Draft date: 11/10/25

2025 Fall National Meeting
Hollywood, Florida

PHARMACY BENEFIT MANAGEMENT (D) WORKING GROUP
Tuesday, December 9, 2025
2:15 – 3:15 p.m.
Diplomat Convention Center—Grand Ballroom East—Level 2

ROLL CALL

Joylynn Fix, Chair	West Virginia	Norman Barrett/T.J. Patton	Minnesota
Susan Jennette, Co-Vice Chair	Delaware	David Dachs	Montana
Ashley Scott, Co-Vice Chair	Oklahoma	Cheryl Wolff	Nebraska
Molly Nollette/ Sarah S. Bailey/ Heather Carpenter	Alaska	Jonathan Wycoff	Nevada
		Ralph Boeckman/ Erin Porter	New Jersey
Tolanda McNeal	Arizona	Maren Gill	New York
Sophie Thomas	Colorado	Robert Croom	North Carolina
Lena Bahar/Kurt Swan	Connecticut	Janelle Middlestead	North Dakota
Sheryl Parker	Florida	Kristin Cly	Ohio
Paula Shamburger	Georgia	TK Keen/Keith Turner	Oregon
Shannon Hohl	Idaho	Joseph Handline	Pennsylvania
Jack Engle	Illinois	Scott McAnally	Tennessee
Grant Lindman	Indiana	Tanji J. Northrup	Utah
Andria Seip	Iowa	Sebastian Arduengo/ Karla Nuissl	Vermont
Vicki Schmidt	Kansas		
Shaun Orme	Kentucky	Sandy Ray	Washington
Nina Hunter	Louisiana	Lori Luder	Wisconsin
Mary Lou Moran	Massachusetts	Lauren White/Jill Reinking	Wyoming
Joe Stoddard	Michigan		

NAIC Committee Support: Jolie H. Matthews/Tim Mullen

AGENDA

1. Consider Adoption of its Summer National Meeting Minutes
   —*Joylynn Fix (WV)*

2. Hear a Presentation on a Proposed Automated Pharmacy Complaint Tool
   —*Kris Rhea (Pharmacy Marketplace)*

3. Discuss the Draft Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators Document—*Joylynn Fix (WV)*

4. Discuss the Draft PBM Examination Chapter—*Joylynn Fix (WV)*

5. Hear an Update on Potential State Based Systems (SBS) Changes to Better Handle PBM Complaints—*Susan Jennette (DE)*

6. Discuss Any Other Matters Brought Before the Working Group —*Joylynn Fix (WV)*

7. Adjournment

Agenda Item #1

Consider Adoption of its Summer National Meeting Minutes—*Joylynn Fix (WV)*

Draft: 8/15/25

Pharmacy Benefit Management (D) Working Group
Minneapolis, Minnesota
August 11, 2025

The Pharmacy Benefit Management (D) Working Group of the Market Regulation and Consumer Affairs (D) Committee met in Minneapolis, MN, Aug. 11, 2025. The following Working Group members participated: Joylynn Fix, Chair, and Allan L. McVey (WV); Susan Jennette, Co-Vice Chair (DE); Ashley Scott, Co-Vice Chair (OK); Sarah S. Bailey (AK); Erica Bowsher (AZ); Kurt Swan (CT); Sheryl Parker (FL); Paula Shamburger (GA); Andria Seip (IA); Shannon Hohl (ID); Matthew Pickett (IL); Grant Lindman (IN); Isaac Henson and Kenneth Scott (KS); Shaun Orme (KY); Nina Hunter (LA); Mary Lou Moran (MA); Michele Riddering (MI); Norman Barrett (MN); Robert Croom and Tracy Biehn (NC); John Arnold (ND); Michael Muldoon and Margaret Otto (NE); Ralph Boeckman (NJ); Jonathan Wycoff (NV); Tony Bonofiglio (OH); Numi Griffith (OR); Gary Jones (PA); Jud Jones (TN); Shelley Wiseman and Ryan Jubber (UT); Sebastian Arduengo and Karla Nuissl (VT); Andrew Davis (WA); Darcy Paskey (WI); and Lauren White (WY). Also participating was: Howard Liebers (DC).

1. Adopted its Spring National Meeting Minutes

Swan made a motion, seconded by Seip, to adopt the Working Group's March 25 minutes (*see NAIC Proceedings – Spring 2025, Market Regulation and Consumer Affairs (D) Committee, Attachment Five*). The motion passed unanimously.

2. Heard a Presentation from URAC on Pharmacy Benefit Management and Pharmacy Accreditation

Heather Bonome (URAC) discussed URAC's pharmacy benefit management accreditation and specialty pharmacy accreditation programs. She said URAC's pharmacy benefit management accreditation program was launched in 2007. Currently, approximately 25 pharmacy benefit managers (PBMs) are accredited under the program. Bonome discussed the program's scope, which is designed to emphasize transparency, continuous quality improvement, and regulatory compliance. She detailed the requirements PBMs must satisfy to achieve URAC accreditation, including requirements concerning: 1) pricing transparency; 2) clinical decision disclosures; and 3) member support. Bonome discussed URAC's 2025 revisions to the accreditation standards designed to: 1) promote best practices and solid foundational principles; 2) update format to match updated scoring; 3) align PBM and other pharmacy programs; and 4) ensure the program accurately reflects industry standards. She also discussed URAC's accreditation review process.

Bonome discussed URAC's specialty pharmacy accreditation program, including the requirements specialty pharmacies must satisfy to receive URAC accreditation. URAC launched the program in 2008. Currently, over 600 specialty pharmacies are accredited. Requirements include those related to pharmacy operations, medication distribution, patient services and communications, and patient management. She also discussed recent updates to the standards.

Seip asked how URAC monitors PBM price transparency with their clients. She said that Iowa and other states are struggling to obtain such information from PBMs. Bonome said URAC's pharmacy benefit management accreditation standards do not require a PBM to have a specific pricing structure. The standard requires a PBM to have a mechanism for communicating its pricing structure to its clients, so that clients have a clear expectation and understanding of the pricing structure.

Kenneth Scott asked what results URAC is finding with respect to complaints, complaint tracking, and response to those complaints during its accreditation process. He also asked how URAC validates the information PBMs provide about such complaints. Bonome said the pharmacy benefit management accreditation standard for complaints requires the PBM to have a process for handling complaints, as well as a requirement that the PBM sets the turnaround time as a goal for how they resolve complaints. She said that during its desktop review process, URAC looks to understand the process and the PBM's turnaround time for resolving complaints. Following this, URAC conducts a validation review. It requests that the PBM provide a list of all its complaints from which URAC pulls a sample, looking for documentation that the PBM has a process for handling complaints and that those complaints are resolved in accordance with its established turnaround time.

Arduengo asked how URAC developed specialty pharmacy accreditation standards without a clear definition of "specialty drug." Bonome agreed that there is no universal definition of "specialty drug." She explained that despite the lack of such a definition, many categories are typically considered specialty pharmacy. She said URAC has a broad definition of "specialty drug." It defines a "specialty drug" as a drug that requires additional clinical services. It may require additional special handling. Bonome said URAC has structured its accreditation program less around dispensing a specific drug and more around specific services, such as patient management and additional clinical services, that the pharmacy is providing.

Pickett asked about URAC's pricing structure for pharmacy benefit management program accreditation. Bonome explained that URAC has a tiered pricing structure based on the number of lives. She said that for PBMs in the tier one category, accreditation costs between $35,000 and $40,000. Pickett asked about the pricing structure for specialty pharmacy program accreditation. Bonome said URAC's tiered pricing structure is based on the number of scripts. She noted that URAC makes accommodations in pricing for independent and smaller pharmacies.

Jones asked about the structure and role of URAC's board of directors in reviewing and approving new accreditation standards and revisions to existing accreditation standards. Bonome said URAC is a unique independent third-party accrediting organization where patients, providers, and payers all have a seat at the table on establishing what constitutes best practice. She said URAC's board of directors reflects this melding of stakeholders and approves the creation of all its programs. Bonome said its board of directors also oversees the direction of the accreditation programs URAC offers. She said it also serves as the final approval of all URAC standards, whether it is a new accreditation program or a revision to existing accreditation program standards. Bonome said the board of directors is the last step in the review and approval process to ensure the standards are relevant and apply to the industry.

3. Received an Update on the Work to Develop the PBM Examination Chapter

Fix said the Working Group's PBM Examination Chapter Drafting Group has completed work on two sections of the draft PBM examination chapter and plans to complete the remaining sections soon after the Summer National Meeting. She said that after the Working Group receives all the sections and completes its own review, it plans to distribute the initial draft of the PBM examination chapter for public comment. Fix said that after the Working Group finishes its work, the Working Group will forward the draft PBM examination chapter to the Market Conduct Examination Guidelines (D) Working Group for its consideration. She also said that at the request of the Market Conduct Examination Guidelines (D) Working Group, as the subject matter experts on PBMs, a few of the Working Group members plan to participate in the Market Conduct Examination Guidelines (D) Working Group's discussions on the draft PBM examination chapter.

4. Received an Update on the Work to Develop PBM Licensing and Registration Standards

Ashley Scott said the Working Group established a drafting group after the Spring National Meeting to develop an initial draft of the PBM licensing and registration standards. She said the drafting group recently finished its work and forwarded the draft to the full Working Group for its review. She said that following the completion of this review, the Working Group plans to distribute the draft for public comment.

5. Discussed Necessary Changes to SBS to Better Handle PBM Complaints

Fix said she has heard from many states about the need for changes to the State Based Systems (SBS) to better handle PBM complaints. She said she recently reached out to SBS staff to discuss the issue and the best path for moving forward with potential SBS changes. Fix said that after talking to the Working Group's co-vice chairs, Jennette volunteered to spearhead this project and work with any other Working Group members or interested regulator volunteers to develop recommendations for the Working Group's consideration during a future meeting. Jennette said she has some ideas for potential changes and would welcome input from other states to increase the prospect of achieving uniformity across the states in addressing this issue. She asked that anyone interested in volunteering reach out to her.

Having no further business, the Pharmacy Benefit Management (D) Working Group adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/D CMTE/PBMWG/PBMWG MtgMin 8-11-25.docx

Agenda Item #2

Hear a Presentation on a Proposed Automated Pharmacy Complaint Tool
—Kris Rhea (Pharmacy Marketplace)

Building PBM Accountability Through Transparency and Technology

Bridging the Gap: PBM Accountability Through Pharmacy Data Transparency

How States, PSAOs, and Pharmacies Can Collaborate for Sustainable Reform

pharmacy marketplace

pharmacy marketplace

HELLO
MY NAME IS

KRIS RHEA

- Spent the last 15 years working with wholesalers, GPOs, and other strategic partners to help **independent pharmacies**
- Has **visited over 2,500 pharmacies nationwide** to better understand their operations, struggles, and the incredible value they bring to their communities

Make it Possible

pharmacy marketplace

Framing the Core Question:

Key Discussion Points:

Are pharmacies participating and accurately following the appeals process?

What assumptions, and blocks are happening to limit enforcement?

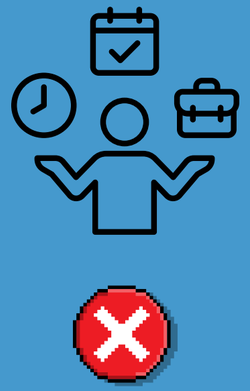
As more states explore reforms,
Are they connecting with **peers** to share lessons and build **standardization**?

Across the board,
As we build out our knowledge base and regulatory framework what are some best practices to eliminate loopholes and invalid appeals?

Purpose of Today's Talk:

To highlight patterns, pitfalls, and opportunities to create an accountability **bridge** between PBMs, pharmacies, and regulators.

PBM Appeal Reform: 50 State Audit



- **Benchmarking Models:** Invoice | NADAC | AAC
- **Timelines:** Law variation for enforceable deadlines for appeal processes. Laws are all over the board for appeal and response.
- **External Complaints:** Dedicated PBM form or General Complaint Form. Is there a contact or documentation for SOP specific to PBM appeals?

pharmacy marketplace

PSAO-Level Constraints

Legal & Regulatory Constraints:

- NDAs and gag clauses restrict transparency.
- Contract terms prevent successful submission of full invoice-to-reimbursement documentation.

Reporting & Operational Limitations:

- PSAO appeal process is a blanket approach.
- PBM contracts often limit data sharing.

pharmacy marketplace

PHARMACIES STRUGGLE TO APPEAL EFFECTIVELY

Key Barriers:

Time Management: High-volume stores can't dedicate staff to track individual claims.

Understanding of Law: Pharmacies unsure of corrective actions to take with PBMs or state complaints. Competency level is limited to get through completed internal and external process.

Assumptions: Many assume PSAO appeal is good enough or PBM will "self-correct" without appeal.

