

December 3, 2025

Joylynn Fix, Chair
Susan Jennette, Co-Vice Chair
Ashley Scott, Co-Vice Chair
PBM (D) Working Group
National Association of Insurance Commissioners
1101 K Street, N.W., Suite 650 Washington, DC 20005

Submitted via email: Jolie Matthews (jmatthews@naic.org)

RE: BCBSA Comments on Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators Document

Dear Chair Fix, Vice Chair Jennette and Vice Chair Scott,

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators ("Draft") as distributed through the NAIC PBM Working Group.

BCBSA is a national federation of 33 independent, community-based and locally operated BCBS companies (Plans) that collectively cover, serve, and support 1 in 3 Americans in every ZIP code across all 50 states and Puerto Rico. BCBS Plans contract with 96% of hospitals and 95% of doctors across the country and serve those who are covered through Medicare, Medicaid, an employer, or purchase coverage on their own.

BCBSA acknowledges NAIC's charge to develop licensing and registration standards for PBMs in alignment with state and federal requirements. However, we have concerns that the best practices in this Draft go beyond licensing and recommend or highlight select policy options for PBM regulation without deference to state laws that regulate PBMs. Below we outline our key perspectives. Attached you will find additional recommendations in the Draft document for NAIC's consideration as you work toward a final version.

- Market Regulation Handbook Process: We seek clarification on how this guideline
 document will be adopted through the NAIC process and potentially incorporated into
 the handbook chapter that is still in development. We note that the Draft appears to
 extend beyond guidance or best practices related to licensure and could be
 misconstrued by examiners to establish policy standards that have not been adopted by
 a state.
- Licensing Requirements vs. Policy Requirements: As this document does not constitute a model act, the guidelines should focus on licensure and fundamental

Department of Insurance (DOI) requirements directly associated with licensure. Several provisions in this section are inconsistent with a guidance or best practices document pertaining to licensure. We recommend NAIC remove provisions that are outside the scope of licensure, as outlined below and in the attachment, or include a drafting note indicating states should confirm whether the best practices align with existing state law.

- Section 5(G)(1)(2): NADAC reporting. NADAC prices are publicly available and updated on a regular basis. Requiring PBMs to report this data is not additive. If this subsection is related to reimbursement requirements based on NADAC pricing or other substantive policy, we recommend removal.
- Section 5(G)(4): Network Adequacy Reporting. Pharmacy network adequacy standards are specific to state laws and regulations and should not be included in this licensing guideline document. Similarly, guidelines should not limit a PBM from applying more quality and cost-reduction standards to PBM contracts with pharmacies, particularly when higher standards are warranted for patient safety (e.g., specialty pharmacies).

Thank you for the opportunity to continue collaborating with NAIC on this important work. If you have any questions or want additional information, please contact Tyler Hoblitzell at tyler.hoblitzell@bcbsa.com.

Sincerely,

Clay S. McClure

Senior Director, State Affairs

Clay & Mcha

Blue Cross Blue Shield Association

Attachment

Draft 11/7/25

Comments are being requested on this draft on or before Dec. 1, 2025. Comments should be sent by email only to Jolie Matthews at imatthews@naic.org.

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

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Section 1. Short Title

This best practice document shall be known and may be cited as the Pharmacy Benefit Manager Licensure and Regulations Guidelines for Regulators.

Section 2. Purpose

- A. This document establishes best practices for regulators in developing the standards and criteria for standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug and or device services for health benefit plans.
- B. The purpose of this document is to provide guidelines for regulators to:
 - (1) Promote, preserve, and protect the public health, safety and welfare through effective regulation and licensure of pharmacy benefit managers;
 - (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 provide for consumer savings, and fairness in prescription drug benefits;
 - (3) Provide for powers and duties of the commissioner; and
 - (4) Prescribe penalties and fines for violations.

Section 3. Definitions

Drafting Note: States should adjust terminology in this document review and modify the definitions below, if needed, for consistency with definitions under their state laws or regulations.

