January 30, 2026

Ms. Jolie Matthews
Pharmacy Benefit Management (D) Working Group
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700
Washington, DC 20001
EMAIL: JMatthews@naic.org

**Re: Comments on PBM Exam Standards DRAFT dated November 25, 2025**

Dear Ms. Matthews:

On behalf of our Coalition, we appreciate the opportunity to provide comments on the November 25, 2025, PBM Exam Standards Draft ("draft standards"). We appreciate the extensive work that went into developing the draft standards and value the NAIC's continued efforts to promote clarity, consistency, and applicability of examination standards across jurisdictions.

After reviewing the draft standards in detail, our Coalition proposes targeted revisions intended to increase language precision, promote regulatory consistency, align standards with existing statutory authority, and reduce operational burden without diminishing regulatory visibility.

Below is a consolidated, high-level summary of the key recommendations included in our submission. In addition to the summary below, we are also including a red-line version and a clean version of our suggested revisions to the draft standards.

**Enhance overall clarity of standards**.
Many of the revisions we made to the draft standards were to ensure that:

1. Standards are clear and actionable;
2. Requirements are tied to applicable state statutes and examinations are limited to fully insured plans and non-ERISA ASO; and
3. Obligations can be operationalized by both PBMs and regulators.

Where helpful, we also converted questions into standards or tightened language to reduce ambiguity.

**Improve accuracy and consistency of PBM role descriptions and operational processes.**
Our proposed revisions ensure the standards accurately reflect PBMs' delegated functions and distinguish them from activities retained by health plans. Several edits clarify that PBMs *support* health plans and non-ERISA ASOs but do not independently design or determine benefits. These revisions avoid misinterpretation of contractual roles and align terminology with other chapters of the Market Regulation Handbook (Handbook).

For the specialty drug and formulary sections, our revisions ensure the standards reflect how formulary committees operate, protect sensitive P&T committee information, and apply state definitions accurately. The language was refined to avoid requiring personal identifiable information beyond what is needed for compliance.

Additionally, many edits correct assumptions or processes that do not reflect how PBMs operate today including:

1. Clarifying that effective rate reconciliation is not performed at the individual claim level;
2. Aligning claims-related standards with NCPDP requirements and state timelines; and
3. Adjusting language around network participation, contracting, vendor oversight, dispensing fees, and pharmacy audits to reflect operational realities and state variation.

**Consolidate and streamline redundant text.**
Throughout the draft standards, we identified repeated explanations (e.g., employer/Taft–Hartley definitions, glossary material, and examination procedure descriptions). We recommend removing duplicative language and consolidating background sections to improve readability and align the structure with other chapters included in the Handbook.

**Clarify statutory vs. non-statutory requirements.**
In many areas, the draft appeared to imply obligations not supported by state law or to apply insurer-centric concepts to PBMs (e.g., solvency, market analysis, concurrent review processes). Our revisions ensure the standards align with regulatory authority, clarify that certain requirements apply only where state law is applicable (e.g., fully insured and non-ERISA ASO plans), remove references to "covered entities" when statutory definitions may vary, and reduce the risk of inconsistent enforcement across states. Our edits clearly distinguish between:

1. PBM obligations established by state statute or regulation;
2. Plan-level requirements that cannot be imputed to PBMs; and
3. Optional examiner tools vs. mandatory review items.

**Ensure safe treatment of confidential and proprietary information and adopt guidelines for the use of outside contracting firms/examiners.**
Our revisions clarify where unredacted documents are appropriate and highlight the need for confidentiality protections—particularly around pricing terms, amendments, rebate contracts, and vendor agreements. Several edits emphasize that regulators should receive only the minimum necessary information to verify compliance, consistent with state public records laws. We also suggest incorporating recommendations on states' use of contract firms for consistency with the accreditation guidance adopted by the Financial Condition (E) Committee and Financial Regulation Standards and Accreditation (F) Committees in 2025.

**Focus document requests on material, relevant information.**
Many sections requested all contracts, all amendments, all correspondence, or all versions of network materials, which would generate enormous volumes of non-material data. Our revisions preserve examiner access to essential information while preventing burdensome, unmanageable audits. Our recommendations include:

1. Limiting requests for documentation and communication to in scope final, fully executed communications (rather than routine back and forth communication between contracting entities);
2. Allowing and encouraging sampling when large volumes of pharmacy contracts or audits exist;
3. Aligning claims-data requests to the subsets affected by state statute; and
4. Adding clarifying language to recognize that PSAOs—not PBMs—often control downstream communications to individual pharmacies.

**Align claims, reconciliation, and dispensing fee standards with industry practice and state law.**

Our proposed revisions ensure:

1. Effective rate reconciliation is not treated as a claim-level or state specific process;
2. Dispensing-fee reviews are conducted only in states with explicit statutory requirements;
3. PBM processes are evaluated based on clear, concise communication requirements applicable under state laws; and
4. Examinations recognize that fee structures, unless prohibited, may differ for specialty, mail-order, and affiliate pharmacies.

**Modernize network adequacy provisions.**

When considering network adequacy standards, it is important to recognize that maintaining multiple networks is not an indicator that all networks were used or available for use in a certain state or type of client. For the network adequacy standards, we recommend revisions to:

1. Reflect that PBMs maintain multiple pharmacy networks with differing purposes;
2. Distinguish PBM network obligations from health plan adequacy obligations;
3. Ensure any adequate-access standard is tied directly to state law requirements; and
4. Remove comparisons that could misinterpret affiliate networks selected solely by a client.