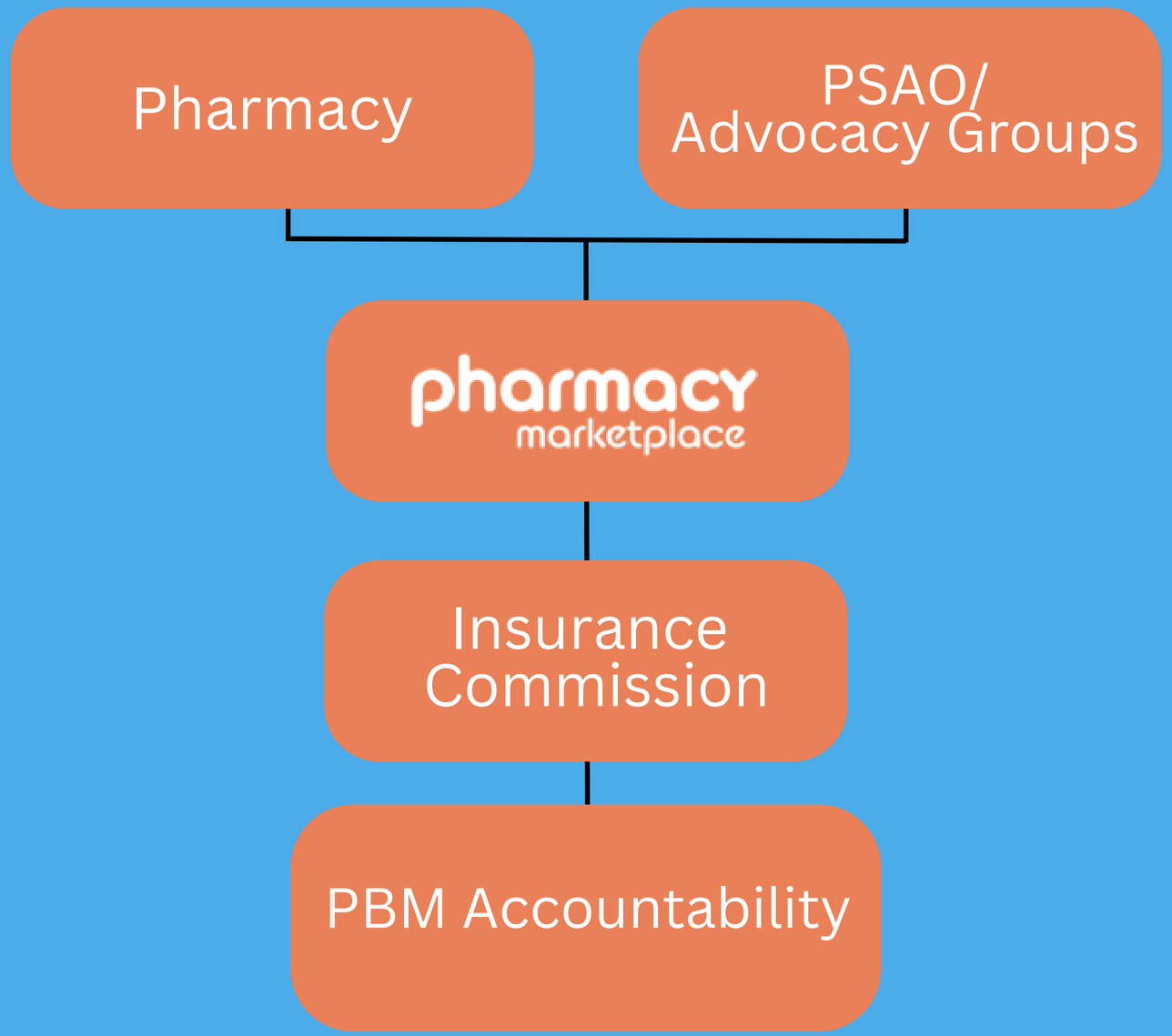
pharmacy marketplace

High Noise, Low Participation:

Pain Points:

- **Invalid Complaints:** Invalid and incomplete complaint submissions.
- **Resource Drain:** Staff time lost reviewing incomplete claims.
- **Low Pharmacy Participation:** States not seeing expected appeal volume after enacted legislation.

pharmacy marketplace



pharmacy
marketplace

How Our Technology Drives Accountability:

Core Features:

- Organization, Verification & Execution:
  - Central dashboard for all appeal data.
  - Validates eligibility and documentation before submission.
  - Keeping pharmacies in compliance with appeal timelines.

- **Intelligence Tools:**
  - Tracks approval rates between internal vs. external appeals.
  - Reconciliation of recoupment rates after claims adjustments.
  - Aggregate state-level data for enforcement insights.

Result:

→ Reduces burden on both pharmacies and state commissions.

pharmacy marketplace

The Path Forward

Key Takeaways:

- PBM fragmentation and fatigue leads to frustrated pharmacies that file invalid complaints if they file at all.
- PBM reform must include **collaboration among all stakeholders**.
- **Technology + collaboration** can declutter enforcement and expose true patterns.

pharmacy marketplace

Agenda Item #3

Discuss the Draft Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators Document—*Joylynn Fix (WV)*

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 jmatthews@naic.org.

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

Table of Contents

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 the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.

B. The purpose of this document is 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 review and modify the definitions below, if needed, for consistency with 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:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. "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.

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.

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;

(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.

I. “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 claims processing services or 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.

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. 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.

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.

(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;

(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.

(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 relating to the 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 promulgate regulations relating to pharmacy benefit managers that are not inconsistent with this document.

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 (6) 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.

COMMENTS

Agenda Item #4

Discuss the Draft PBM Examination Chapter—*Joylynn Fix (WV)*

Draft 11/25/25

Comments are being requested on this draft on or before Jan. 16, 2026. Comments should be sent by email only to Jolie Matthews at jmatthews@naic.org.

Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:
The standards set forth in this chapter are based on state procedures, not on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination process. Since there are limits to state procedures and state laws vary, use of the handbook should be adapted to reflect each state's own laws and regulations with appropriate consideration for any bulletins, audit procedures, examination scope and the priorities of examination. Further important information on this and how to use this handbook is included in Chapter 1—Introduction.

This chapter provides a suggested format for conducting pharmacy benefit manager (PBM) examinations and reviews. In addition to this chapter, the examiner should be familiar with the NAIC white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (NAIC White Paper).

Background, Scope and Types of Examinations

"Pharmacy Benefit Manager" is defined in the NAIC White Paper as entities that negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs are responsible for the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols). PBMs engage in negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

Examinations of Pharmacy Benefit Manager can be either comprehensive or targeted. A Pharmacy Benefit Manager examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the Pharmacy Benefit Manager's systems and procedures are similar, if not identical, for every state, the examination and resulting report should be acceptable in all states, regardless of which jurisdiction conducts the examination.

Unlike insurance company examinations, there generally is little, if any, "market analysis" for Pharmacy Benefit Manager examinations. Similarly, Pharmacy Benefit Managers are not regulated for solvency. Rather, Pharmacy Benefit Manager negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.

For additional information on background and scope, please refer to chapter 12&13 of the Market Regulation Handbook.

Definitions:

Regulators may want to consider state specific definitions when conducting a PBM Examination.

Biologic Drugs - Biologic drugs are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, and certain vaccines. [16] Biologics are sometimes

referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process.[17] Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.[18] A biosimilar drug product may be produced following the expiration of the biologic's patent and exclusivity period.

Brand-Name Drugs - Manufacturers who produce brand-name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name drugs receive patents and exclusivities from the FDA.[12] Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market.

Employers/Unions/Taft Hartley Trusts - Employers have a variety of options available when designing the health benefits that they offer to their employees. They may choose a self-insured model, where the employer holds the risk, but sometimes hires an insurance company, PBM, or other benefit manager to administer the benefits. Employers choose how much of the benefits they will allow a contracted insurance provider or PBM to design and may choose to "carve out" the pharmacy administration and have external entities perform different functions.

Generic Drugs - Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Like brand-name drugs, the FDA must approve a generic drug application to ensure its equivalence to the brand-name drug before it can be produced.[14] Generic drugs comprise the largest portion of the pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers.

Insurers - Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees.[4] Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management.[5] In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks.[6] Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer. [7] Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

Manufacturers - Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions.[8] The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition.[9] Manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Manufacturers may also purchase prescription drugs developed by other manufacturers to market as their own.

Payors - Payors of health care services include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (individual, small group, large group) and the arrangement that the payor chooses. In this paper, when PBM functions are referenced, payors may choose to do those tasks internally.

Pharmacies - A pharmacy chain refers to a third-party entity that engages in a retail business and that owns or operates multiple retail outlets at which an individual consumer may have a prescription drug order filled. Retail outlets may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling.

Independent
Independent pharmacies refer to pharmacies that are privately and independently owned and operated by one or more pharmacists, and whose primary function is to provide direct pharmaceutical care to patients. These services include dispensing drugs, providing immunizations, performing health screenings, testing at point-of- care, and providing medication counseling in the community setting.

Pharmacist - The basic duty of a community pharmacist is to assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing the medication to the patients to ensure that the patients do not receive the wrong drugs or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals.

Pharmacy Benefit Managers (PBMs) - PBMs negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms.[23] PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.[24] PBMs are responsible for the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols).[25] PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

Pharmacy Benefits Manager Network – means a network of pharmacists or pharmacies that are offered by an agreement or contract to provide pharmacy goods or services.

Pharmacy Services Administrative Organizations (PSAOs) - Pharmacy Services Administrative Organizations (PSAOs) are organizations that provide administrative services to independent pharmacies to support the evaluation and execution of a contract with PBMs or wholesalers. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly. The PSAO's overall administrative function is to assist with contract evaluation and execution, customer service, central payment and reconciliation, and patient data evaluation.[30] In many instances a PSAO is owned by a wholesaler.

Rebates – means a discount or other price concession, or payment that is both of the following: 1. Based on utilization of a prescription drug. 2. Paid by a manufacturer or third party, directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

Specialty drug - is a high-cost, complex, or high-touch medication used to treat rare, complex, or chronic conditions. These drugs often require specialized handling, administration, and dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

Wholesalers/Distributors - Wholesalers purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. About 92 percent of prescription drugs in the United States are distributed through wholesalers, with three companies accounting for more than 90 percent of wholesale drug distribution in the United States. Wholesalers own the largest PSAOs used by independent pharmacies.

Qualifications of Examiners

Information on qualifications, please refer to chapter 14 of the Market Regulation Handbook**.**

Types of Examinations

When planning the examination, it is helpful to first identify which services and products are regulated and the impact on regulated entities. A Pharmacy Benefit Manager examination can take the form of a comprehensive examination, a targeted examination, a risk-focused examination, a re-examination, a multistate cooperative examination or a desk examination. Most of the elements found in Chapter 13—Types of Examinations will apply to the Pharmacy Benefit Manager examination. Because most operations for these entities remain consistent in all states, it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Scheduling, Coordination and Planning Scope

The procedures discussed in this section are to assist the regulator in determining if an examination or other type of regulatory action needs to be scheduled. It will also assist in developing a plan for conducting examinations, investigations, desk audits, interrogatories, letters or interviews when deemed necessary.

1. Determine the jurisdiction's requirements for licensing and examining the Pharmacy Benefit Manager and determine if the jurisdiction is permitted to accept the examination report of another state;
2. Survey appropriate divisions within the insurance department to identify potential areas of concern or interest relating to Pharmacy Benefit Managers operating in the jurisdiction.
3. For those Pharmacy Benefit Managers that have provided a current examination report and no unaddressed regulatory concerns exist, no additional analysis should be necessary. If analysis indicates that a market regulation action—such as a desk audit, letter, interrogatory, interview, investigation or examination—is appropriate, consider the possibility of coordinating with other jurisdictions with similar requirements or market regulation issues. Consider use of NAIC tools such as the Market Action Tracking System (MATS) for recording continuum types of regulatory responses and the Pharmacy Benefit Manager Examination Oversight (D) Working Group for multistate coordination of regulatory responses.
4. Survey the NAIC Research Division for relevant information to identify potential areas of concern in the evaluation process; and
5. Determine what specialists may be necessary to assist with the examination, such as an actuary (ideally one with experience with the functions of a Pharmacy Benefit Manager).

For very narrow or specific regulatory issues, or for situations in which an examination is not required by statute, consider use of regulatory options other than an examination. For example, certain issues can be handled by a telephone call, letter or email; a data request; policy and procedure review; interrogatories; or desk audits. The remainder of this chapter is primarily written to facilitate examinations; however, certain information may be adaptable for the above-mentioned "continuum" type responses. An additional discussion of continuum of market actions is in Chapter 2 of this handbook.

Procedural Considerations

Although not an insurance company examination, the basic procedures for a market conduct examination in Chapter 20 of this handbook should be followed in a Pharmacy Benefit Manager examination:

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;
- Notification of the examination;
- Preexamination procedures;
- On-site coordination;
- Communication management;
- Post-examination procedures; and

- The examination report.

Where possible, each state's defined examination protocols applicable to the examination of insurers—such as time frames and report submissions—should be applied to PBM examinations, as well.

Writing the Examination Report

The report preparation elements of the report are generally applicable to Pharmacy Benefit Manager examinations. However, the following special considerations also apply:

- In addition to safeguarding the confidentiality of individual policyholder information, care should be taken to not disclose trade secret information of the examinees or insurers that are customers of the examinees (e.g., individual insurer information in class or territory detail, or the processes and procedures of the examinee). The PBM should be given the opportunity to mark exhibits and/or portions of the report as "confidential and proprietary," if such is allowed under state law and these are not subject to otherwise applicable public release laws outside the regulatory community; and
- The PBM should be given the opportunity to review the examination findings prior to issuing a final report, if such practice is consistent with the state's insurers' examination act or other applicable statute.

Use of Examination Standards

Each of the following examination standards may be applicable to specific functions performed by a Pharmacy Benefit Manager. The examination plan should indicate which standards for review will be used for each specific examination.

A. Pharmacy Benefit Manager Operations/Management
B. PBM Pricing and Methodologies
C. Provider/Pharmacy Relations
D. Pharmacy Claims
E. PBM Pricing Methodologies
F. Pharmaceutical Manufacturer Rebates
G. Network Adequacy
H. Utilization Review
I. Drug Formulary, Placement and Specialty Drug
J. Complaints, Grievances, and Appeals
L. Audits

A. Pharmacy Benefit Manager Operations/Management

Use the standards for this business area that are listed in Chapter 20—General Examination Standards.

The following standards would be the most applicable to a PBM examination.

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.
Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.
Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.
Standard 4 - The PBM has a valid disaster recovery plan.
Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.
Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.
Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.
Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.
Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.
Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.
Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.
Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.
Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 1
The PBM demonstrates it does not charge a covered entity or health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations. AKA SPREAD PRICING.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ Complete and unredacted contracts between the PBM and health plan.

_____ Complete and unredacted contracts between the PBM and pharmacy.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges.

_____ A schedule of claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total reimbursement amount paid to the pharmacy for each prescription drug claim.

_____ Documentation of health plan billings during the exam period including a itemized breakdowns.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

STANDARDS
PHARMACY BENEFIT MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBMS AND HEALTH PLANS)

Standard 2
The PBM demonstrates the difference in its payment rates received by a covered entity or health plan compared to the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to PBM's billing with health plans.

