may use any document or information provided during the regulatory examination to determine compliance with all applicable state laws and regulations.

- Enforcement of additional operational standards – If a state imposes additional operational standards on PBMs, the state may grant the commissioner authority to impose a penalty on a pharmacy benefit manager or the health plan with which it is contracted, or both, for any violation of those operational standards enumerated in state laws and regulations.

- Appeals – Unless addressed in a general statute, states should provide for an appeals process for any administrative action or fine imposed upon a pharmacy benefit manager in accordance with state laws and regulations.

Effective and Compliance Dates

When establishing new licensing standards, a state's statutes should clarify the transition period for a person doing business in the state as a pharmacy benefit manager on or before the effective date of any changes in state laws or regulations. Depending on the complexity of the standards, PBMs should be given at least six (6) months to one (1) year to come into compliance following the effective date of the change.

Note: States' laws or regulations may vary on when a change in state law or regulation is effective and when compliance is required. As such, states should review their laws and regulations and ensure the effective and compliance dates are drafted accordingly, ensuring there is clarification on the application to existing PBM-health plan contracts that are in-force on the effective date, compliance date, or date of licensure, whichever is applicable.

SECTION 3: ILLUSTRATIVE OPERATIONAL REQUIREMENTS UNDER LICENSE

The following section moves beyond core licensure standards. These include additional PBM operational standards that some states have enacted or proposed that are tied to a PBM's license to operate in the state.

Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices

Some states have adopted or considered restrictions to prohibit specified practices to address concerns about transparency and patient access to information. These standards go beyond core licensure requirements but may be enforced as part of the PBM's authority to operate in the state. The following language illustrates approaches states may consider when addressing related prohibited practices tied to a PBM's license.

- Gag clause prohibition – While gag clauses are generally not permitted, states may wish to specify that in any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription services for health plans subject to state insurance regulation, no pharmacy or pharmacist may be prohibited, restricted or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding:

  (1) The nature of treatment, risks or alternative thereto;

  (2) The availability of alternate therapies, consultations, or tests;

  (3) The decision of utilization reviewers or similar persons to authorize or deny services;

  (4) The process that is used to authorize or deny healthcare services or benefits; or

  (5) Information on financial incentives and structures used by the health plan.

- Total cost transparency – States may consider providing that a pharmacy benefit manager may not prohibit a participating pharmacy or pharmacist providing prescription services for health plans subject to state insurance regulation from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

- Permissible disclosure to regulators – States may consider providing that a pharmacy benefit manager contract with a participating pharmacist or pharmacy providing prescription services for health plans subject to state insurance regulation may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials, provided that:

  (1) The recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and

  (2) Prior to disclosure of information designated as confidential the pharmacist or pharmacy:

    (a) Marks as confidential any document in which the information appears; or

(b) Requests confidential treatment for any oral communication of the information.

- Limits on contract termination – States may wish to prohibit a pharmacy benefit manager from terminating the contract of or penalizing a participating pharmacist or pharmacy providing prescription services for health plans subject to state insurance regulation for:

  (1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by law or the commissioner; or

  (2) Sharing any portion of the pharmacy benefit manager contract with the commissioner pursuant to a complaint or a query regarding whether the contract is in compliance with state law or regulation.

Submission of Key Service Contracts and Arm's Length Agreements

Some states have adopted or considered requiring applicants for PBM licenses to submit representative copies of key service contracts or arm's length agreements to confirm compliance with prohibited practices or other non-core licensing requirements, such as network adequacy and reporting. These standards go beyond core licensure requirements but may provide the regulator with additional information to confirm the PBM's compliance with state law prior to license issuance. The following language illustrates approaches states may consider when requiring additional materials prior to license issuance.

- Representative service contracts – States may wish to specify that a person submitting an application for a pharmacy benefit manager license must file representative copies of its standard pharmacy network/provider participation agreement, standard health carrier/client services agreement, and any material subcontracting or delegation agreements as part of the license application.

- Arm's length agreements – States may wish to specify that if any facilities, personnel, services, or networks are provided or held by an entity other than the person submitting the application, including a parent company, subsidiary, or affiliate, the person submitting the application must maintain and submit an arm's length agreement establishing the person's legal right of access to and use of those resources in accordance with good corporate governance.

Digital Infrastructure and Information Security

Some states have adopted or considered requiring applicants for PBM licenses to provide information relating to their digital infrastructure and information security. These standards go beyond core licensure requirements but may provide the regulator with additional information to confirm the PBM's compliance with state law prior to license issuance. The following language illustrates approaches states may consider when requiring additional materials prior to license issuance.

- Digital infrastructure – States may wish to specify that a person submitting an application for a pharmacy benefit manager license must demonstrate, as part of the license application, that it has adequate digital infrastructure, personnel, systems, and processes to securely process claims, safeguard records, and implement reasonable cybersecurity and breach-reporting measures.

- Information security – States may wish to specify the documentation applicants must provide to demonstrate operational readiness and information security controls, including:

  (a) A written attestation from a responsible officer confirming the existence of policies, personnel, and systems designed to protect data and ensure secure claim processing;

(b) A summary description of digital infrastructure and cybersecurity measures, including data encryption, access control, and backup protocols;

(c) Copies or summaries of the applicant's cybersecurity and incident response policies; and

(d) Representative copies of any third-party or affiliate service agreements governing digital systems, data access, or hosting arrangements, which must include provisions ensuring confidentiality, breach notification, and legal right of access.

- Maintenance – States may wish to, further, specify that licensees must maintain such infrastructure, controls, and documentation on an ongoing basis throughout the term of licensure and make them available to the commissioner upon request.

SECTION 4: ADDITIONAL POLICY RESOURCES

States may choose to explore policy options that go beyond core and non-core PBM licensure requirements. These considerations often involve regulating aspects of PBM operations or the pharmacy benefit itself. For additional detail on these policy approaches, states should consult the following resources:

- The *Health Carrier Prescription Drug Benefit Management Model Act* (#22), which provides standards for the establishment, maintenance and management of prescription drug formularies and other procedures used by health insurance issuers that provide prescription drug benefits.
- The *Health Benefit Plan Network Access and Adequacy Model Act* (#74), which establishes standards for the creation and maintenance of networks by health carriers to ensure the adequacy, accessibility and quality of health care services offered under a managed care plan.
- Chapter XX, Conducting the Pharmacy Benefit Manager Examination, of the *Market Regulation Handbook*
- *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* and *Guidance Document – ERISA Preemption and State PBM Laws* (NAIC Guidance Documents)
- *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (NAIC White Paper)
- *Compilation of State Pharmacy Benefit Manager Business Practice Laws*

The following sample requirements reflect policy standards that some states have explored or implemented as part of broader PBM regulation. These examples illustrate obligations linked to pharmacy benefits and PBM business practices. For more information, consult the *Compilation of State Pharmacy Benefit Manager Business Practice Laws*.

Sample Requirements Beyond Licensure Include:

- Parity in treatment of affiliated and non-affiliated pharmacies
- Retroactive or point of sale fees limits
- Reporting or transparency requirements relating to pharmacy reimbursements and/or rebates
- Pharmacy credentialing or network participation requirements