A. "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

Commented [BCBSA1]: We recommend that this be revised to clarify that these are best practices and are not regulations, absent the appropriate adoption in a state. See also 4.D.

Commented [BCBSA2]: We recommend the removal of Section 3 definitions. Every state already has definitions in their insurance codes and this is not required in a guidance document. A brief drafting note in the guidance that acknowledges the state's definitions for purposes of licensure and oversight is all that is needed.

Should NAIC retain Section 3, BCBSA provides recommendations to align with current NAIC language or common definitions.

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- (1) Receiving payments for pharmacist services;
- (2) Making payments to pharmacists or pharmacies for pharmacist services; or
- (3) Both paragraphs (1) and (2).
- 3. "Commissioner" means the Commissioner of Insurance.

Drafting Note: Use of the title of the chief insurance regulatory officer wherever the term "commissioner" appears.

- C. "Covered person" means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.
- D. "Data calls" generally means a request for specific information or datasets from various sources, such as organizations, departments, or individuals. It often serves as a crucial step in gathering and consolidating data for analysis, reporting, or decision-making.
- E. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services. A health benefit plan does not include a self-funded group health plan.
- F. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting 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.

Drafting Note: Federal law uses the term "health insurance issuer" instead of "health carrier." The definition of "health carrier" is consistent with the term "health insurance issuer" and does not include self-funded group health plans.

- G. "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:
 - (1) Negotiating rebates, discounts or other financial incentives and arrangements with drug companies;
 - (2) Disbursing or distributing rebates;
 - (3) Managing or participating in incentive programs or arrangements for pharmacist services;

Commented [BCBSA3]: Should the NAIC retain Section 3, BCBSA recommends amending this definition to clarify this licensure guidance document does not extend to self-funded plans.

Commented [BCBSA4]: Should the NAIC retain Section 3, BCBSA recommends adding this Drafting Note which is similar to language used in other NAIC model rules and is intended to clarify the scope of these guidelines.

- (4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;
- (5) Developing and maintaining formularies;
- (6) Designing prescription benefit programs; or
- (7) Advertising or promoting services.
- H. "Pharmacist" means an individual licensed as a pharmacist by the [state] Board of Pharmacy.
- "Pharmacist services" means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.
- J. "Pharmacy" means the place licensed by the [state] Board of Pharmacy in which drugs, chemicals, medicines, prescriptions and poisons are compounded, dispensed or sold at retail.
- K. (1) "Pharmacy benefit manager" means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides both claims processing services or and other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans.
 - (2) Pharmacy benefit manager does not include:
 - (a) A health care facility 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 performs any claims processing and other prescription drug or device services exclusively for its enrollees.

Section 4. Applicability

- A. This document shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of any regulatory changes as prescribed by the commissioner including any health carrier that performs claims processing or other prescription drug or device services through a third party. The commissioner shall establish a timeline for compliance.
- B. As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this state shall comply with the guidelines of this document.
- C. Nothing in this document is intended or shall be construed to conflict with existing relevant federal law.

Drafting Note: Nothing in this document is legally binding unless it is formally adopted in accordance with section 8.

Commented [BCBSA5]: Should the NAIC retain Section 3, we recommend the definition of PBM include both the functions of claims processing services and the services outlined in subsection (G).

"(1)"Pharmacy benefit manager" means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides both claims processing services or and other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans."

We are concerned that as written the definition of PBM would include any entity that provides any one service under subsection (G) for health benefit plans. For example, an advertising firm providing promotional services for a health benefit plan would be considered a PBM under this definition. A contracted actuarial firm that "designs a prescription benefit program" would also be classified as a PBM.

Commented [BCBSA6]: We recommend including this to clarify that this document, as drafted and named, is a best practices document and does not carry the weight of law unless adopted as such by the applicable state.

Section 5. Licensing Requirement

- A. A person may not establish or operate as a pharmacy benefit manager in this state for health benefit plans without first obtaining a license from the commissioner.
- B. The commissioner may adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers.
- C. A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the commissioner with the following documents and forms:
 - (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 solvency;
 - (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.
- D. 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. Attached to this document is a list of fees by state.
- E. (1)The commissioner may 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.