_____ An index of all policies and procedures relating to the PBM's payment to pharmacies.

_____ Complete and unredacted contracts between the PBM and health plan.

_____ Complete and unredacted contracts between the PBM and pharmacies.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- The total amount charged to the covered entity or health plan for each prescription drug claim.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures to determine if internal standards regarding the PBM pricing exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the implementation of the policies and procedures.

Determine if contracts between the PBM and health plans are consistent state requirements and with the PBM's policies regarding PBM pricing.

Determine if amounts charged to health plans are supported by claims data, are consistent with contracts between the PBM and the health plan and are consistent with state requirements.

STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies or all brand effective rate (BER) policies. Request documents in an unredacted format.

_____ PBM contracts with pharmacies or PSAOs in an unredacted format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.

_____ All documents provided to pharmacies that support or describe the PBM's effective rate reconciliation process to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.

_____ All reports or accounting documents provided to pharmacies or PSAOs showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and claims data.

_____ Request all claims data for a specified time period and in a standardized template showing how each claim was 'reconciled' by the PBM. Claims detail may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims;
- The drug pricing source used for reimbursement of each claim when
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its initial payment to the pharmacy when the pharmacy submitted the claim.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid

the pharmacy when it submitted the claim; the amount should not include the dispensing fee).
- The total initial reimbursement of any dispensing fee;
- The reconciled percentage of 'discount' applied to each claim.
- The total final reimbursement amount for each drug claim after reconciliation. This should not include the dispensing fee amount.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each drug. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO.

_____ Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's effective rate reconciliation process with pharmacies and that describe the carrier or employer group's oversight of the processes. Request the entire contract in an unredacted format.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost list information, provider updates or manual amendments. Ensure all contractual language is transparent and sufficiently clear to enable the pharmacy to understand how the effective rate reconciliation process will be implemented prior to the PBM beginning the annual (or quarterly) reconciliation.

Request a listing of all network pharmacies or PSAOs that have an effective rate contract and all pharmacies or PSAOs that do not have one. Ensure the PBM is offering contracts to all similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer an effective rate contract to any specific pharmacies or pharmacy types, such as independent pharmacies.

Assess how the PBM determines which claims will be part of the reconciliation process. Confirm the selection of the claims is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language.

Review all documents and communications sent from the PBM to the pharmacy as part of the reconciliation process. This should include but not be limited to any reconciliation reports, any claims data that is provided or can be requested by the pharmacy, any emails or other correspondence between the PBM and the pharmacy. Ensure all communications from the PBM provide sufficient detail to enable the pharmacy to understand the process and that all questions are appropriately addressed.

- If PBM provides any reports or charts to the pharmacy, ensure the document explains all use of acronyms and use of differing claims categories for example, through use of a key.
- Review all documents describing the final reconciliation amount that may be owed to or from pharmacies or PSAOs. Does the PBM provide reasonably sufficient detail to ensure that pharmacies understand how and when they will receive payment or make payments, if applicable.
- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that enables pharmacies to provide information to the PBM that may change the outcome of the reconciliation amount. Consider requesting specific examples of correspondence to review.

Review a sampling of (or all) claims to ensure the PBM follows its own policies and procedures regarding reconciliation process. Compare the original 'discount' and price paid to the pharmacy to the reconciled 'discount' and price to determine if the reconciled 'discount' applied to each claim is within the contractually stated 'discount' amounts.

Review contracts between the PBM and the carrier or employer group to determine whether the reconciliation process as described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Consider verifying the accuracy of all the data and reports sent from the PBM with the pharmacy or pharmacy group. For example, if the PBM provides an annual report of all reconciled claims, did the pharmacy receive the same version?

STANDARDS
PHARMACY BENEFITS MANAGERS
PBM PRICING AND METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 4
The PBM demonstrates it has transparent payment methodologies for the dispensing fees of all drugs that enable a pharmacy to understand dispensing fee amount for each claim.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all policies and procedures relating to pharmacy dispensing fees.

_____ All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted format.

_____ PBM contracts with pharmacies in an unredacted format.

_____ All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.

_____ All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to mail order, specialty, or affiliate pharmacies.

_____ Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the carrier or employer group's oversight of the processes. Request the entire contract in an unredacted format.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims;
- The drug pricing source used for reimbursement of each claim
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee;
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured;
- The status of the claim for example paid, rejected, under appeal.
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the

PBM is timely when paying clean claims.

- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

**This information may be pared down if the regulator is only looking at dispensing fees and not all claims data. But pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review all contracts between the PBM and pharmacies, including but not limited to, the provider manual, network reimbursement forms, maximum allowable cost lists, drug discount or manufacturer coupon contracts. Ensure all contractual language is transparent and sufficiently clear to enable the pharmacy to understand the dispensing fee payment prior to the pharmacy being paid.

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language.

Assess the PBM's ability to change the dispensing fee amount. Confirm the 'change' process is transparent & communicated to pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plane language. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

Review contracts between the PBM and the carrier or employer group to determine whether the payment of dispensing fees described to pharmacies is consistent with the PBM's requirements described in the carrier or employer group's contract with the PBM.

Review a sampling of (or all) claims to ensure the PBM follows its own policies and procedures regarding dispensing fees paid to pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment of dispensing fees should be consistent across pharmacies within the same network.

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACY (AKA PROVIDER))

Standard 1
The PBM demonstrates that it exercises good faith and fair dealing in its contracting and contract negotiation processes with pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

_____ From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted format.

_____ A listing of all pharmacies in the PBM's network. The listing should also require the PBM to provide a listing of all contracts (including provider manuals) and contract amendments the PBM has in place with each pharmacy. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document.

_____ All documentation and correspondence, including but not limited to emails and red-lined documents, between pharmacies and the PBM that pertain to the contact and contact amendments. The documentation should provide examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses. The Examiner should review the documentation to assess whether the PBM is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example.

Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Including how PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as who can submit the information and how i.e. via email, web portal or postal mail, any fees required. Ensure the PBM's process is described to pharmacies in clear and concise language such that the pharmacies understand how to request changes to the contract terms.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review PBM communications to pharmacies to assess the PBM's responses to pharmacy negotiation requests. Ensure the PBM provides sufficient information to support or deny the pharmacy's requests. Ensure PBM contracting process is not unilateral or one-sided to prevent pharmacies from negotiating.

Review PBM's communications to pharmacies to assess if PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether PBM appears to contract with certain pharmacy types and not others. For example, does PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM explanation for such outcomes.

Assess how the PBM responds to pharmacy inquiries about the PBM's or the pharmacy's contractual obligations. For example, does the PBM have processes for pharmacies to initiate inquiries or obtain assistance from the PBM? Assess the PBM's responses to pharmacies during the inquiry process. Assess whether the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's response or final determination. Review specific examples of inquiries and follow-up from the PBM.

**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 2
The PBM demonstrates that it exercises good faith and fair dealing in implementing its contractual obligations with its vendors that work with its network pharmacies.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide an index of all contracts with vendors that provide pharmacy benefits management services on behalf of the PBM including a description of those services provided by each vendor and how the services impact pharmacies.

_____ From the index provided, review all policies and procedures that are applicable to the practices with pharmacies being examined. Request documents in an unredacted format.

_____ Unredacted PBM contracts from vendors that provide pharmacy benefit management services on behalf of the PBM.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Standards should be applied in a non-discriminatory manner such that PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example.

Review policies and procedures for providing information to pharmacies about vendors with whom the PBM contracts to perform certain functions. Review all documentation to assess if the PBM provides reasonably sufficient information to pharmacies such that they would understand the exact function of the vendor and how the pharmacy is to interact with the vendor.

Review contracts between PBM and its vendors to ensure the PBM does not permit its vendors to engage in activities that are prohibited under state law. For example, if state law prohibits a PBM from charging fees to a pharmacy, the PBM should not have a contract with a vendor that allows the vendor to charge the prohibited fees.

Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is

consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its affiliate pharmacies over non-affiliated pharmacies.

**We believe this standard is applicable to the relations between the PBM and the pharmacy (aka provider)*

STANDARDS
PHARMACY BENEFITS MANAGERS
PROVIDER/PHARMACY RELATIONS

Standard 3
The PBM demonstrates that it has a reasonable and easily accessible dispute resolution process for pharmacies to address matters of conflict with the PBM.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ PBM to provide a data dictionary or list (and definitions) of all types of disputes that it considers 'disputes.' This may include but not be limited to complaints, independent third-party reviews, and arbitration.

_____ PBM to provide an index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.

_____ From the index provided, request all policies and procedures that are applicable to dispute resolution process being examined. Request documents in an unredacted format.

_____ PBM documentation of showing how disputes are addressed and finalized. PBM should provide examples of actual disputes and provide all documentation sent to or received by a pharmacy showing how the dispute was initiated, the correspondence between the PBM and pharmacy, any documentation that is exchanged, and documentation showing how the dispute is resolved.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding the PBM's dispute resolution process with pharmacies. Review criteria for the different types of disputes to assess whether PBM has clear protocols, timeframes, and documentation requirements for addressing and resolving each type of dispute.

Review contracts and manuals for details provided to pharmacies about the dispute resolution process. Review how PBM informs pharmacies of how disputes may be initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail, any fees required), PBM's obligation to provide a justification for the final determination and timeframes for PBM response and resolution of the dispute.

Review contracts and manuals with details about the dispute resolution process to ensure the information provided to pharmacies is clear, concise, and easily understood.

Assess whether the PBM's requirements for pharmacies are convenient and accessible or whether the requirements create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute. Examples of requirements that may dissuade a pharmacy from initiating a dispute may include but are not limited to, requiring pharmacies to initiate disputes and send supporting documentation solely through postal mail or requiring exorbitant fee amounts to request or initiate a dispute resolution process.

Assess the PBM's responses to pharmacies during the dispute resolution process. Ensure the PBM provides timely responses and provides reasonably sufficient responses to the pharmacy to justify the PBM's final determination.

Ensure PBM's policies and procedures and implementation of those policies and procedures are consistent with state law.

Assess whether PBM has staffing models to effectively resolve disputes.

STANDARDS
PHARMACY BENEFITS MANAGERS
PHARMACY CLAIMS

Standard 1
The PBM demonstrates that it has timely and transparent claims submission and adjudication processes for pharmacy claims that enable pharmacies to understand the payment rate prior to claims submission.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format

_____ PBM to provide an index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.

_____ PBM to provide an index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.

_____ Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted format.

_____ Other than contracts and manuals, request all documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted format.

_____ All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format.

_____ All contacts with carriers or employer groups in an unredacted format.

_____ Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Retail, mail order, and specialty drug claims;
- The drug pricing source used for reimbursement of each claim
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee;
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-

funded vs. fully insured;
- The status of the claim for example paid, rejected, under appeal.
- The dates of when the claim was submitted and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons. *The regulator should verify the PBM provides a reasonable basis to pharmacies for the status of the claim.*

_____ Regulatory actions

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures for pharmacy requirements to be able to submit claims that may include but are not limited to the following:
- Claims processing software requirements
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:
- Dispensed as written codes
- Over-the-counter products
- Multi-ingredient compound processing
- Override
- Coordination of benefits
- Reversals
- Submission timeframes

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:
- PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any 'discount' the PBM may apply to reduce the price paid to the pharmacy
- PBM should have clear criteria for claims approvals, denials or rejections.
- PBM should have clear timeframes for claims adjudication either through payment or denial/rejection of the claim.
- PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is denied or rejected.
- PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or appeals for example, about any claims that are rejected or denied.

Review all PBM policies and procedures to assess whether the PBM applies different standards to different types of claims such as self-funded, specialty drug, mail order, nonresident or discount card claims. Verify that any differing standards are consistent with state law.

Review all pharmacy contracts, including any Provider Manuals, to ensure the claims submission and adjudication processes are clearly and concisely described to pharmacies. The PBM should provide pharmacies with detailed

information about:

- Each step necessary to submit a claim.
- The process and timeframe for the PBM to review and make a determination about whether a claim will be paid.
- How a pharmacy may submit an inquiry, appeal or otherwise contest the PBM's response to a pharmacy's claim. Information should include timeframes for each step in the process and should describe an easily accessible process for the pharmacy.
- Ensure information describes how pharmacies are reimbursed in accordance with applicable laws that may dictate payment amount and applicable dispensing fees.

Review all documentation to assess whether the PBM provides reasonably sufficient information about its claims payment methodology to ensure that pharmacies understand what they will be paid prior to submitting claims. This should include but not be limited to:

- If the PBM publishes a MAC list, is the list readily available and useful to pharmacies? Does the listing provide a 'search' function to find a specific drug or is the list formatted in a way that requires the pharmacy to scroll through thousands of drugs to find a specific drug? The latter would not be reasonable.
- If the PBM applies a 'discount' to the drug pricing source it uses to pay pharmacies, is that discount reasonably described in documentation to pharmacies such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a 'discount' and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, is that process clearly described to pharmacies? Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Does the pharmacy have the ability to'opt0in' or 'opt-out' of any such programs? Does the PBM provide reasonably sufficient information such that the pharmacy will know its reimbursement level prior to submitting the claim?

When requesting claims data, require the PBM to submit <u>*all*</u> claims being examined. *Regulators have had challenges getting mail order and specialty drug claims from some PBMs.* Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of dispensing fee. Ensure PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

Consider requesting the PBM provide a live demonstration of its claims adjudication process for each type of claim being examined which may include but not be limited to: claims that are approved, claims that are denied, claims that are rejected, claims that are mail order only, claims that are for self-funded employer groups, or claims that are for fully insured carriers.

Review all, or a sampling of PBM contracts with carriers/employer group to assess if the PBM is compliant with the claims payment requirements in those contracts and that those terms are consistent with in all messaging to pharmacies. For example, if pass-through pricing is required by the carrier contract, is that consistent with the payment method (and applicable description) to pharmacies?