**Refine utilization review standards to reflect PBM functions.**

Several sections of the draft standards referenced processes (e.g., concurrent review) that apply to medical benefit administration rather than PBM administration. In order to ensure that the standards reflect PBM functions we:

1. Aligned terminology with pharmacy-specific utilization review;
2. Ensured timelines and notification standards remain state-specific; and
3. Permitted disclosure of reviewer roles without requiring unnecessary personal information.

**Standardize and clarify complaint, grievance, and appeals expectations.**

For the complaint, grievance and appeals draft standards our Coalition recommends:

1. Aligning standards with existing state complaint-handling rules;
2. Focusing on PBM-specific responsibilities rather than insurer obligations;
3. Eliminating ambiguous standards (e.g., “easily understood”); and
4. Emphasizing accurate logging, timely response, and availability of documentation consistent with state law.

**Improve audit standards for clarity and workability.**

Our revisions regarding audit standards aim to ensure audits remain fair, efficient, and transparent while avoiding unnecessary administrative burdens. We suggested practical guardrails for audit-related documentation and addressed statutory limitations on audit methods such as extrapolation. Specifically, we recommend:

1. Limiting examiner requests to fully executed documents and final communications;
2. Eliminating production of informal, non-record communications;
3. Requiring clear PBM procedures for notice, documentation, timelines, and dispute processes; and
4. Ensuring audit standards reflect only those processes permitted or required under state law.

Our Coalition appreciates the NAIC's willingness to work with us on refining the draft standards to enhance clarity, reduce ambiguity, and align them with established regulatory authority. As we have noted in the past, we support the creation of the standards and believe our suggested revisions will ultimately promote a more consistent and workable examination process for regulators and PBMs alike.

We welcome the opportunity to discuss any of these recommendations in more detail and look forward to our continued collaboration.

Sincerely,

**Franca D'Agostino**
**Director, Regulatory Affairs**
**The Cigna Group**

**Leanne D. Gassaway**
**VP State Government Affairs**
**CVS Health**

**Christine Cappiello**
**Sr. Director, State Affairs and NAIC**
**Elevance Health**

**Mollie Zito**
**Deputy General Counsel, Regulatory Affairs**
**UnitedHealth Group**

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~~not based on the laws and regulations of any specific jurisdiction. This handbook is a guide to assist examiners in the examination ~~process~~of Pharmacy Benefit Managers, as defined by state law. 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~~Pharmacy Benefit Managers provide a variety of services to health plans including negotiating and contracting ~~with all the various types of~~ pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms. PBMs work with a variety of clients including employers, health plans, and unions to help administer the benefits offered to members and may be~~are~~ contracted to develop , negotiate, implement, and administer ~~manage~~ formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. PBMs may be delegated ~~are responsible for~~ the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example, drug coverage tiers~~, 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.**~~

**Commented [A1]:** Refined PBM role description to accurately reflect the PBM's role of working with clients rather than being solely responsible for activities such as plan design, etc.

**Commented [A2]:** Recommend deletion as this is addressed in "Types of Examinations" below.

**Commented [A3]:** Recommend deletion of language as it is redundant to language in the first paragraph.

**Commented [A4]:** Recommend moving this language to "Scheduling, Coordination, and Scope."

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~~Definitions~~Glossary of Terms~~:~~

***For general background, what follows is an explanation of key terms related to PBM examinations.*** ***Regulators ~~may want to consider~~ however, must use state specific definitions when conducting a PBM Examination as the following general explanations do not replace, supersede, or modify definitions prescribed under applicable state or federal law, which remain the controlling authority*****.**

**Biologic Drugs -** ~~Biologic drugs~~ are distinct from traditional brand-name and generic drugs because they are made of living organisms. Examples include, ~~cells, such as~~ monoclonal antibodies, antitoxins, ~~and~~ certain vaccines, and cell and gene therapies.~~[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 is FDA-approved as having no clinically meaningful difference from the reference product and may be marketed~~produced~~ following the expiration of the reference biologic's patent and exclusivity period. All FDA-approved biological products, including biosimilar and interchangeable biological products as well as a limited number of products available over the counter, are included in the FDA's ***Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*** (commonly known as the Purple Book). Certain biologics, including many biosimilars and cell and gene therapy products, are administered by health care providers and are typically covered under the medical benefit.

Statutory Definitions: Federal law defines key terms relevant to biologics, including biological product, reference product, biosimilar, and interchangeable biosimilar (42 U.S.C. §262). State pharmacy practice acts often include additional definitions, including when and under what conditions a pharmacist may substitute a generic for a brand name drug or a biosimilar for a biologic.

**Brand-Name Drugs -** ~~Manufacturers who produce brand-name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name~~ are drugs sold by a manufacturer under a specific name or trademark that is protected by a ~~receive~~ patent.~~nts 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. All FDA-approved brand-name drugs that are available by prescription, and some that are available over the counter, are included in the FDA's ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

**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. Regardless of the risk model, ~~but~~ payors sometimes contract with ~~hires~~ another entity, such as an insurance company, PBM, or other benefit manager , on a third party basis t~~o~~ administer the benefits. ~~Employers~~ These payors retain ultimate, discretionary control of the benefit plan design but may choose to delegate certain services, including carving out pharmacy benefit administration entirely, to one or more ~~choose how much of the benefits they will allow a~~ contracted benefits administrators. ~~to design and may choose to "carve out" the pharmacy administration and have external entities perform different functions.~~

Groups that are collectively bargained under ERISA Section 3(40), Taft-Hartley trusts established under 29 USC §186, and self-funded employer groups are not subject to state insurance regulation. Examiners may need to consult others in the insurance department or other regulatory agencies to correctly determine jurisdiction. Some states have enacted the NAIC Jurisdiction to determine Jurisdiction of Providers of Health Care Benefits Model Act which also provides guidance. Examiners may reference the NAIC Health and Welfare Plans Under the Employee Retirement Income Security Act (ERISA): Guidelines for State and Federal Regulation for more information about determining whether a state law is preempted by ERISA.