(2) In the event that the action by the insurance commissioner is to nonrenew or to deny an application for a license, the insurance commissioner shall notify the applicant or licensee and advise, in writing, the applicant or licensee of the reason for the denial or nonrenewal of the applicant's or licensee's license. The applicant or licensee may make written demand upon the insurance commissioner within [insert appropriate time period from state's administrative procedure act] for a hearing before the insurance commissioner to determine the reasonableness of the insurance commissioner's action. The hearing shall be held within [insert time period from state law] and shall be held pursuant to [insert appropriate reference to state law]

- F. Renewal requirements.
 - (1) 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 this state and remains in compliance with the provisions of this act and any applicable rules and regulations, including the payment of an annual license renewal fee as prescribed by the commissioner and applicable state laws and regulations and completion of a renewal application on a form prescribed by the commissioner.
 - (2) Such renewal fee and application shall be received by the commissioner on or before 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) The renewal application shall include:
 - (a) An attestation by an officer of the pharmacy benefit manager whether or not in the previous year, the licensee or any contracted health plan engaged in the practice of steering or imposed point of sale or retroactive fees in connection with its health plans and insureds;
 - (b) Audited financials or other financial statement form approved by the commissioner showing financial solvency as determined by the commissioner; and
 - (c) Proof of continuation of previously submitted bonds or newly executed surety and error and omissions bonds.
- G. Requirements after approval of license in the form and process prescribed by the commissioner and all applicable state laws and regulations.
 - (1) Provide the National Average Drug Acquisition Cost (NADAC) established by the federal Centers for Medicare & Medicaid (CMS) report:
 - (a) For the months of January through April, no later than June 15;
 - (b) For the months of May through August, no later than October 15; and
 - (c) For the months of September through December, no later than February 15 of the following year.
 - (2) On or before March 1 of each year, provide the website domain and uniform resource locator (URL) for public access to the pharmacy benefit manager's NADAC reports.

Commented [BCBSA7]: We recommend including the following language from the NAIC <u>Producer Licensing Model Act</u>, Section 15(G) to provide avenues for the appeal of a commissioners' decision to align with other model acts and to ensure a fair licensing process

Commented [BCBSA8]: We recommend that this section be removed. Some states require that pharmacies be reimbursed based on the NADAC prices, but it is not uniform. This is a state-specific requirement and should not be in a licensing guidance document as written.

In addition, NADAC reports are public, with the National Average Drug Acquisition Cost (NADAC) reference files being freely available on the Medicaid.gov and Data.Medicaid.gov. These resources are updated regularly and contain the calculated average prices for prescription drugs, making them accessible to the public.

- (3) Report all rebates and other payments received in the preceding year from pharmaceutical manufacturers on behalf of each health plan the pharmacy benefit manager is contracted with on a form or process as prescribed by the commissioner.
- (4) Proof of Network Adequacy Requirements and Reporting.
 - (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 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 may result in the suspension or revocation of a pharmacy benefit manager's license by the commissioner.
 - (d) A pharmacy benefit manager may not require a pharmacy or pharmacist, as a condition for participating in the pharmacy benefit manager's network, to obtain or maintain accreditation, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or other relevant federal or state standards.

Drafting Note: States may not be able to include mail order to meet network adequacy or other standards to meet regulatory reporting standards.

- H. Requirements After Inactivation of License.
 - (1) The pharmacy benefit manager shall maintain a 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 shall be required for the months the pharmacy benefit manager was actively licensed and conducting business in the state.

Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices

- A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, 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;

Commented [BCBSA9]: We recommend adequate guardrails for any disclosure of submitted rebate information to protect propriety and competitive data. Reported data should be protected consistent with state Uniform Trade Secrets Acts and not be subject to the [Freedom of Information Act] of the state.

Commented [BCBSA10]: We recommend Section 4(a) and (b) be removed. These are subject to state specific network adequacy requirements and regulations and should not be included in a licensing guideline document.