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to Aggregators) are passed through to health plans or covered entities as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ Complete and unredacted contracts between the PBM and manufacturers.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually implemented and applied.

Determine if manufacturer rebates received were properly forwarded to applicable health plans.

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebate discounts, administrative fees, credits, incentives and penalties are passed through to health plans or covered entities as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's rebates, fees and discounts.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.

_____ A listing of all health plans or covered entities with which the PBM provides services in the state (for the applicable examination period).

_____ Complete and unredacted contracts between the PBM and health plans or covered entities.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates fees and discounts received by the PBM and/or amounts remitted to health plans.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates, fees and discounts exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually implemented and applied.

Determine if manufacturer rebates, fees and discounts received were properly forwarded to applicable health plans.

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 3
The PBM demonstrates pharmaceutical manufacturer rebate payments are passed through directly to the patients as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's rebates.

_____ An index of all training manuals relating to the PBM's rebates.

_____ Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.

_____ A listing of all pharmacies that the PBM utilizes to pass rebates through to patients at the point of sale (for the applicable examination period).

_____ Complete and unredacted contracts between the PBM and pharmacies.

_____ An index of periodic reports, certifications, or real-time systems made available to health plans or patients to monitor rebates received by the PBM and/or amounts passed through directly to patients.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the forwarding of manufacturer rebates exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually implemented and applied.

Determine if manufacturer rebates received were properly amounts passed through directly to patients.

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 4
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly provided to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ An index of all policies and procedures relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all training manuals relating to the PBM's reporting requirements to the commissioner/department.

_____ An index of all policies and procedures relating to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.

_____ A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).

_____ Complete and unredacted contracts between the PBM and manufacturers.

_____ An index of internal reports, certifications, or real-time systems used by employees in the preparation of statutorily required reports.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review the PBM's policies and procedures and training manuals to determine if internal standards regarding the preparation of statutorily required reports exist and whether those standards comply with state requirements.

Determine if applicable policies and procedures were actually communicated to employees responsible for the preparation of statutorily required reports.

Determine if the statutorily required reports were complete, accurate, and timely filed.

STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for all pharmacies in its network. Must show its credentialling criteria from beginning to end.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ Pharmacy contracts and manuals for PBM's language relating to credentialing.

_____ PBM to provide an index of all internal policies and procedures for the credentialing process.

_____ All policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted format.

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for all pharmacies and pharmacy staff including but not limited to the pharmacist in charge (pharmacy manager), pharmacists, pharmacy technicians, and any customer service representatives. Review all exclusionary criteria such as requirements that pharmacists cannot be excluded or revoked by any licensing board.

Review any requirements for other personnel including but not limited to pharmacy owners, officers or directors. Review all exclusionary criteria that may apply.

Review all requirements for pharmacies including but not limited to application documents, insurance requirements such as professional liability coverage, any required minimum stock of drugs, and technological capabilities such as claims submission platforms.

Review policies and procedures for providing information to pharmacies about the credentialing process. Including how PBM informs pharmacies of required documentation, timeframes for submission of information, processes for

submission of information such as via email, web portal or postal mail, any credentialing fees required.

Review policies and procedures for providing information to pharmacies about the PBM's documentation review process, timeframes for PBM's review, how PBM provides feedback to pharmacy, how pharmacy may correct deficiencies or provide additional information.

Review contracts and manuals for details provided to pharmacies about the credentialing process. PBM should provide clear and concise information that is consistent with its own policies and procedures. Information provided to pharmacies should address all the requirements and steps for credentialing and should provide pharmacies with adequate time to provide all documentation and provide pharmacies with ability to address any questions about the process.

Request a listing of all pharmacies and staff that went through the credentialing process during the examination period. Request the results of each process (i.e. was the pharmacy 'approved' to be in the PBM's network or not). Request the reasoning for all approval or denials. *It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*

Request *all correspondence* between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sampling of those that went through the credentialing process. "Correspondence" may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM and any emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy. Require documents to be provided in an unreadable format. Ensure all correspondence from the PBM is clear and concise and provides reasonably sufficient information to pharmacies to understand the credentialing process and any decisions made by the PBM.

In any Summary of the PBM Network Adequacy that proceeds these standards, need to describe the difference between the *PBM's network* and *pharmacy networks*. The PBM's network encompasses all pharmacies with which it contracts in the state. The PBM may have multiple pharmacy networks that may be designed based on types of drugs dispensed, how drugs are dispensed (i.e. mail order or retail), geographic location and will likely have differing reimbursement levels.

STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 2
The PBM demonstrates compliance with state law (if any), carrier/employer contracts, or other reasonable criteria, that it creates and maintains a network of pharmacies in a transparent manner.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts and manuals. This should include all network contracts and forms. Request documents be provided in an unredacted format.

_____ PBM to provide an index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, Examiners should request all relevant policies and procedures for areas being examined. Request documents be provided in an unredacted format, including requiring all pricing information be unredacted.

_____ PBM & carrier or employer plan contracts. Request the entire contract, including any amendments, in an unredacted format.

_____ PBM to provide a listing of all the pharmacies it contracts with. The listing should require PBM to identify each pharmacy's location (or identify if it is a mail order pharmacy), the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, whether the pharmacy is an affiliate pharmacy or not, whether the pharmacies' network participation changed at any time during the examination period and the reason for such change (i.e. PBM changed terms, pharmacy opted out, carrier requested change). *It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy.

_____ PBM to provide a description of the differences in each unique pharmacy network. For each pharmacy network, the PBM should identify the types of drugs dispensed, consumer access (such as mail order or retail), the reimbursement levels including any 'discounts' applied and dispensing fees provided, any criteria for participation and any participation limits or restrictions. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ PBM to provide a list of all carriers and employer groups and each plan for the entity for which the PBM administers prescription drug benefits. Require the PBM to identify every network associated with each plan. *It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*

_____ If required by state law, the PBM files with the department of insurance all required contract forms and any material changes to a contract proposed for use with its participating providers and intermediaries.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal policies and procedures regarding PBM requirements for ensuring PBM has appropriate number of pharmacies in applicable geographic areas to ensure network pharmacies provide appropriate access to consumers. Ensure PBM is compliant with state law and any requirements within its contracts with carriers and employer groups.

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure PBM has clear and concise requirements. PBM internal requirements should include but not be limited to:

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy desserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its carrier/employer group clients.
- Requirements for pharmacy network reimbursement levels. Ensure these are applied consistently among all pharmacies in each network.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear, concise, and easily understandable. Areas to review include but are not limited to:

- Do contracts/manuals clearly describe the requirements for participation in each pharmacy network?
- How does the PBM change the terms of the pharmacy network requirements? Any changes should be made in a transparent manner and with timely notice to the pharmacies.
- Do the contracts/manuals clearly describe the reimbursement including dispensing fees for each network?

Review the pharmacy listing to assess how often the PBM made changes to the pharmacy network requirements and participation levels during the examination period. Ensure the specific reasons for such changes are reasonable. Request all correspondence with pharmacies impacted by any changes. Request all correspondence with carriers/employer groups about the network changes. Ensure the message conveyed to carriers/employer groups is consistent with the message provided to pharmacies.

Review the listing of pharmacies and description of pharmacy network differences to ensure compliance with state and federal requirements. Depending on the state's legal requirements, areas to consider include by are not limited to:

- Does PBM have networks that are comprised solely of affiliate pharmacies?
- Does PBM have networks that are comprised solely of mail order pharmacies?
- Are the reimbursement rates among the differing networks reasonable? Or do the rates show differing levels for affiliate only networks?

In any Summary of the PBM Network Adequacy that proceeds these standards, consider reviewing the PBM's contracts and manuals with pharmacies as part of how to ask for specific information about "contracting."

STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY

Standard 3
The PBM demonstrates compliance with state law (if any) or other reasonable criteria, that it maintains a network of pharmacies that is sufficient in number and types of pharmacies to ensure that all services to covered persons will be accessible without unreasonable delay.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ PBM policies and procedures for providing information to covered persons about pharmacy directories.

_____ PBM policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.

_____ The PBM will demonstrate how it makes its provider directory (that lists all providers who participate in its network) available to covered persons. It also makes available, on a timely and reasonable basis, updates to its directory.

_____ All documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how the covered persons may contact the PBM with inquiries.

_____ PBM to provide a listing of all the pharmacies it contracts with. The listing should require PBM to identify each pharmacy's location or identify if it is a mail order pharmacy, the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

_____ PBM to provide a state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Ensure the PBM has established and will maintain adequate arrangements to ensure reasonable proximity of participating pharmacies to the business or personal residence of covered persons. In determining whether a PBM has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

Review policies and procedures for providing information to covered persons about in-network pharmacies and emergency services.

Review all information provided to covered persons to ensure the information is provided in a clear and concise manner and updated regularly. PBMs should have clear information that describes how consumers may contact the PBM with any inquiries about pharmacy options.

H. Utilization Review

1. Purpose

The utilization review portion of the examination is designed to verify that companies and their designees that provide or perform utilization review services comply with standards and criteria for the structure and operation of utilization review processes.

The areas to be considered in this kind of review include the company's written utilization review policies and procedures, annual summary reports, timeliness in making utilization review decisions and handling appeals, communications with members about the program and oversight of delegated utilization review functions.

2. Techniques

The analysis of utilization review activities should include an overview of the pharmacy benefit manager's written utilization review policies, procedures and scripts, in addition to an overview of how utilization review activities are applied to individual cases. Utilization review issues may also surface during the examiners' inspection of claims, complaints and grievance procedures.

a. Examiners should request a written overview of the pharmacy benefit managers' utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the pharmacy benefit manager maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.

b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.

c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.

d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.

e. Obtain listings of utilization review approvals or certifications, denials and requests for reconsideration. Use sampling techniques to review specific cases. Evaluate handling for adherence to written guidelines and standards.

3. Tests and Standards

The utilization review assessment includes, but is not limited to, the following standards related to the performance of utilization review activities by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 1
The pharmacy benefit manager establishes and maintains a utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations, including those related to mandated benefits and services

_____Utilization review policies and procedures

_____Utilization review program or plan documentation

_____Medical criteria used to make utilization review determinations

_____Job description of the staff position functionally responsible for day-to-day management

_____Minutes of the Pharmacy Benefit Managers' board of directors

_____Minutes of the Pharmacy Benefit Managers' utilization review committee

_____Documentation of clinical staff credentialing maintenance and education requirements

_____Program assessment reports

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager implements procedures to ensure effective corporate oversight of its utilization review program.

Verify that a Pharmacy Benefit Manager that requires a request for benefits under the covered person's health benefit plan to be subjected to utilization review, implements a written utilization review program that describes all review activities, both delegated and nondelegated for:

- The filing of benefit requests;
- The notification of utilization review and benefit determinations; and
- The review of adverse determinations in accordance with applicable state statutes,

- Verify that the Pharmacy Benefit Managers' written utilization review program document describes all the following:
    - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of health care services;
    - Data sources and clinical review criteria used in decision-making;
    - Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
    - Data collection processes and analytical methods used in assessing utilization of health care services;
    - Provisions for ensuring confidentiality of clinical and proprietary information;
    - The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the health carrier's governing body; and
    - The staff position functionally responsible for day-to-day program management.

- Verify that the Pharmacy Benefit Manager ensures that appropriate personnel have operational responsibility for conducting the carrier's utilization review program.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 2
The pharmacy benefit manager establishes and maintains a utilization review program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager utilization review program uses documented clinical review criteria that are based on sound clinical evidence-based medicine and evaluated periodically to assure ongoing efficacy.

Note: The Pharmacy Benefit Manager may develop its own clinical review criteria or may purchase or license clinical review criteria from qualified vendors.

Verify that the Pharmacy Benefit Manager makes its clinical review criteria available upon request to authorized government agencies.

Verify that the Pharmacy Benefit Manager ensures that qualified health care professionals administer the utilization review program and oversee review decisions. Verify that the Pharmacy Benefit Manager has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

Verify that the Pharmacy Benefit Manager issues utilization review decisions and benefit determinations in a timely and efficient manner pursuant to the requirements set forth in applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager has a process to ensure that utilization reviewers apply clinical review criteria in conducting utilization review consistently.

Verify that the Pharmacy Benefit Manager conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the Pharmacy Benefit Manager's data systems are sufficient to support utilization review program activities and to generate management reports to enable the Pharmacy Benefit Manager to monitor and manage health care services effectively.

If a Pharmacy Benefit Manager delegates any utilization review activities to a utilization review organization, verify that the Pharmacy Benefit Manager maintains adequate oversight, to include all the following:

- A written description of the utilization review organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the utilization review organization program by the Pharmacy Benefit Manager or respective carrier; and
- A process by which the Pharmacy Benefit Manager evaluates the performance of the utilization review organization.

Verify that the Pharmacy Benefit Manager coordinates its utilization review program activities with other medical management activity conducted by the health carrier, such as quality assurance, credentialing, provider contracting, data reporting, grievance procedures, claims adjudication, processes for assessing member satisfaction and risk management.

Verify that the Pharmacy Benefit Manager provides covered persons, or, if applicable, the covered person's authorized representatives and participating providers with access to its utilization review staff via a toll-free number or collect call telephone line.

Verify that the Pharmacy Benefit Manager, when conducting utilization review, collects only the information necessary, including pertinent clinical information, to make the utilization review or benefit determination.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 3
The Pharmacy Benefit Manager discloses information about its utilization review and benefit determination procedures to covered persons, or, if applicable, the covered persons' authorized representative, in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Member materials

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager provides a clear and accurate summary of its utilization review and benefit determination procedures to the covered person's authorized representative.

Verify that the Pharmacy Benefit Manager provides a clear and comprehensive description of its utilization review procedures, including the procedures for obtaining adverse review determinations, and a statement of rights and responsibilities of covered persons.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 4
The Pharmacy Benefit Manager makes standard utilization review and benefit determinations in a timely manner and as required by applicable state statutes, rules and regulations, as well as the provisions of HIPAA.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Activity reports

_____Provider manual

_____Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the Pharmacy Benefit Manager by the covered person, or, if applicable, the covered person's authorized representative, for benefits and for notifying the covered person, and, if applicable, the covered person's authorized representative, of its determinations with respect to these requests within the specified time frames required pursuant to applicable state statutes, rules and regulations.