**Commented [A5]:** This has been updated to improve consistency with the approach of other Handbook chapters and to reflect that these terms are not based on an NAIC Model Law. The proposed changes reflect the goal of providing general background information/ context while referring examiners to state or federal law for how to define specific terms during the examination process. Where possible, references to specific federal statutes have been added.

**Commented [A6]:** Removing numbers that appear to be unlinked references throughout and instead inserting federal law citations, consistent with other health-related Handbook chapters.

**Commented [A7]:** Many state pharmacy practice laws reference the Orange and Purple Books.

**Commented [A8]:** This is a general explanation taken from Healthcare.gov's glossary of terms, available at Brand name (drugs) - Glossary | HealthCare.gov. FDA also has a glossary of terms, available at Drugs@FDA Glossary of Terms | FDA

**Commented [A9]:** Many state pharmacy practice laws reference the Orange and Purple Books.

**Commented [A10]:** Edits to attempt to improve consistency with how TPA is explained in Ch. 30 (Conducting the TPA Examination). Please note that the terms union and Taft Hartley Trusts are not used throughout the standards that follow.

**Commented [A11]:** Added for consistency with the explanation of "Exempt Benefit Plans" in Ch. 24 (Conducting the Health Examination).

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**Generic Drugs -** ~~Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing~~ are small molecule drugs that are therapeutically equivalent ~~generic~~(or bioequivalent) to their reference brand name ~~-~~drug products in dosage, safety, strength, and other factors and are only available after the brand-name drug is no longer patent-protected. 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.~~13~~ ~~G~~ Prescription generic drugs comprise the largest portion of the U.S. pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers~~.~~. All FDA-approved brand-name and generic drugs available by prescription, as well as certain products that are available over the counter, are listed in the ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (commonly known as the Orange Book).

**Commented [A12]:** This was included because many state pharmacy practice laws reference the Orange and Purple Books.

**Health Plan** refers to how state statutes define regulated fully-insured health benefit plans or non-ERISA Administrative Services Only (ASO) health benefit plans. Examiners should refer to those state definitions, but, generally, references to health plan in this chapter include any fully-insured arrangement or non-ERISA ASO under the regulatory authority of the state insurance department.

**Insurers** may choose to ~~—Insurers~~ contract with PBMs to manage the pharmacy benefit portion of their health care benefits they provide~~d~~ to their insureds and enrollees.~~4~~ Insurers may choose to 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 specific services that help manage or reduce costs, including utilization management, prescription drug rebates, ~~and~~ negotiation of pharmacy dispensing fees and prescription drug reimbursements, and access to pharmacy networks.~~6~~ Ultimately, the scope of the PBM's role in administering~~managing~~ the~~is~~ 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.

Statutory Definitions: Federal law includes definitions for key terms relating to health plans subject to state insurance regulation, including the Health Insurance Portability and Accountability Act (29 U.S.C. § 1191b) and the Public Health Service Act (42 U.S.C. § 300gg-9). In addition, each state has its own laws defining the entities (such as health carriers, health maintenance organizations, or health insurance issuers), products (such as health benefit plans or health insurance coverage), and markets (such as individual, small group, and large group health insurance markets) that are subject to state insurance regulation.

**Manufacturers** ~~—P~~ of p~~P~~harmaceuticals ~~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.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

**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 (e.g., individual, small group, large group or government program) and the arrangement that the payor chooses. In this ~~paper~~handbook, when PBM functions are referenced, payors may choose to do those tasks internally.

**Pharmacies** offer a range of services to patients, including dispensing drugs, administering immunizations, performing health screenings, testing at point-of-care, and providing medication counseling. State laws often

**Commented [A13]:** Revisions attempt to better reflect how the examiner should view pharmacies and the various classifications a PBM may utilize for pharmacies.

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impose regulatory classifications and pharmacies, further, self-classify with the National Council for Prescription Drug Programs (NCPDP) based on various attributes, such as class (meaning their ownership structure, as explained herein), and the categories of prescription drugs dispensed and to what patient population (for example, specialty pharmacies, community/ retail pharmacies, compounding pharmacies, and long-term care pharmacies). The regulatory classifications, which vary by jurisdiction, create core parameters governing pharmacy operations.

PBMs and health plans use this information and may also use additional attributes, such as location (for example, urban, suburban, and rural), level of service, negotiated rates (for example, preferred v. non-preferred), network status (meaning in-network or out-of-network), or delivery mode to classify pharmacies. Unlike regulatory classifications, these categorizations are created for network management, reimbursement methodologies, and to administer benefit design.

A pharmacy chain typically refers to a third-party entity that engages in a ~~retail~~ business and that owns or operates four or more pharmacies under common ownership ~~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.~~

**Commented [A14]:** This edit reflects the NCPDP Dispenser Class Code definition.

**Commented [A15]:** Deleted as this is now covered at the lead-in

~~**Independent**~~

Independent pharmacies generally include ~~refer to~~ pharmacies that are privately and independently owned and operated by one or more pharmacists or under common ownership with no more than three pharmacies, 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.