Commented [BCBSA11]: We recommend substituting a more appropriate penalty for failure to report, other than suspension or revocation of a PBMs license. For example, a corrective action plan may better serve enforcement while not disrupting access to prescription drugs.

Consumers would face a substantial disruption to their prescription drug access in a scenario where a license is revoked. If a health plan's contracted PBM loses a license due to a missed report, that would impact member access to prescriptions, processing of claims, and loss of programs intended to support member adherence to prescriptions and prevent harmful drug-to-drug interactions.

Commented [BCBSA12]: We recommend striking "more stringent than" in Section 4(d). These guidelines for regulators document should not prevent a PBM from applying more quality and cost-reduction standards than minimum credentialing requirements under the state, as long as the requirements are applied uniformly.

Additional accreditations are sometimes necessary specifically for pharmacies that dispense specialty medications that require special handling and patient counseling.

- (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 insurer.
- B. A pharmacy benefit manager may not prohibit a pharmacy or pharmacist 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.
- C. A pharmacy benefit manager contract with a participating pharmacist or pharmacy 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.
- D. A pharmacy benefit manager may- not terminate the contract of or penalize a pharmacist or pharmacy due to a pharmacist or pharmacy:
 - (1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by state 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.
- E. (1) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.
 - (2) Any amount paid by a covered person under this subsection shall be attributable toward any deductible or, to the extent consistent with section 2707 of the Public Health Service Act, the annual out-of-pocket maximums under the covered person's health benefit plan.

Section 7. Enforcement

- A. The commissioner shall enforce compliance with all applicable laws and regulations of the state.
- B. Regulatory Examinations.
 - (1) The commissioner may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance with all state laws and regulations.

Commented [BCBSA13]: We suggest striking Section 6 as this goes beyond the traditional scope of licensing.

Although many states already restrict gag clauses that prohibit pharmacists from telling a patient about lower-cost Rx options—which BCBSA supports—Section 6 adds further restrictions on PBM-pharmacy contracts. Contract requirements should comply with existing state law and recognize that not all states have the same contract requirements.

If NAIC retains this section in this document we recommend adding a drafting note advising states to review relevant statutes regarding PBM and pharmacy network agreements.

- (2) All pharmacy benefit managers operating 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 the pharmacy benefit manager business affairs.
- (3) The cost of the examination shall be the responsibility of the pharmacy benefit manager. The state should refer to the *Model law on Examinations* (#390) for additional guidance. 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.
- C. The commissioner may use any document or information provided during the regulatory examination to determine compliance with all state laws and regulations.
- D. The commissioner may impose a penalty on a pharmacy benefit manager or the health carrier with which it is contracted, or both, for any violation of state laws and regulations.
- E. An appeals process for any administrative action or fine should be provided to the pharmacy benefit manager in accordance with state laws and regulations.

Section 8. Regulations

The commissioner may, after notice and hearing, promulgate reasonable regulations relating to pharmacy benefit managers that are not in consistent with [this document]. The regulations should be subject to review in accordance with [insert statutory citation providing for administrative rulemaking and review of regulations.]

Section 9. Effective Date

A person doing business in this state as a pharmacy benefit manager on or before the effective date of any changes in state laws or regulations shall have six-twelve (12) months to come into compliance.

Drafting Note: States laws or regulations may vary on when a change in state law or regulation is effective. As such, states should review their laws and regulations and modify the language in this section accordingly.

Commented [BCBSA14]: Should the NAIC include Section 8, we recommend these revisions which are similar to other NAIC regulatory sections.

Commented [BCBSA15]: Should the NAIC include Section 9, we recommend an implementation period of 12 months to allow organizations to establish new processes for compliance and reporting. Enough time to establish these protocols will be important to ensure accurate reporting. States will also need to establish processes for receiving reporting data and to ensure proprietary information and trade secrets and not publicly shared.

Commented [BCBSA16]: We recommend the removal of Sections 8 and 9, as they do not align with the purpose of a licensing guideline or best practices document.