For prospective review determinations, verify that the Pharmacy Benefit Manager makes the determination and notifies the covered person, or, if applicable, the covered person's authorized

representative, of the determination, whether the Pharmacy Benefit Manager certifies the provision of the benefit or not, within a reasonable period of time appropriate to the covered person's medical condition, but in no event later than 15 days after the date the Pharmacy Benefit Manager receives the request.

Whenever the determination is an adverse determination, verify that the Pharmacy Benefit Manager makes the notification of the adverse determination in accordance with state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination.

Verify that if the Pharmacy Benefit Manager extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the Pharmacy Benefit Manager has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 15-day time period, of the circumstances requiring the extension of time and the date by which the Pharmacy Benefit Manager expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Whenever the Pharmacy Benefit Manager receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the health carrier's filing procedures, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of this failure and provides in the notice information on the proper procedures to be followed for filing a request.

Verify that the notice referenced in the previous paragraph is provided by the Pharmacy Benefit Manager as soon as possible, but in no event later than five days following the date of the failure.

Verify that the Pharmacy Benefit Manager provides the notice orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to meet the health carrier's filing procedures apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and

- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a Pharmacy Benefit Manager has certified an ongoing course of treatment to be provided over a period of time or number of treatments, examiners need to be aware that:

- Any reduction or termination by the Pharmacy Benefit Manager during the course of treatment before the end

of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and

- The Pharmacy Benefit Manager shall notify the covered person, or, applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the covered person's authorized representative, to file a grievance to:
  - Request a review of the adverse determination pursuant to state statutes, rules and regulations; and
  - Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

Verify that the health care service or treatment that is the subject of the adverse determination is continued by the Pharmacy Benefit Manager without liability to the covered person with respect to the internal review request made pursuant to state statutes, rules and regulations.

For retrospective review determinations, verify that the Pharmacy Benefit Manager makes the determination within a reasonable period of time, but in no event later than 30 working days after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination to the covered person, or, if applicable, the covered person's authorized representative, in accordance with applicable state statutes regarding procedures for standard utilization review and benefit Pharmacy Benefit Manager determination.

Verify that if the health carrier extends the time period for making a determination and notifying the covered person, or, if applicable, the covered person's authorized representative, of the determination one time for up to 15 days pursuant to applicable state statutes, rules and regulations, the health carrier has:

- Determined that the extension was necessary due to matters beyond the Pharmacy Benefit Manager's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial 30-day time period, of the circumstances requiring the extension of time and the date by which the health carrier expects to make a determination.

If the extension referenced above is necessary due to the failure of the covered person, or, if applicable, the covered person's authorized representative, to submit information necessary to reach a determination on the request, verify that the Pharmacy Benefit Manager issues a notice of extension that:

- Specifically describes the required information necessary to complete the request; and
- Gives the covered person, or, if applicable, the covered person's authorized representative, at least 45 days from the date of receipt of the notice to provide the specified information.

Verify that the Pharmacy Benefit Manager calculates the time periods, within which a prospective or retrospective determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is received by the Pharmacy Benefit Manager in accordance with the health carrier's procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to make the determination, verify that the Pharmacy Benefit Manager calculates the time period for making the determination to begin on the date on which the Pharmacy Benefit Manager sends the notification of the extension

to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:

- The date on which the covered person, or, if applicable, the covered person's authorized representative, responds to the request for additional information; or
- The date on which the specified information was to have been submitted.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 5
The Pharmacy Benefit Manager provides written notice of an adverse determination of standard utilization review and benefit determinations in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager issues notification of an adverse determination, in a manner calculated to be understood by the covered person, to include all the following:

- The specific reason or reasons for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to perfect the benefit request, including an explanation of why the material or information is necessary to perfect the request;
- A description of the Pharmacy Benefit Manager's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;
- If the Pharmacy Benefit Manager relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative, upon request;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination;
- The written statement of the scientific or clinical rationale for the adverse determination; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered

person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the Pharmacy Benefit Manager's grievance procedure process as provided under state statutes, rules and regulation, to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the health carrier provides the notice in writing or electronically.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 6
The Pharmacy Benefit Manager conducts expedited utilization review and benefit determinations in a timely manner and in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or performing utilization review services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Form letters

_____Utilization review files

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the Pharmacy Benefit Manager has established written procedures pursuant to applicable state statutes, rules and regulations for receiving benefit requests from covered persons, or, if applicable, their authorized representatives, and for making and notifying the covered person, or, if applicable, the covered person's authorized representative, of expedited utilization review and benefit determinations with respect to urgent care requests and concurrent review urgent care requests.

Verify that the Pharmacy Benefit Manager, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request, notifies the covered person, or, if applicable, the covered person's authorized representative, of the failure and the proper procedures to be followed for filing the request.

Verify that the Pharmacy Benefit Manager's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request:

- Is provided to the covered person, or, if applicable, the covered person's authorized representative, as appropriate, as soon as possible, but not later than 24 hours after receipt of the request; and
- May be oral, unless the covered person, or, if applicable, the covered person's authorized representative, requests the notice in writing.

Note: The provisions regarding the covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the Pharmacy Benefit Manager's procedures for filing an urgent care request apply only in the case of a failure that:

- Is a communication by a covered person, or, if applicable, the covered person's authorized representative, that is received by a person or organizational unit of the Pharmacy Benefit Manager responsible for handling benefit matters; and
- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific health care service, treatment or provider for which approval is being requested.

For an urgent care request, unless the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the Pharmacy Benefit Manager to determine whether, or to what extent, the benefits requested are covered benefits or payable under the health carrier's health benefit plan, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of the Pharmacy Benefit Manager's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, but in no event later than 72 hours after the receipt of the request by the Pharmacy Benefit Manager.

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

If the covered person, or, if applicable, the covered person's authorized representative, has failed to provide sufficient information for the health carrier to make a determination, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, either orally or, if requested by the covered person, or, if applicable, the covered person's authorized representative, in writing of this failure and states what specific information is needed as soon as possible, but in no event later than 24 hours after receipt of the request.

Verify that the Pharmacy Benefit Manager provides the covered person, or, if applicable, the covered person's authorized representative, a reasonable period of time to submit the necessary information, taking into account the circumstances, but in no event less than 48 hours after notifying the covered person, or, if applicable, the covered person's authorized representative, of the failure to submit sufficient information, pursuant to applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible, but in no event more than 48 hours after the earlier of:

- The Pharmacy Benefit Manager's receipt of the requested specified information; or
- The end of the period provided for the covered person, or, if applicable, the covered person's authorized representative, to submit the requested specified information.

If the Pharmacy Benefit Manager's determination is an adverse determination, verify that the Pharmacy Benefit Manager provides notice of the adverse determination accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

For concurrent review urgent care requests involving a request by the covered person, or, if applicable, the covered person's authorized representative, to extend the course of treatment beyond the initial period of time or the number of treatments, if the request is made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments, verify that the Pharmacy Benefit Manager makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the covered person's medical condition, but in no event more than 24 hours after the Pharmacy Benefit Manager's receipt of the request.

If the Pharmacy Benefit Manager's determination is an adverse determination, the Pharmacy Benefit Manager shall provide notice of the adverse determination or coordinate with the carrier in accordance with applicable state statutes, rules and regulations regarding procedures for expedited utilization review and benefit determination.

Verify that the Pharmacy Benefit Manager calculates the time period within which a determination is required to be made pursuant to applicable state statutes, rules and regulations, to begin on the date the request is filed with the either the health carrier or Pharmacy Benefit Manager in accordance with the health carrier's procedures established pursuant to applicable state statutes, rules and regulations for filing a request without regard to whether all of the information necessary to make the determination accompanies the filing.

Verify that the Pharmacy Benefit Manager's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative, to include all the following:

- The specific reason or reasons for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to complete the request, including an explanation of why the material or information is necessary to complete the request;
- A description of the health carrier's internal review procedures established pursuant to applicable state statutes, rules and regulations including any time limits applicable to those procedures;
- A description of the Pharmacy Benefit Manager expedited review procedures established pursuant to applicable state statutes, rules and regulations;
- If the Pharmacy Benefit Manager relied upon an internal rule, guideline, protocol or other similar criterion to make the adverse determination, either the specific rule, guideline, protocol or other similar criterion, or a statement that a specific rule, guideline, protocol or other similar criterion was relied upon to make the adverse determination and that a copy of the rule, guideline, protocol or other similar criterion will be provided free of charge to the covered person, or, if applicable, the covered person's authorized representative upon request;
- If the adverse determination is based on a medical necessity or experimental or investigational treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination, applying the terms of the health benefit plan to the covered person's medical circumstances or a statement that an explanation will be provided to the covered person, or, if applicable, the covered person's authorized representative, free of charge upon request;
- If applicable, instructions for requesting:
    - A copy of the rule, guideline, protocol or other similar criterion relied upon in making the adverse determination, as set forth in applicable state statutes, rules and regulations; or
    - The written statement of the scientific or clinical rationale for the adverse determination, as set forth in applicable state statutes, rules and regulations; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the health carrier's grievance procedure process as provided under applicable state statutes, rules and regulations to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

Verify that the Pharmacy Benefit Manager provides the notice orally, in writing or electronically.

If the Pharmacy Benefit Manager provides the notice of adverse determination orally, verify that the Pharmacy Benefit Manager also provides written or electronic notice of the adverse determination within three days following the oral notification.

STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW

Standard 7
The Pharmacy Benefit Manager monitors the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and ensures that the contracting organization complies with applicable state provisions accompanying regulations.

Apply to: PBMs contracting out utilization review services.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures

_____Contracts with organizations or entities

_____Reports of entity reviews and audits (if any) by health carrier

_____Periodic reports from the organization or entity

_____Minutes of the Pharmacy Benefit Manager's board of directors

_____Minutes of the Pharmacy Benefit Manager's utilization review committee

_____Policies and procedures for oversight

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a Pharmacy Benefit Manager contracts to have a utilization review organization or other entity perform the utilization review functions required by the Utilization Review and Benefit or applicable state statutes, rules and regulations, the Pharmacy Benefit Manager is responsible for monitoring the activities of the utilization review organization or entity with which the Pharmacy Benefit Manager contracts and for ensuring that the requirements of the Utilization Review and applicable state statutes, rules and regulations are met.

Verify that the Pharmacy Benefit Manager has policies and procedures in place that ensure the utilization review programs of designees comply with all applicable state and federal laws establishing confidentiality and reporting requirements.

The Drug Formulary, Placement and Specialty Drug review includes, but is not limited to, the following standards related to how the Formulary is managed and controlled by the pharmacy benefit manager. The sequence of the standards listed here does not indicate priority of the standard.

STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 1
The pharmacy benefit manager establishes and maintains a Formulary program in compliance with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Formularies and Formulary Templates used during the examination period.

_____All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period are appropriate to all applicable state statutes, rules and regulations

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period are appropriate to all applicable state statutes, rules and regulations

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other Committees decisions and statement comport with all applicable state statutes, rules and regulations

STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 2
The pharmacy benefit manager establishes and maintains a Formulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and Formulary Templates used during the examination period. Utilization review policies and procedures.

_____ All policies, procedures, and other documentation relevant to drug utilization management; including but not limited to, all fail-first policies including step-therapy protocols, prior authorization requirements, and medical necessity guidelines.

_____Any and all list(s) of medications included in and excluded from the mail order benefit.

_____Any and list(s) of all medications allowed for a 90-day supply, and those only allowed for 30-day supply or less, for both mail order and retail pharmacies.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to comport with all applicable state statutes, rules and regulations.

Verify that all the Pharmacy Benefit Manager's formularies utilized during the examination period do not restrict access to drugs to select pharmacies in violation of any required and applicable state statutes, rules or regulations.

STANDARDS
PHARMACY BENEFITS MANAGERS
DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 3
The pharmacy benefit manager defines and appropriately places any specialty drug on the formulary when a state has a specialty drug definition to comport with applicable statutes, rules and regulations.

Apply to: PBMs providing or maintaining formulary services to an insurer.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Formularies and Formulary Templates used during the examination period. Utilization review policies and procedures

_____Specialty drug list(s)

_____All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty

_____A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that all the Pharmacy Benefit Manager's formulary and drug placement-related systems utilized during the examination period use the applicable definition in accordance with all applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager formularies utilized during the examination period have any drug that meets the definition of specialty placed appropriately and further that any drug that does not meet the definition tiered appropriately in accordance with all applicable state statutes, rules and regulations.

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other Committees decisions and statements use and apply the correct definition of specialty drug to comport with all applicable state statutes, rules and regulations.

J. Complaints, Grievances, and Appeals

1. Purpose

The purpose of complaints, grievances and appeals handling procedures is to provide a process for consumers or providers to address issues, and to evaluate how well a regulated entity complies with laws, resolves issues, and timely responds to dissatisfaction expressed by consumers or providers. This includes:

- Ensuring compliance with applicable statutes and/or regulations[1], including:
    - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
    - Establishing whether violations were committed; and
    - Monitoring future conduct for compliance;

- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers or providers; and

- Identifying problem areas that may indicate broader operational issues.

All sections emphasize the importance of reviewing how concerns-whether classified as complaints, grievances or appeals-are processed, documented, and used to improve consumer service.

2. Techniques

The examination approach for complaints, grievances, and appeals procedures include the following shared techniques:

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems.
- **Documentation Review:** Assessing written policies, procedures, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, and providers are informed of the procedures and their rights.

All procedures call for reviewing the frequency and nature of the issues raised and whether they were resolved in accordance with the applicable standards

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, resolution)
- **Procedural Adequacy:** Verifying that the regulated entity has adequate written procedures for handling and resolving the issue, and that these are disclosed to consumers

[1] The term statutes and/or regulations refers to all legally binding statutes, rules, regulations, policies or other documents promulgated by an entity with said power.

- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law
- **Compliance and Fairness:** Determine that responses:
    - Fully address the issue(s) that was raised.
    - Include adequate supporting documentation.
    - Are compliant with policy statutes and regulations.
    - Provide appropriate remedies when necessary.

Complaints, Grievances and Appeals stress maintaining records that are accessible to regulators and retaining them for appropriate time periods.

STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 1
The pharmacy benefit manager maintains a detailed, accessible register documenting each complaint, grievance, or appeal, in accordance with the applicable records retention schedule.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations

_____Regulated entity register

_____Insurance department records

_____Direct consumer complaint, grievance, or appeal

_____Member evidence of coverage

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify accurate logging of the issue, date received, review actions, and resolution

Verify that the register includes enough detail to support regulatory review

Verify that the PBM retains the register for at least 3 years.

STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 2
The pharmacy benefit manager has written procedures for handling complaints, grievances and appeals and communicates such procedures to consumers and contracted providers.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations

_____Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.

_____Member evidence of coverage

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the company maintains a complaint register.

Verify that the PBM included the complaint log and procedures that include the audit, credentialing, and network enrollment departments.

Verify that the PBM's procedures comply with applicable statutes and regulations.

Verify that the PBM's procedures are communicated to consumers and contracted providers

Verify that the PBM has filed procedures with the insurance commissioner where required.

STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 3
The pharmacy benefit manager must resolve and respond to complaints, grievances, and appeals within prescribed timeframes.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review test sample to ensure the PBM is maintaining adequate documentation.

Determine if the PBM's response is timely. The Examiner should refer to state laws and regulations for the required time frame. *Note:* Timing is measured from the date the issue is received.

STANDARDS
PHARMACY BENEFITS MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4
The pharmacy benefit manager actions taken in response to complaints, grievances, or appeals must comply with insurance laws, contracts, and regulations as well as address all identified concerns.

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations

_____Contracts, including provider manuals

_____PBM register

_____Test Sample

_____Complaint, grievance, or appeal letter or email and PBM response

_____Supporting documentation (claim files, extension requests, etc)

_____PBM response

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Review documentation to determine if the PBM response fully addresses the issues raised. If the PBM did not properly address/resolve the complaint, the Examiner should ask the PBM what corrective action it intends to take.

For reviewing responses:
- Was the response timely.
- Was the response complete and responds to all issues raised.
- Does the response include adequate documentation to support the respondent's position.
- Were the respondent's actions appropriate from a business standpoint.
- Were the respondent's actions compliant with applicable statutes and regulations.
- Were the appropriate remedies for the consumer identified.

Document potential violations.

STANDARDS
PHARMACY BENEFITS MANAGERS
AUDITS

Standard 1
The PBM demonstrates that it has reasonable and uniform criteria and procedures for pharmacy audits and demonstrates that it follows those reasonable standards.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.

_____ Listing of all types of audits that may include but not be limited to, on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)

_____ From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted format.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format.)

_____ Listing of all audits initiated or that were ongoing during the examination period. (As part of this request, require a timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal. *It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*)

_____ A*ll correspondence* between the PBM and a pharmacy as part of audits during the examination period. (Consider whether to request information from all audits or just a sampling of the audits. 'Correspondence' may include but not be limited to, all documents sent by the PBM to the pharmacies, all documents sent by the pharmacies to the PBM and any emails, notes from phone conversations, and any other communications about the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format.)

_____ Summary of any use of artificial intelligence (AI) that it may use as part of auditing a pharmacy.

_____Policies and procedures associated with the use of AI.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review internal PBM policies and procedures regarding the PBM's audit process with pharmacies. Review criteria for the different types of audits to assess whether PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit including but not limited to processes for initiating, conducting and resolving each type of audit.

Review contracts and manuals with details about the audit process to ensure the information provided to pharmacies is clear, concise, and easily understood. *While the details of the audit process are important, the information must be provided in a manner that will be easily understood by pharmacies.*

Review contracts and manuals for details provided to pharmacies about the audit process. Review how PBM informs pharmacies of how audits are initiated, any required documentation, timeframes for submission of information, processes for submission of information (i.e. via email, web portal or postal mail), any fees required by the PBM that are outside the audit finding, how the pharmacy may address and rectify potential findings, PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

Assess whether the PBM's requirements for pharmacies are reasonable and provide pharmacies with the following:

- The scope, frequency (including the maximum annual amount) and method of all audits.
- Detailed guidelines, including metrics and data, used during audits.
- Advanced notice of an upcoming audit.
- Sufficient time to prepare and collect required information.
- Convenient and accessible methods for corresponding with the PBM during the audit, for example does the pharmacy have a point of contact to ask questions and obtain clarification on the PBM's expectations.
- Sufficient time to review and correct any audit findings prior to the PBM's final determination.
- Sufficient input into the implementation of a corrective action plan (if applicable) and sufficient time to comply with the requirements of a corrective action plan.
- An appropriate dispute resolution process that pharmacies may use to dispute audit findings. The process for pharmacies should be convenient and accessible and should not create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute resolution process.

If the regulator feels the PBM's policies and procedures are reasonable, ensure the PBM also follows and implements its own policies & procedures. Review timeframe requirements, whether the PBM provides reasonable and concise information to pharmacies in response to any questions, and whether the PBM provides appropriate justifications in the draft and final audit reports.

Review the results of all audits to determine if audits are conducted in a manner that appears reasonable for each of the individual pharmacy being audited and that there are no concerning trends with how the PBM conducts audits. For example, when conducting routine audits, are pharmacies selected randomly or does the PBM only audit non-affiliated, independent pharmacies? *The latter trend would be problematic.*

Verify that the PBM conducts pharmacy audits in compliance with applicable state laws and regulations. Ensure such methods are reasonable, utilized appropriately and consistent with any regulatory requirements (or prohibited

if required by state law or regulation). For example, if use of auditing techniques such as extrapolation is prohibited by state law or regulation, the PBM should not apply the method in any audits.

Assess whether PBM has staffing models to effectively initiate, conduct and finalize audits.

Assess the PBM's use of AI to ensure it is reasonable and that any results or findings from the use of AI are conveyed to the pharmacy in a clear and transparent manner.

Agenda Item #5

Hear an Update on Potential State Based Systems (SBS) Changes to Better Handle PBM Complaints—*Susan Jennette (DE)*

Agenda Item #6

Discuss Any Other Matters Brought Before the Working Group—*Joylynn Fix (WV)*

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
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 jmatthews@naic.org.

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

Table of Contents

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.

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.

~~Section 3. Definitions~~

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.

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:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. "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.

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.

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.

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.

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;

(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.

I. "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.

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.

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 [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 Producer Licensing Model Act, 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.

FROM THE NAIC CONSUMER REPRESENTATIVES

December 1, 2025

To: Joylynn Fix, Chair, Pharmacy Benefit Management (D) Working Group

RE: Consumer Representatives' Comments on "Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators"

On behalf of the undersigned Consumer Representatives to the National Association of Insurance Commissioners (NAIC), we write to voice our strong support of the draft **"Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators"** document that has been proposed by the Pharmacy Benefit Management (D) Working Group. After consideration of the suggested changes that we are proposing, along with others, we support its adoption.

After urging the NAIC to address the issue of licensure and regulation of Pharmaceutical Benefit Managers (PBMs) for several years, we are pleased that the NAIC has moved forward with these comprehensive PBM licensure and regulation guidelines, as was recommended in the NAIC PBM White Paper. States that are regulating PBMs, which are almost all by now, will find them useful as they seek to carry out their state laws. It will also be helpful for the regulated entities to have consistent definitions, requirements and data requests across the states. PBMs have a profound impact on prescription drug access and affordability, and increased regulation is needed due to this impact and the opaqueness of their operations, which until now has gone largely unregulated.

We do have a couple of suggestions that we urge you to adopt as you consider the draft:

1) In order to increase clarity in the **Licensing Requirement** section , we propose adding the words "the aggregate amount of all" in **Section 5G(3)** so that it reads: "*Report **the aggregate amount of all** rebates and other payments received in the preceding year from pharmaceutical manufacturers, for each health plan with which the pharmacy benefit manager is contracted, using a form or process prescribed by the commissioner."*
2) We recommend PBMs also disclose ownership relationships within the health care ecosystem, such as specialty pharmacies, in order to bring more transparency to practices like pharmacy-steering and to shine a light on favorable terms PBM-owned entities might receive relative to other entities.
3) To ensure compliance with the court ruling regarding accumulator adjustment programs, we propose adding "or on behalf of" after "paid by" in **Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices Section 6E(2)** *"Any amount paid by **or on behalf of 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."*
4) While collection of utilization management data may fall outside the scope of this document, we think it is important to have more transparency around certain practices that are clearly

driven by rebates. For example, one of the Congressional PBM reform proposals would require PBMs to disclose when they require an enrollee to step through a higher list price reference product before accessing a lower price biosimilar or generic.

We thank you for your consideration of these suggested edits and look forward to providing continued consumer perspectives as this important work moves forward.

If you have any questions or comments, please feel free to contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org.

Thank you very much.

Sincerely,

Theresa Alban
Kellan Baker
Bonnie Burns
Lucy Culp
Deborah Darcy
Joe Feldman
Stephanie Hengst
Marguerite Herman
Anna Schwamlein Howard
Anna Hyde
Carl Schmid
Deborah Steinberg
Harry Ting
Wayne Turner
Silvia Yee

MICHIGAN DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES (DIFS) COMMENTS

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 jmatthews@naic.org.

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

Table of Contents

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 the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.

B. The purpose of this document is 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 review and modify the definitions below, if needed, for consistency with their state laws or regulations.

MICHIGAN DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES (DIFS) COMMENTS

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

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. "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.

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.

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;

(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.

I. "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 claims processing services or 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.

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.

MICHIGAN DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES (DIFS) COMMENTS

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. 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.

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

Commented [JS1]: Consider amending Section 5(C) to require the submission of key service contracts as part of the license application. The amendment should include a new subparagraph requiring the applicant to file representative copies of:

- its standard pharmacy network/provider participation agreement,
- its standard health carrier/client services agreement, and
- any material subcontracting or delegation agreements.

Additionally, require applicants to submit arm's length agreements for any facilities, personnel, services, or networks provided or held by a legal entity other than the applicant, including any parent, subsidiary, or affiliate.

Review of these contracts is critical to verify compliance with Section 6 (Prohibited Practices), transparency obligations, network adequacy requirements, and other consumer protection provisions prior to license issuance.
In recent years, it has become increasingly difficult to determine ownership, control, and legal rights to key operational components—such as networks, systems, and service agreements—because many services and assets are held or performed by affiliated entities. Often, there is no formal documentation memorializing the relationship or establishing the applicant's legal authority to use those assets.
Requiring the submission of representative service contracts, along with documentation of any affiliate arrangements, will ensure that applicants maintain appropriate corporate governance and demonstrate legal access to the systems, personnel, and networks necessary to conduct business.

Section 5(C)(#) – Submission of Key Service Contracts
The applicant shall 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.
If any facilities, personnel, services, or networks are provided or held by an entity other than the applicant—including a parent company, subsidiary, or affiliate—the applicant shall maintain an ...

Commented [JS2]: Also, consider adding another subparagraph for digital infrastructure and information security:

(1) Each applicant shall 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.
(2) Applicants shall provide documentation sufficient 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. ...

Commented [JS3]: The proposed guidelines reference *financial solvency* as the standard for assessing an applicant's financial condition. While solvency addresses the entity's current ability to meet its obligations, it provides only a short-term, balance-sheet view of financial health.

To ensure a more comprehensive assessment, regulators should consider replacing *financial solvency* with *financial viability.* Viability encompasses both solvency and the PBM's long-term ability to sustain operations, maintain adequate capital, and manage business risks over time.

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.

(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 pharmacy benefits but have a mix of mail order and physical stores in this state.

Commented [JM4]: Michigan's statute includes the more specific term retail pharmacy. Also, what if they only wanted retail in their network? Would that not be allowed?

(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 subsection (4)(a) may result in the suspension, ~~or~~ revocation, or denial 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.

Commented [JM5]: Michigan's statute includes a waiver provision, as a possible idea to consider here or in a drafting note.

Commented [JM6]: This could be clarified; I'm not sure what it's trying to communicate.

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;

(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.

(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 relating to the 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 promulgate regulations relating to pharmacy benefit managers that are not inconsistent with this document.

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 (6) 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.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

December 1, 2025

Jolie Matthews
Sr. Health & Lift Policy Counsel
National Association of Insurance Commissioners (NAIC)
1101 K Street, NW, Ste. 650
Washington, DC 20005

Delivered via email: jmatthews@naic.org

Re: Proposed Draft of the Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Dear Jolie,

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to review and provide comment on NAIC's proposed draft Pharmacy Benefit Manager Licensure and Regulation Guidelines document. For your convenience, we have attached our comments with tracked changes.

We look forward to working with you and members of the Pharmacy Benefit Management (D) Working Group to develop guidelines for regulators to help facilitate meaningful oversight and enforcement of PBM practices to protect consumers and provide access to pharmacist services in local communities where they live and work. If we can provide any further assistance, please do not hesitate to contact Sandra Guckian, Vice President, State Advocacy, at sguckian@nacds.org or 703-837-4195.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

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 jmatthews@naic.org.

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

Table of Contents

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 the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.

B. The purpose of this document is 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 access to pharmacist services, and fairness in prescription drug benefits;

(3) Provide for powers and duties of the commissioner, including but not limited to suspension, revocation, or refusal to renew a pharmacy benefit manager's license; and

(4) Prescribe penalties and fines for violations.

Section 3. Definitions

Drafting Note: States should review and modify the definitions below, if needed, for consistency with 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:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. “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. “Group purchasing organization” means any entity affiliated with a pharmacy benefit manager or a pharmacy benefits plan or program which uses purchasing volume aggregates as leverage to negotiate discounts and/or rebates for covered prescription drugs with pharmaceutical manufacturers, distributors, and/or wholesale vendors.