**Commented [A16]:** NCPDP defines an independent pharmacy as one to three pharmacies under common ownership.

**Commented [A17]:** Moved to lead-in as most pharmacies offer these services, not just independent pharmacies.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). Federal law defines pharmacies as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

**Pharmacist**s are licensed and trained health care providers that ~~. The basic duty of a community pharmacist is to~~ assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a ~~the~~ medication to a~~the~~ patient~~s~~ to ensure that the patients do not receive the wrong drug~~s~~ 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. Pharmacists' permissible activities are subject to state scope of practice laws.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The DSCSA defines pharmacists as "dispensers" while the CSA uses the term "practitioner." State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

**Pharmacy Benefit Managers (PBMs)** ~~. PBMs~~ provide claims processing services or other prescription drug services on behalf of insurers to insureds or administer an insurer's prescription drug coverage pursuant to its contract or under an employment relationship with an insurer or health plan that directly manages the prescription drug coverage provided by the insurer or health plan. Insurers determine through contractual delegation which activities a PBM may perform on their behalf, which may include N~~n~~egotiating~~e~~ and contracting 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 may also develop~~design~~, negotiate, implement, or ~~-~~administer clinical, formulary or other preferred lists~~designs~~ for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers.~~24~~ PBMs may be delegated ~~are responsible for~~ the design and implementation of preferred and non-preferred pharmacy networks, metric-

**Commented [A18]:** Edits attempt to clarify the role of PBMs and the broad range of services they may offer.

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based payment arrangements, and formulary design elements (for example, drug coverage tiers, and utilization management protocols).[25] ~~PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.~~ PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews.

**Pharmacy Benefits Manager Network** – means ~~a network of~~ the group or groups of participating pharmacists or pharmacies ~~that are offered by an agreement or contract to~~ providing~~e~~ pharmacy goods or services.

**Pharmacy Services Administrative Organizations (PSAOs)** ~~– Pharmacy Services Administrative Organizations (PSAOs)~~ are organizations that provide administrative services to independent pharmacies, who contract with PSAOs ~~to~~ perform services such as ~~support~~ the evaluation, negotiation, and execution of a contract with PBMs or payors, or wholesalers. In most cases, an independent pharmacy contract is with the PSAO, rather than with the PBM directly, for PBM network participation. The PSAO's ~~overall administrative function is to assist with~~ also performs contract evaluation, negotiation of key terms like reimbursement rates, dispensing fees, billing requirements, payment frequency, effective rate reconciliations and value-based or quality payment adjustment terms and execution~~,~~. PSAOs often perform credentialing services and may also offer their customers services such as, central payment and reconciliation, software, and patient data evaluation.[30] In many instances a PSAO is owned by a wholesaler and most others facilitate business relationships with wholesalers to negotiate for, purchase, or deliver prescription drugs to their pharmacy clients.

**Rebate**~~**s**~~ – means a formulary discount or ~~other~~ pric~~e~~ing concession~~, or payment that is both of the following: 1. Based on~~ attributable to the utilization of ~~a~~ prescription drugs in this state~~. 2.~~ and that is ~~P~~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~~ to a pharmacy benefits manager.

Statutory Definitions: While these programs are out of scope for purposes of state examinations, examiners should be aware that federal law establishes standards for certain rebates, including the Medicare Prescription Inflation Rebate Program (42 U.S.C. § 1395w-114a and -114b) and the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).

**Specialty drug**~~**s**~~ - is a term that generally refers to drugs and biologics that are typically high-cost, and can be complex~~,~~ to ship, or store, require specialized administration, subject to limited or exclusive distribution or may require specialized clinical care such as frequent dosage adjustments, intensive patient monitoring or counseling, or ongoing clinical support (i.e. high-touch). It often references ~~-~~medications used to treat rare, complex, life threatening or ~~or~~ chronic conditions. Because of this, t~~T~~hese drugs often require ~~specialized handling, administration, and~~ dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

There is no unified regulatory definition of the term specialty drug. Examiners should consult applicable state law and impacted health plan formulary definitions.

**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 several of ~~-~~the largest PSAOs used by independent pharmacies.

Statutory Definitions: Federal law includes definitions for key entities in the Drug Supply Chain Security Act (21 U.S.C. § 360eee), who are also subject to the Controlled Substances Act (21 U.S.C. §802). The Drug Supply Chain Security Act also establishes national standards for state licensing of wholesale drug distributors (21 U.S.C. § 353). State pharmacy practice acts also define many of these terms for the purposes of state licensure and regulation.

**Commented [A19]:** Updated for greater consistency with The Health Benefit Plan Network Access and Adequacy Model Act #74.

**Commented [A20]:** Attempted to simplify this explanation

**Commented [A21]:** Deleting since this irrelevant for a handbook and can change over time.

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**Qualifications of Examiners**

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

If a department elects to use contractors to complete a PBM examination, the department should demonstrate involvement of appropriate department personnel (i.e., department designees) during the course of the examination in accordance with the following guidelines and the department's policies and procedures. This should result in the department designee providing effective contractor oversight (e.g., status updates, budget oversight, approval of exam procedures), as well as understanding and assessing the overall quality of the work performed.

Use of Contract Personnel:

Standard: A department that utilizes contract personnel to assist in "Conducting the Pharmacy Benefit Manager Examination" should ensure that those hired in the capacity of a contractor are subject to standards that are comparable to or exceed those standards applicable to employees of the state, including disclosure of any conflicts of interest and agreeing to maintain confidentiality of examination records, proprietary data and other sensitive information they may be exposed to while under contract.

Results-Oriented Guidelines:

- The department should assess contractors used in performing examination and regulation activities to ensure the work being performed is commensurate with the department's processes and procedures.

Process-Oriented Guidelines:

- The department should have a process in place to consider qualifications, training and professional development of contractors performing PBM surveillance and market regulation activities.
- The department should have the authority to terminate a contract for services related to PBM surveillance and market regulation on the basis of poor performance.
- The department should have a process in place to consider any potential conflicts of interest among the contract personnel.
- The department should have a process in place to ensure the contract personnel will protect confidential information like PBM examination records, proprietary data and other sensitive information they may be exposed to while under contract.

**Types of Examinations**

When planning the examination, it is essentialhelpful to first identify which services and products are subject to regulatoryed oversight, the scope of clients impacted by those services and products, and the resulting implications 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, I it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Examiners should apply only those statutory and regulatory requirements that expressly govern PBMs. Requirements applicable to health plans—regardless of any delegation to a PBM—should not be treated as PBM compliance obligations. PBMs act in a support capacity, while compliance responsibility for plan level laws remains with the plan. PBMs contract with health plans to administer their pharmacy benefits in accordance with the plan's chosen benefit design. Each health plan retains the sole authority to design their pharmacy benefits and maintains discretionary control over the health plan's assets.

**Commented [A22]:** The following recommendations relating to states' use of contract firms is consistent with handbook and accreditation guidance adopted by the Financial Condition (E) Committee and Financial Regulation Standards and Accreditation (F) Committee in 2025.

**Commented [A23]:** It is crucial for regulators to know impacts of law, not to product/services but clients in scope as well.

**Commented [A24]:** It is important to make this distinction

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**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).

**Commented [A25]:** The addition of specialists increases costs for conducting exams – we suggest a trigger to initiate when a specialists' involvement is warranted (ex. Large-scale claim analysis where spread pricing or rebate pass through model analysis is necessary).

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.

**For additional information on Market Conduct Examinations, please refer to Chapters 12 and 13 of the Market Regulation Handbook.**

**Procedural Considerations**

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

**Commented [A26]:** Basic procedures for a MCE in Chapter 20 of the handbook are not well aligned to PBMs. Recommend that PBM-specific protocols be adopted as many of the insurer centric standards in Chapter 20 do not apply to PBMs and will be burdensome to incorporate.

- 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~~ Pharmacy Benefit Manager examinations, as well.

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**Writing the Examination Report**

The report preparation elements as outlined in Chapter 19 of this handbook ~~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

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## 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.

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**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 (i.e., spread pricing) as required by applicable statutes, rules and regulations. ~~AKA SPREAD PRICING.~~**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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~~ copies of contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

~~Complete and unredacted~~ Copies of contracts or material amendments thereto between the PBM and pharmac~~y~~ies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

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

_ A schedule of only impacted 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~~charged to a health plan for each prescription drug claim.

_____ Documentation demonstrating ~~of~~ health plan billings ~~in comparison to~~and pharmacy reimbursement ~~at a claim level~~for a prescription drug claim during the exam period including an itemized breakdown~~s~~ if applicable, are identical.

Others Reviewed

_____ _____

_____ _____

**Commented [A27]:** References to "covered entity" have been removed throughout as this does not align to the terminology used in the glossary.

**Commented [A28]:** Edits to contract-related documents are intended to reflect that contracts regularly involve multiple documents that may not be co-located as amendments are made over time and, further, to clarify that material that is not relevant to the examination standard is redactable to protect sensitive/ proprietary information.

**Commented [A29]:** Claims data should only be requested for claims that are related to spread pricing as defined under state law.

**Commented [A30]:** Added "if applicable" language to documents to be reviewed as every plan may not require real-time monitoring or periodic reports.

**Commented [A31]:** Revised language to align with processes.

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**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 with 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 ~~contracts between the PBM and the health plan and are consistent~~ with state requirements.

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**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~~ if required by applicable statutes, rules and regulations.**

**Apply to:** All PBMs if services are delegated by the health plan

**Priority:** Essential if required by applicable state law,

**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~~ Copies of contracts or material amendments thereto between the PBM and health plan in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

~~Complete and unredacted~~ Copies of contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent the data is needed to confirm the PBM's compliance with applicable state law.

**Commented [A32]:** See previous comments on concerns with unredacted documents.

_____ Request all impacted 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 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's 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 with state requirements and with the PBM's policies regarding PBM pricing.

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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.

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**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 if services are delegated by the health plan

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

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

_Based on information submitted with the policies ~~&~~ and 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, state-specific policies. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM contracts with pharmacies or PSAOs in an unredacted format to the extent needed to confirm compliance with state law.

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

_____ All documents provided to pharmacies applicable during the examination period 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 applicable during the examination period showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and impacted claims data.

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

- Pharmacy information including but not limited to name, ~~NPN~~NPI, and address.
- Pharmacy network name associated with each claim.
- Claim identifiers for all reconciled claims, to include ~~R~~retail, mail order, and specialty drug claims, including prescription number, date of service and product identifier.~~;~~
- ~~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~~

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~~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~~reconciled effective rate. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO for the reconciliation period(s) associated with the specified time period.

_____ ~~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 or applicable material amendments thereto between the PBM and pharmacies in effect during the examination period, 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 regarding the rate reconciliation process is clear and concise. ~~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. If required by state law, e~~E~~nsure 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~~a 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 final and fully executed official 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~~,~~ and 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 are clear, and concise, and reflect applicable state law. For example: 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

**Commented [A33]:** Removed documentation that is not related to effective rate reconciliation.

**Commented [A34]:** Removed this documentation request as effective rate reconciliation is not performed at the claim level.

**Commented [A35]:** Added language to clarify that the time period sampled may or may not align with how a pharmacy is reconciled and could span multiple reconciliations.

**Commented [A36]:** Removed this document as PBM contracts with health plans do not typically reference effective rate reconciliation with pharmacies.