F. “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.

G. “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.

H. “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/manufacturers;

(2) Disbursing or distributing rebates;

(3) Managing or participating in incentive programs or arrangements for pharmacist services;

(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.

I. "Pharmacist" means an individual licensed as a pharmacist by the [state] Board of Pharmacy.

J. "Pharmacist services" means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.

K. "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.

L. (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 claims processing services or 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.

K. "Rebate" means all payments, discounts, fees, or price concessions that remitted to a pharmacy benefit manager or its pharmacy benefits plan or program client , or affiliated entity, or an affiliated group purchasing organization, directly or indirectly, from a pharmaceutical manufacturer, distributor, or wholesale vendor including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a pharmacy benefits plan or program client.

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.

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~~shall 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, including but not limited to the entities that share common ownership with the pharmacy benefit manager or any of the pharmacy benefit manager's affiliated companies, with a health plan company or an affiliate of a health plan company, a group-purchasing organization, an entity that contracts on behalf of a pharmacy or any pharmacy services administration organization and its affiliates, a drug wholesaler or distributor and its affiliates, a third-part payer or its affiliates, or a pharmacy and its affiliates;

(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 common ownership and/or affiliations ~~of~~including but not limited to, ~~a~~ health insurers, health care centers, hospital service corporations, medical service corporations, group purchasing organizations, pharmaceutical manufacturers, wholesale drug distributors, specialty pharmacies, mail order pharmacies, community retail pharmacies, other pharmacy benefit managers, discount card programs for prescription drugs, and/or 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. All fees collected by the commissioner may be used to offset the cost of pharmacy benefit manager oversight and enforcement through a dedicated fund.

E. 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.

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. The renewal application shall include updates pursuant to "C" under Section 5. Licensing Requirements.

(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~~.~~; and

(d) Updates pursuant to Section 5(C)2 and 5(C)9.

(4) The commissioner may request a renewal applicant to submit additional information to clarify any new information presented on the renewal application.

G. Requirements after approval of license in the form and process prescribed by the commissioner and all applicable state laws and regulations.

(1) Provide to the commissioner 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 to the commissioner the website domain and uniform resource locator (URL) for public access to the pharmacy benefit manager's NADAC reports.

(3) Report to the commissioner 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 and no less than prevailing Medicare Part D standards for convenient access to network pharmacies pursuant to CFR § 423.120 Access to covered Part D drugs, 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 provided by [state] board of pharmacy-licensed facilities but have a mix of [state]-licensed 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 [state]-licensed 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;

(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.

(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 relating to the 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 promulgate regulations relating to pharmacy benefit managers that are not inconsistent with this document.

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 (6) 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.

November 25, 2025

Ms. Jolie Matthews

Submitted via electronic mail: jmatthews@naic.org

RE: NAIC Pharmacy Benefit Management (D) Working Group Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Dear Ms. Matthews:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to share feedback to the Pharmacy Benefit Licensure and Regulation Guidelines for Regulators. NCPA represents the interest of America's community pharmacists, including the owners of more than 18,900 independent community pharmacies across the United States. Our perspective is incorporated into the draft guideline below.

If you have any questions, please don't hesitate to contact me at joel.kurzman@ncpa.org or (703) 600-1186. Thank you.

Respectfully,

Joel Kurzman
Director, State Government Affairs

PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION GUIDELINES FOR REGULATORS

Table of Contents

100 Daingerfield Road
Alexandria, VA 22314-2888
703.683.8200 PHONE
703.683.3619 FAX

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 the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.

B. The purpose of this document is 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, which increase in severity for repeat violations, and include suspension and/or revocation.

Section 3. Definitions

Drafting Note: States should review and modify the definitions below, if needed, for consistency with 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:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. "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.

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.

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;

(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.

I. "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 claims processing services or 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.

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 ownership and/or affiliations ~~of a~~ to health insurers, pharmaceutical group purchasing organizations, pharmaceutical manufacturers, wholesale drug distributors, specialty and mail order pharmacies, long term care pharmacies, retail pharmacies, health care centers, hospital service corporations, medical service corporations, 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. Fee structures can be used to cover the cost of oversight and enforcement through the establishment of a dedicated fund.

E. 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.

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.

(d) Updated list of ownership and/or affiliations per Section 5(C)9.

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.

(3) Provide information related to reimbursing the pharmacy for acquiring the drug and the associated pharmacy professional dispensing fee.

(4) 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.

(5) 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~~. A reasonable distance is one that is no less accessible than standards used by Medicare.

(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;

(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 or unduly audit 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. The commissioner shall collaborate with the state's Office of the Attorney General as necessary.

C. 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.

(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 relating to the 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.

D. The commissioner may use any document or information provided during the regulatory examination to determine compliance with all state laws and regulations.

E. The commissioner ~~may~~ shall 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.

F. 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 promulgate regulations relating to pharmacy benefit managers that are not inconsistent with this document.

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 (6) 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.

December 3, 2025

Ms. Joylynn Fix, Chair
Ms. Susan Jennette, Co-Vice Chair
Ms. Ashley Scott, Co-Vice Chair
PBM (D) Working Group
NAIC
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512
EMAIL: jmatthews@naic.org

SENT VIA EMAIL

RE: PCMA comments on PBM Licensure and Regulation Guideline Document

Dear Chair Fix and Co-Vice Chairs Jennette and Scott:

On behalf of our member companies, the Pharmaceutical Care Management Association ("PCMA")[1] appreciates the opportunity to provide feedback on the National Association of Insurance Commissioners' ("NAIC") draft of a proposed Pharmacy Benefit Manager ("PBM") Licensure and Regulation Guidelines for Regulators document ("Draft"). We understand the goal of this Draft is to provide regulators with guidance on PBM licensure and basic regulatory procedures and we have no objections to that goal.

However, we are concerned that the Draft goes far beyond guidance and attempts to set policy standards for states. Many of the provisions in the Draft are substantive in nature and necessitate statutory authority for promulgation of rules and regulations. Therefore, this is not appropriate for any NAIC guidance document.

In our reading of the Draft, many of the requirements appear to be much closer in character to a model law, which is described by the NAIC as "proposed insurance laws drafted by the NAIC to promote uniformity among the states."[2] The PBM (D) Working Group ("Working Group") was charged to develop PBM licensing and registration standards aligned to state and federal requirements to support uniformity in the licensure process, not to develop a model law. The guideline document (i.e., the Draft) should be amended accordingly to help states with overall licensure while deferring to their state laws for critical items such as definitions, operational expectations, and compliance targets.

What is more, the NAIC previously attempted to pass a PBM model law via the proper NAIC committee process in 2021. Noteworthy is that this PBM model law failed to be adopted by the entirety of the NAIC December 2021. Thus, PCMA and its members companies are concerned that this Draft incorporates the failed model's language throughout and is a guidance document in name only.

[1] For background, PCMA is the national trade association representing PBMs. PCMA's PBM member companies administer drug benefits for more than 289 million Americans, who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others.
[2] NAIC Library. *NAIC Model Laws 101: What are model laws?* Available here: (http://content.naic.org/sites/default/files/topic-model-laws-101.pdf).

Pharmaceutical Care Management Association
505 9th Street, NW, 10th Floor
Washington, DC 20004
www.pcmanet.org

With all that said, PCMA and its member companies offer the comments below, to help the Working Group achieve its goal of developing licensing guidance for state regulators.

***

Specific Requests for Changes

- **Section 2. Purpose**: The purpose of the Draft is to provide a foundation of standards to assist state departments of insurance ("DOIs") in licensing PBMs. The language in that section is not appropriate for any guidance document as powers for licensure, oversight of solvency, providing for the commissioner's authority and proscription of fines will already be outlined in the state's existing statute. This section should acknowledge those already enumerated powers and simply note that its purpose is to provide a framework for licensure of the PBM entity.

- **Section 3. Definitions**: Remove the section on definitions as they are unnecessary as every state has definitions in their insurance code that defines key terms (i.e., "health carrier," "health plan," "PBM," "pharmacy," etc.) and the addition of new defined terms may inadvertently lead to conflicts with state or federal law. Additionally, definitions related to market conduct exams or investigatory powers are also delineated and defined in insurance codes in each state.

  As noted above, a simple "drafting note" in the guidance that acknowledges the state's definitions for purposes of licensure and oversight is all that is needed. And the inclusion of terms such as "health benefit plan," may lead a state to erroneously believe it has regulatory authority over self-funded health plans, which it generally does not. Finally, a term such as "claims processing center," is unfamiliar. PCMA and its members have not seen the term defined in state law, and therefore, we respectfully request that it be deleted.

- **Section 4. Applicability**: Clarify that the applicability of the Draft should only be effective for health benefit plan contracts and services as delineated in statute. As you know, each state DOI's regulatory authority is governed by state and federal law, along with legal precedent. If a state has questions as to its authority, the guidance should remind the DOI to refer to the state and federal law and jurisprudence, as well as consult the NAIC's ERISA Handbook for additional, general guidelines.

  Furthermore, this section should be updated with a "drafting note" to address the timing of applicable standards. For example, as a condition of licensure, any contract that is *issued, renewed, recredentialed, amended, or extended* ***on or after*** the date the PBM receives its license to do business in this state should comply with the state's relevant licensing and regulation requirements in effect as of the time of licensure. This is consistent with many states' laws applicable to other regulated entities, which often avoid requiring a change to the terms of an in-effect contract prior to the contract's renewal and/or expiration.

Pharmaceutical Care Management Association
505 9th Street, NW, 10th Floor
Washington, DC 20004
www.pcmanet.org

- **Section 5. Licensing Requirement**: Since this is not a model law, the guidelines here need to be limited to licensure and basic DOI requirements tied to licensure. Many of the provisions in this section are substantive in nature, are not tied to licensure, and would need statutory authority for a regulator to promulgate rules or demand compliance as part of a licensure process. We recommend all non-licensure substantive provisions be deleted, including the following:
    - Remove the reference to reporting requirement from subsection B given such requirements and elements of reporting would require statutory authority.
    - Delete Subsection F (3)(a) as this requirement is not tied to licensure and statutory authority is needed for the state to require the provision. Some states have requirements on "steering" or "point of service" rebates, but most do not. This is a policy issue that should not be included in licensure requirements.
    - Delete Subsection G (1), (2) & (3) as these requirements are not tied to licensure and statutory authority is needed for the state to require the provisions. Similar to above, most states do not have a payment mandate nor reporting mandate related to National Average Drug Acquisition Cost ("NADAC") payment standards.
    - Delete Subsection 4 (a), (b), (c), & (d) as these requirements are not tied to licensure and statutory authority is needed for the state to require the provisions. Network adequacy standards as well as pharmacy contracting standards must be delineated by state law and not under licensure guidelines. In addition, NADAC reports are public, with the NADAC reference files being freely available on the Medicaid.gov website and Data.Medicaid.gov. These resources are updated regularly and contain the calculated average prices for prescription drugs, making them accessible to the public, including healthcare providers, policymakers, and the public.

- **Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices**: While gag clauses are generally not permitted, this section includes additional provisions that relate to contractual standards between a PBM and their contracted network. Any requirements relating to pharmacy contracts should follow the state law and not assume that all states have these provisions in place. A "drafting note" that advises a state to review any statutory requirements relating to agreements between PBMs and their contracted network is all that is needed here. And provisions E (1) and (2) within this section both pertain to plan enrollee cost-sharing. Thus, they are directly related to plan benefit design, which is not under the purview of the PBM. Rather, the plan sponsor makes such decisions.

- **Section 7 Enforcement**: we suggest the following clarifications:
    - Clarify in B (2) that the information sought by the Commissioner or designee must be relevant to PBM services that are the subject of state regulatory authority.
    - Remove the reference in B (3) to the Model law on Examinations (#390) which applies to financial exams of insurers as this is not relevant for any guidance document on PBM licensure and regulation.
    - Clarify the scope of regulatory examination authority to activities conducted within the state's jurisdiction.

Pharmaceutical Care Management Association
505 9th Street, NW, 10th Floor
Washington, DC 20004
www.pcmanet.org

- Provide operational guidance for multi-state health plans to ensure compliance without excessive audits or conflicting requirements.

We respectfully request that the Working Group revise the Draft to ensure it functions as a true guidance document, rather than a model law. To assist in this effort, below we offer the following overview of standards that should be included, as well as policy issues that should be excluded, to maintain the Draft's intended purpose.

Standards Appropriate for Inclusion

- **General purpose**: The guidelines should establish a foundational framework for PBM licensing and registration standards.
- **Reference to State Law:** Include a drafting note advising states to rely on their existing PBM statutes for definitions, applicability, and scope.
- **Licensure or Registration Requirements:** Limit requirements to those consistent with other licensed entities and prevailing state laws, such as:
  - Standard application information;
  - Renewal procedures;
  - Process for license disapproval or revocation; and
  - Recordkeeping standards during and after licensure.
- **Regulatory Oversight:** Affirm the general authority of state insurance regulators to examine books and records relevant to PBM services subject to state insurance regulation.
- **Introduce materiality thresholds:** The guidance should specify when licensure may be refused, consistent with other licensed entities and prevailing state laws. For example, licensure may only be refused for material violations, not minor infractions.
- Clearly **outline an appeals process** for PBMs to contest licensure refusals, ensuring fair treatment and due process that complies with the state's administrative disputes statutes and procedures.
- **Limit officer attestation** to PBM activity rather than plan activity.
- **Limit renewal and reporting requirements** to PBM activities and plans subject to the state's regulatory authority.
- Where possible, recommend insurance departments **access data (such as NADAC) directly from federal or public sources**, rather than requiring PBMs to furnish it.

Policy Issues That Should Be Excluded

- **Data Calls and Reporting:** Exclude requirements for data calls, reporting, or examination standards beyond those generally applicable to other regulated entities.
- **Network Adequacy:** Exclude network adequacy requirements, as these are typically addressed in separate statutory provisions applicable to health insurance issuers that a PBM supports.