**Commented [A37]:** We recommend that, to make this more manageable for the regulator and the PBM, document reviews should be limited to a sample of final/fully executed documents and communications.

Unless there is a statutory requirement to provide routine, informal communications, this sample should be limited to a sample of final/fully executed communications and not routine back and forth, which is not relevant to examination for compliance with state law.

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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~~.~~? If a pharmacy is making a payment, are claims subject to an applicable state law prohibiting collection properly excluded?

- 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 and how the claims sample fits into the final reconciliation. Where applicable, demonstrate that pharmacy claims that are reconciled through a contractually authorized program (i.e. effective rate or other performance-based program) allows the pharmacy to understand which claims have been included in the program and have been reconciled. ~~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 a sample of contracts between the PBM and the pharmacy services administration organization or group pharmacy contract 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?~~

**Commented [A38]:** Removed this documentation requirement as effective rate reconciliation is not governed by client agreements.

**Commented [A39]:** Revised language as the current language does not accurately reflect the rate reconciliation process.

**Commented [A40]:** Removed this documentation requirement as PBMs do not know what was sent to the pharmacy - that goes from the PSAO to the pharmacy (not the PBM).

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

**Standard 4**
**The PBM demonstrates it has ~~transparent~~ payment methodologies ~~for~~ regarding the dispensing fees on a drug claim if required by statues, rules, and regulations. ~~f all drugs that enable a pharmacy to understand dispensing fee amount for each claim~~**

**Apply to:** All PBMs if services are delegated by the health plan

**Priority:** Essential if required by applicable state law

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ 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 to the extent needed to confirm a PBM's compliance with state law.

_____ ~~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~~health plan 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~~ health plan's oversight of the processes. Request the ~~entire~~ contract or applicable material amendments thereto in an unredacted format to the extent needed to confirm a PBM's compliance with state law.

_____ Request all impacted 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-~~

**Commented [A41]:** Limit to jurisdictions where there are requirements defining what a dispensing fee is and what is to be paid.

**Commented [A42]:** Delete as duplicative to #2 above

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~~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.*
***States have different requirements regarding dispensing fees paid to pharmacies in their jurisdiction.*

Others Reviewed

____ _____

____ _____

**Review Procedures and Criteria**

Review all contracts or material amendments thereto between the PBM and pharmacies in effect during the exam period, 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~~regarding dispensing fees ~~payment prior to the pharmacy being paid~~is clear and concise.

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 and~~&~~ 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~~health plan 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~~ health plan'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. If required by state law, ~~S~~standards based on the type of pharmacy should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies~~, for example.~~ and p~~P~~ayment of dispensing fees should be consistent across pharmacies within the same network.

**Commented [A43]:** Removed to reflect that the documentation requested should only include information for plans subject to state DOI regulatory authority (i.e., fully-insured and non-ERISA ASO plans).

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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 to the extent needed to confirm compliance with state law.

_____ 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 material 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 final/fully executed documentation and correspondence~~, including but not limited to emails and red-lined documents,~~ between pharmacies and the PBM that pertain to the contract and material contract 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~~ may 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~~and pharmacies' good faith negotiations.

**Commented [A44]:** Revised to limit to final/fully executed documentation. The proposed requirement to provide all documents including "red-lined documents" between the pharmacy and the PBM pertaining to contract amendments is extremely burdensome as this is not typically available in a centralized database and instead would require manual processes that increase the risk of error. This level of documentation may, further, include privileged communications.

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 to the extent such differentiated standards are prohibited by state law. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location if such limitations are permitted by law. Standards should be applied in a non-discriminatory

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manner such that PBM does not favor affiliate over non-affiliate pharmacies to the extent required by state law. ~~for example.~~

Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Examples include ~~Including how~~ how the 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 contracting process, including requests for changes to contract terms, 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.

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**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 if services are delegated by the health plan

**Priority:** Essential if required by applicable state law

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide an index of all contracts with vendors that provide pharmacy benefits management services within scope 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 that are being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ ~~Unredacted~~ PBM contracts ~~from~~ or applicable material amendments thereto with vendors that provide pharmacy benefit management services within scope on behalf of the PBM. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

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, to the extent required by state law.

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~~ whether 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~~information that the PBM provides regarding its vendors is clear and concise.

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,

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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.

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ PBM to provide a ~~data dictionary or~~ list (and definitions) of all categories ~~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 the dispute resolution process being examined. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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 and~~,~~ the final correspondence between the PBM and pharmacy~~, any documentation that is exchanged,~~ and fully executed documentation showing how the dispute is resolved. Documentation should be consistent with other handbook standards regarding privacy and the sharing of PHI.

**Commented [A45]:** Revised to limit to final correspondence and fully executed documentation as the broader language would result in an unmanageable volume of documents.

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 or applicable material amendments thereto 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

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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~~ and concise.

Assess whether the PBM has provided pharmacies with a clear, transparent appeal process, including all information that must be shared or documented to support an appeal. ~~'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.

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals ~~in an unredacted format~~ that relate to the payment and adjudication of claims. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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 to the extent needed to confirm compliance with state law.

_____ 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 to the extent needed to confirm compliance with state law.

_____ All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format to the extent needed to confirm compliance with state law..

_____ All impacted contacts with ~~carriers or employer groups~~health plans in an unredacted format to the extent needed to confirm compliance with state law.

_____ Request all impacted 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

**Commented [A46]:** We recommend limiting to related documents; otherwise, this will result in an unmanageable volume of documents to produce or review.

**Commented [A47]:** We recommend the NAIC look to NCPDP for industry standards regarding policies and procedures review rather than create new process or standards

Consider adding to Review Criteria below.

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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~~(e.g., 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~~ related to requirements for pharmacies 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.
- Any NCPDP industry standards applicable.

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~~ reduction in reimbursement~~e 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 in compliance with state claims timelines.
- 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 payment appeals for example, about any claims that are rejected or denied. This does not include benefit or coverage appeals that would be initiated by the member.

**Commented [A48]:** Delete language where state DOIs do not have jurisdiction (Medicare, Medicaid, Self-funded).

Examiners may encounter documents in the course of a health plan examination that refer to "ERISA plans." Many health carriers perform administrative functions on behalf of self-funded employers, union trusts and other collectively bargained groups (under ERISA Section 3(40)) that are not subject to state insurance regulation," 2024 *Market Regulation Handbook*, p. 570.

**Commented [A49]:** Revise language to reflect that it is a reduction in reimbursement.

**Commented [A50]:** Suggest revising to reflect state claims timeline standards.

**Commented [A51]:** Revised to clarify - actions of pharmacy v. member

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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 is 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 calculates payment from a ~~applies a 'discount' to the~~ drug pricing source it uses to pay pharmacies, ~~is that~~any reduction ~~discount~~ is 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~~the process is 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 ***all*** impacted claims being examined including mail order and specialty drug claims. ~~*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 a sample of 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 insurers~~carriers~~.

Review all, or a sampling of PBM contracts with ~~carriers/employer group~~health plans 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~~ health plan contract, is that consistent with the payment method (and applicable description) to pharmacies?

**Commented [A52]:** Revise language to accurately reflect process.

**Commented [A53]:** Remove language - may be inconsistent with state law.

**Commented [A54]:** Revised to set standards rather than questions.

**Commented [A55]:** Suggest limiting live demos to a sample to reduce administrative burden while accurately demonstrating the data being requested.

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**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 aAggregators) are passed through to health plans ~~or covered entities as applicable to~~if required by current statutes, rules and regulations.**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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~~health plan within scope for this examination standard to the extent needed to confirm compliance with state law.

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

_____ C~~omplete and unredacted c~~ontracts or applicable material amendments thereto between the PBM and manufacturers within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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~~for compliance with state ~~requirements~~laws.

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

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

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**STANDARDS**
**PHARMACY BENEFIT MANAGERS**
**PHARMACEUTICAL MANUFACTURER REBATES**

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

**Commented [A56]:** Suggest combining with Standard 1 in this section as it is duplicative.

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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~~health plan within scope for this examination standard to the extent needed to confirm compliance with state law.

**Commented [A57]:** Updates are to ensure the documents requested are limited to those relevant to compliance with this examination standard.

_____ 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 c~~All impacted contracts or applicable material amendments thereto between the PBM and health plans ~~or covered entities~~ within scope for this examination standard. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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.

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**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~~if required by current statutes, rules and regulations.**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ An index of all policies and procedures relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ An index of all training manuals relating to the PBM's rebates to the extent needed to confirm the PBM's compliance with applicable state law.

_____ 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~~ to the extent needed to confirm compliance with state law.

_____ 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 c~~Contracts or material amendments thereto between the PBM and pharmacies that serve health plan members in the state in effect during the examination period. Such copies should be unredacted to the extent needed to confirm the PBM's compliance with applicable state law.

_____ 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.

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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~~PBM.

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

_____ ~~Complete and unredacted c~~Impacted contracts or material amendments thereto between the PBM and manufacturers. Request documents in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**NETWORK ADEQUACY**

**Standard 1**
**The PBM demonstrates its credentialling process for all pharmacies in its network is in compliance with applicable statutes, rules, and regulations. ~~Must show its credentialling criteria from beginning to end.~~**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ Pharmacy contracts and manuals ~~for~~ relating to a 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 to the extent needed to confirm compliance with state law.

_____ 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

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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 o*~~final/fully executed ~~fficial~~ 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 relevant and responsive 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 a~~n~~ ~~un~~readable format. Ensure all correspondence from the PBM is clear, ~~and~~ concise and provides reasonably sufficient information to pharmacies ~~to understand~~regarding the credentialing process and any decisions made by the PBM to the extent required by law.

~~In any Summary of the PBM Network Adequacy that proceeds these standards~~,T-~~t~~he PBM should ~~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.

**Commented [A58]:** Removed "and staff" as this is seeking records not recorded during ordinary course of business

**Commented [A59]:** We recommend limiting to final/fully executed communications to reduce regulator and PBM burden and ensure production of a manageable volume of documents that is sufficient to complete examiner review for compliance.

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations.

_____ PBM and pharmacy contracts or material amendments thereto and manuals. This should include all network contracts and forms. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____ PBM to provide an index of all policies and procedures relating to the PBM's network and its pharmacy networks. From the index, e~~E~~xaminers 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 if needed to validate compliance with applicable state laws.

_____ PBM and~~&~~ ~~carrier or employer~~health plan contracts within scope. Request the entire contract, including any ~~amendments~~material amendments, in an unredacted format if needed to validate compliance with applicable state laws.

_____ PBM to provide a listing of all the pharmacies with which 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.*~~

**Commented [A60]:** Suggest removal of "the types of business it serves" as this is not typically recorded during the ordinary course of business.