Pharmaceutical Care Management Association
505 9th Street, NW, 10th Floor
Washington, DC 20004
www.pcmanet.org

- **Pharmacy Contracting or Reimbursement Requirements:** Exclude requirements related to pharmacy contracting or reimbursement, which are matters of state law and policy, not licensure.
- **Expansion of NAIC Policy:** Avoid including any provisions that would establish NAIC policy beyond general licensing and registration standards.
- **Pharmacy Accreditation**: Exclude requirements that would prohibit or restrict pharmacy accreditation standards for PBMs and/or health plans/carriers, as this issue exceeds requirements for state licensure.

***

Again, PCMA and its member companies look forward not only to your response, but also to collaborating with you on all the aforementioned necessary revisions to the Draft. We appreciate the opportunity to provide comments.

And, PCMA and its member companies look to working with the NAIC on revisions to the Draft, as well as subsequent drafts of the PBM Licensure and Regulation Guideline Document.

Please do not hesitate to contact me with any questions or for further discussion.

Sincerely,

Peter Fjelstad

Peter Fjelstad
Assistant Vice President, State Regulatory & Legal Affairs

Pharmaceutical Care Management Association
505 9th Street, NW, 10th Floor
Washington, DC 20004
www.pcmanet.org

670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

November 21, 2025

Ms. Jolie Matthews

Submitted via electronic mail: jmatthews@naic.org

RE: NAIC Prescription Drug Coverage (B) Working Group Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Dear Ms. Matthews,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we commend the National Association of Insurance Commissioners (NAIC) for its sustained focus on strengthening accountability for pharmacy benefit managers (PBMs). Your work to advance coherent, enforceable standards is critical to ensuring PBMs operate transparently and in the best interests of patients and plan sponsors. PhRMA appreciates the opportunity to provide comments on the draft "Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators" (Regulation Guidelines).

PhRMA represents the nation's leading innovative biopharmaceutical research companies dedicated to developing medicines that transform lives and create a healthier world. Together, we fight for solutions that ensure patients can access and afford treatments that prevent, treat, and cure disease. Over the past decade, PhRMA member companies have invested more than $850 billion in the search for new therapies, supporting nearly five million U.S. jobs.

PBMs play a decisive yet largely unseen role in determining coverage, pricing for plan sponsors, and costs for patients at the pharmacy counter. Without clear and enforceable licensure and transparency requirements, the opaque practices by PBMs (such as spread pricing, undisclosed fees, and retained rebates and other price concessions) can divert savings from patients and plan sponsors and increase out-of-pocket costs for patients.

PhRMA strongly supports:

- PBM licensure and registration backed by real oversight tools;
- Robust transparency of fees and network arrangements;
- Clear prohibitions on spread pricing;
- Standardized reporting to regulators; and
- Policies that require negotiated savings to be passed through at the point of sale to see lower out-of-pocket costs for patients.

These pragmatic steps, increasingly embraced by states, will bring sunlight and accountability to PBM operations.

NAIC's Regulation Guidelines are a necessary foundation to bring clarity and standardization to regulation of the PBM industry. The proposed draft of the Regulation Guidelines offers a solid base for that foundation. PhRMA provides below for your consideration suggestions regarding definitions, applicability, and transparency that we believe will further strengthen the intent of the regulations.

Definition Considerations

Recommendation: PhRMA recommends expanding the definition of "other prescription drug or device services" to encompass a full range of PBM business activities.

Rationale: The amendments clarify the service types and names of services that PBMs and/or their related and affiliated entities perform on behalf of PBMs' clients to help ensure that relevant PBM activities are captured within the regulations.

Amendment: Section 3: Definitions: "Other prescription drug or device services": insert new language

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 the price of prescription drugs, including negotiating and contracting for direct or indirect rebates, discounts, other price concessions, 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;

(4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) Developing and maintaining formularies;

(6) Designing or managing any aspect(s) of prescription benefit programs including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, controlling the cost of covered prescription drugs, managing or providing data relating to the prescription benefit programs, or the provisions of services related thereto; or

(7) Advertising or promoting services.

Applicability Considerations

Recommendation: PhRMA recommends language similar to that within New York Insurance Law, which makes PBMs responsible for the actions of their subcontractors, affiliates, and other downstream entities when those entities are acting on behalf of the PBM.

NY Ins. Law Section 2911(c) states, "The pharmacy benefit manager shall be responsible for the actions of any subcontractor, affiliate, subsidiary, or other individual or entity who violates any provision of this article in performance of any pharmacy benefit management services for the pharmacy benefit manager whether or not the pharmacy benefit manager was aware of, or sanctioned, the conduct."

Rationale: By making a PBM responsible for the actions of entities related to and affiliated with the PBM that act on behalf of the PBM, the suggested amendment helps to close a potential loophole that PBMs may try to exploit to evade accountability.

Amendment: Section 4: Applicability: Insert new applicability requirement: Create new Section 4(D)

Transparency Considerations

Recommendation: To complement and strengthen the existing reporting requirements for license renewal included in the Regulation Guidelines, PhRMA recommends including data elements similar to that enacted in Pennsylvania's "Pharmacy Audit Integrity and Transparency Act – Omnibus Amendments: Act of Jul. 17, 2024, P.L. 852, No. 77" ("Act 77").[i]

Section 7 of Act 77 requires PBMs to submit annual transparency reports to the state insurance department detailing prior-year data for each health insurer client. Reports must include aggregate rebates, aggregate administrative fees received from manufacturers, aggregate retained rebates not passed through to plans, rebate percentage ranges, and any differences in reimbursement between affiliated and non-affiliated pharmacies.

Rationale: Requiring a more comprehensive data will allow states to gain more insight into the financial flows within PBM business activities and brings much-needed accountability by PBMs for the role they play in the rising costs to plan sponsors and out-of-pocket expenses for patients.

Amendment: Section 5: Licensing: Insert new reporting section for renewal: new G(4) subsection

Final Thoughts

States across the country have moved to license PBMs, increase reporting, restrict the use of spread pricing, and require greater transparency into rebates and price concessions. Uniform NAIC Regulation Guidelines for regulators will raise the floor, reduce fragmentation in regulation, and provide regulators with tools to help ensure that PBMs are held accountable to the states they operate in and the patients and clients they serve.

PhRMA applauds the NAIC's commitment to advancing a modern, enforceable framework that holds PBMs accountable. Licensure with real oversight, transparent and auditable reporting, and strong enforcement mechanisms are pragmatic steps that will improve accountability and fairness across the industry. We stand ready to support the Working Group and staff as you refine model provisions, data standards, and implementation guidance.

Thank you for your consideration and for your leadership in protecting consumers.

Sincerely,

Charise Richard
Sr. Director, State Policy
PhRMA

[i] https://www.palegis.us/statutes/unconsolidated/law-information/view-statute?sessind=0&actnum=77&txttype=htm&sessyr=2024

December 1, 2025

Delivered via email: jmatthews@naic.org

Jolie Matthews
Senior Counsel, Life and Health Policy
National Association of Insurance Commissioners
1101 K Street NW, Suite 650
Washington, DC 20005

RE: NAIC Draft Pharmacy Benefit Manager Licensure and Regulation Guidelines for Regulators

Ms. Matthews,

On behalf of URAC, thank you for the opportunity to provide comments in response to the National Association of Insurance Commissioners' (NAIC) November 7 draft Pharmacy Benefit Manager (PBM) Licensure and Regulation Guidelines for Regulators. URAC applauds the NAIC for its ongoing commitment to advancing an important national dialogue on the role of PBMs and the appropriate regulatory response from state insurance departments. We are proud to have engaged with the NAIC on the issues of PBM accreditation and specialty pharmacy accreditation in recent years, discussing the value of accreditation and its critical role as a supplement to state regulation. While we appreciate the NAIC's desire to provide state insurance departments with effective guidance on issues related to PBM regulation, we write today to comment on a provision in the draft guidelines that encourages restrictions on the accreditation of specialty pharmacies despite the clear connection between specialty pharmacy accreditation and patient safety and quality. Specifically, we are concerned about the decision to include the pharmacy accreditation language found in Section 5(G)(4)(d) of the draft guidelines given that a majority of states have declined to adopt such restrictions due to the critical safeguards provided by the accreditation of specialty pharmacies. Recommending that states prohibit important patient safety standards such as specialty pharmacy accreditation will not further the goals of reducing costs or enhancing access to care. It serves only to weaken existing patient safety protections and quality improvement initiatives that benefit all patients who rely on accredited pharmacies to provide high-quality care. We ask that the following be deleted from the draft guidelines:

> ~~(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.~~

URAC is the independent leader in promoting health care quality through accreditation, measurement, and innovation. URAC is a non-profit organization that uses evidence-based measures and develops standards through inclusive engagement with a range of stakeholders committed to improving the quality of health care. URAC accreditation is a symbol of excellence for organizations to showcase their validated commitment to quality and accountability.

As written, the draft guidelines encourage states to effectively prohibit PBMs from using the accreditation process to implement any quality standards or safety programs for pharmacies beyond the basic requirements for licensure from the relevant state board of pharmacy. URAC values the critical role that state Boards of Pharmacy play in ensuring the delivery of quality care and medications to patients, but this role and its scope differs greatly from those of accreditation. While Boards of Pharmacy fulfill functions as a regulator and determine whether pharmacies meet minimum licensure thresholds, specialty pharmacy accreditation builds on the foundational oversight of Boards of Pharmacy by adding a far more comprehensive review of a pharmacy's ability to deliver quality services and care management to patients receiving complex, expensive medications in a consistent and reliable manner. Unlike minimum licensure standards, specialty pharmacy accreditation validates the operations and care management provided by pharmacies based on quality standards defined by national best practices. This differs from boards of pharmacy that focus on a much more limited scope of issues addressing licensure and the environment in which the pharmacy is dispensing drugs. Board of Pharmacy licensure standards on their own are insufficient to deliver high-quality care required for those seeking to serve patients prescribed specialty medications. **The gap that exists between accreditation and minimum licensure represents meaningful steps that result in improved quality and safety.**

As an accrediting entity, URAC has no position on what constitutes effective state regulation of PBMs. Many of the provisions included in the NAIC's draft guidelines may ultimately serve to benefit patients and strengthen access, but we believe that proposed Section 5(G)(4)(d) should be stricken. We do not believe that the prohibition on accreditation requirements contained in the draft guidelines is a provision that will increase transparency, reduce costs or improve safety. Rather, the likely effect of such a prohibition is a decrease in quality and safety in states choosing to adopt the language. For these reasons, a majority of states have chosen not to enact a specialty pharmacy accreditation restriction similar to the one contained in the NAIC draft regulation guidelines. URAC has been supportive of alternative approaches to ensuring that pharmacies have access to PBM networks while also assuring that PBMs have the ability to take steps to ensure patient safety and quality. States such as North Carolina have considered limits on accreditation requirements that prohibit requirements for multiple specialty pharmacy accreditations, but maintain the important role of specialty pharmacy accreditation by permitting PBMs to implement safety and quality measures that include requirements for accreditation from a single national accreditor. There is a legitimate debate that should occur as part of PBM regulation about the use of contracting tools, but this debate does not extend to the value of accreditation. **Accreditation is a quality tool utilized to protect patients and ensure that every patient receives high-quality, high-value care. It does not address or relate to the concerns that the bill seeks to address with PBMs, it only serves to improve quality and safety.**

The goal of appropriately regulating PBMs is a laudable one, but we urge caution whenever legislators or regulators seek to restrict the ability to hold providers to reasonable best practices meant to protect patients from poor quality care. The result of such efforts is likely to be a state in which quality and safety are diminished. Accreditation is intended to be a supplement to basic regulation and

provides necessary oversight in many areas that are simply unaddressed by Board of Pharmacy requirements. As one example, in an article published in 2024 by the New York Times entitled "Hot Summer Threatens Efficacy of Mail-Order Medications," the potential effects of heat exposure on medications were highlighted. The report noted that increasing temperatures have exacerbated the long-term problem of ensuring that medications reach their intended patient at the appropriate temperature range, but highlighted that Boards of Pharmacy were ill-equipped to address this challenge. Conversely, accreditation standards provide enhanced standards for medication shipping and temperature control that supplement traditional regulatory approaches. Other areas where accreditation plays a meaningful role in supplementing Board of Pharmacy requirements include ensuring accurate and detailed communication with patients, as well as applying standards for medication distribution and performance measurement.

The impact of a prohibition against accreditation standards is magnified in areas such as specialty pharmacy, where accreditation plays a critical role in ensuring access to safe and effective specialty pharmacy services. Given the complexity of specialty medications and the potential for serious side effects, pharmacies must deploy specific competencies in a reliable manner to promote and document positive clinical outcomes. Those pharmacies that have achieved URAC Specialty Pharmacy Accreditation have demonstrated their ability to safely dispense and effectively manage the care of patients who require increasingly complex medications. **Organizations that achieve accreditation are less likely to deliver care that results in harm to patients as they have demonstrated their ability and capacity to care for complex patients receiving complex drugs.** As a tool of quality assurance, payors look to accreditation as an independent validation of excellence to ensure that their pharmacy network has the capacity to fully provide these highly specialized services. Eliminating this important tool will provide no benefit to patients, instead potentially subjecting them to ineffective care or care that results in harm.

We appreciate your willingness to take our views into consideration as well as your interest in addressing legitimate concerns about the role of PBMs. However, we urge you to eliminate the language contained in Section 5(G)(4)(d) of the draft guidelines that prohibits the use of accreditation standards in contracts between PBMs and pharmacy providers. Removing this language would be a meaningful step toward ensuring that the draft guidelines do not exceed the scope of appropriate PBM regulation or inadvertently jeopardize patient safety and the quality of specialty pharmacies. If you have any questions, please contact URAC's Director, State Relations, Joshua Keepes at jkeepes@urac.org.

Sincerely,

Shawn Griffin, M.D.
President and CEO of URAC