_____ 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 sample list of all ~~carriers and employer groups~~health plans within scope and each plan for the entity for which the PBM administers prescription drug benefits and which~~. Require the PBM to identify every~~ network is 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.*~~

**Commented [A61]:** Suggest sample list; would require case by case review

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_____ 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 network adequacy law~~s 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~~health plan clients.
- Requirements for pharmacy network reimbursement levels in compliance with state law. ~~Ensure these are applied consistently among all pharmacies in each network.~~

**Commented [A62]:** Revised to align to applicable state laws.

Review contracts and manuals with pharmacies that describe all aspects of the pharmacy networks. Ensure information is provided in a manner that is clear and concise~~, 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~~health plans within scope about the network changes. Ensure the message conveyed to ~~carriers/employer groups~~health plans within scope 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? Are reimbursement rates discriminatory?~~

**Commented [A63]:** We recommend removal as comparing the rates for a client that selects a network of affiliate pharmacies to that of other clients with different networks does not produce relevant information.

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."

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**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 if required by state law.**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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.~~ PBM policies and procedures regarding availability of and updates to its provider network.

_____ 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.

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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.

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**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 as required by state law.

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.

**Commented [A64]:** This is language used in medical services

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.

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**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 if required by applicable state law.

**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,

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- Verify that the Pharmacy Benefit Manager's 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 insurer's ~~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 insurer's ~~carrier's~~ utilization review program.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**UTILIZATION REVIEW**

**Standard 2**
**The pharmacy benefit manager ~~establishes and maintains a~~operates its 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 if required by applicable state law.

**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.

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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 insurer~~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 insurer~~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.

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**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 if required by applicable state law

**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.

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**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 if required by applicable state law

**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.

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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 insurer's~~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~~Pharmacy Benefit Manager'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

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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 insurer~~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 insurer~~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 insurer~~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 insurer's~~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.

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**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 if required by applicable state law

**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, as required by state law. ~~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~~

**Commented [A65]:** Suggesting all the bullets be removed since states will have specific requirements that PBMs must meet around notifications.

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~~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 Pharmacy Benefit Manager ~~health carrier~~ provides the notice as required by state law if they are delegated to do so. ~~in writing or electronically.~~

**Commented [A66]:** Some states require verbal notices and not all are written or electronically

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**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 if required by applicable state law

**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 as required by applicable state statues, rules, and regulations. ~~, 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:

**Commented [A67]:** Concurrent review only happens in medical services

**Commented [A68]:** State laws have specific TAT and notification requirements for urgent request.

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- 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 insurer's~~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, and within the timeline required by applicable state statues, rules and regulations. ~~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 insurer~~carrier~~ to make a determination, verify that the Pharmacy Benefit Manager notifies the covered person, or, if applicable, the covered person's authorized representative, as required by applicable state statues, rules, and regulations around notification and timeframe. ~~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 and as required by applicable state statues, rules and regulations. ~~, 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~~

**Commented [A69]:** Concurrent reviews are for medical services.

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~~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 insurer~~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 insurer~~carrier~~ or Pharmacy Benefit Manager in accordance with the health insurer's~~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 as required by applicable state statutes, rules, and regulations.~~, 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 insurer's~~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 insurer's~~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~~

**Commented [A70]:** State laws have specific requirements that must be followed

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~~following the oral notification.~~

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**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 and accompanying regulations.**

**Apply to:** PBMs contracting out utilization review services.

**Priority:** Essential if required by applicable state law

**Documents to Be Reviewed**

_____Applicable statutes, rules and regulations

_____Utilization review policies and procedures. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Contracts with organizations or entities within scope for this examination standard. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

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

_____Periodic reports from the organization or entity, if required by contract or state law. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's board of directors. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law.

_____Minutes of the Pharmacy Benefit Manager's utilization review committee. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

_____Policies and procedures for oversight within scope. Request documents be provided in an unredacted format to the extent needed to validate compliance with state law

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.

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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.

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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 fFormulary program in compliance with applicable statutes, rules and regulations.**

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

**Priority:** Essential if required by applicable state law

**Documents to Be Reviewed**

_____Applicable statutes, rules and regulations

_____Formularies and fFormulary tTemplates 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. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

**Commented [A71]:** Revised language to permit disclosure of roles and credentials without requiring PII beyond what is necessary for compliance.

_____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~~compliant with applicable state statutes, rules and regulations.

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

Verify that the Pharmacy Benefit Manager Pharmacy and Therapeutics (P&T) Committee or other cCommittee~~s~~ decisions and statements ~~comport~~ comply with all applicable state statutes, rules and regulations.

The identification of members of a P&C Committee shall not be publicly disclosed.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG**

**Standard 2**
**The pharmacy benefit manager establishes and maintains a f~~F~~ormulary 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 if required by applicable state law

**Documents to Be Reviewed**

_____Applicable statutes, rules and regulations.

_____Formularies and f~~F~~ormulary t~~T~~emplates 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~~ comply 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~~ are compliant with applicable state statutes, rules or regulations.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG**

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

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

**Priority:** Essential if required by applicable state law

**Documents to Be Reviewed**

_____Applicable statutes, rules and regulations that are applicable to Pharmacy Benefit Managers

_____Formularies and f~~F~~ormulary t~~T~~emplates 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. Identification of committee members shall only include Personally Identifiable Information (PII) as required by state law.

_____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~~are compliant with applicable state statutes, rules and regulations.

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

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

The identification of members of a P&C Committee shall not be publicly disclosed.

**Commented [A72]:** This highlights that our formularies and utilization management programs are standardized and not tailored to individual state requirements, as compliance with state-specific laws rests with the plan sponsor—not the PBM

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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
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law
- **Compliance and Fairness:** Determine that responses:

[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.

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- 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.

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**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~~applicable statutes, rules and regulations.~~.~~**

**Commented [A73]:** Alternative language proposal: All member, pharmacy, and/or state department of insurance complaints are documented in accordance with applicable state requirements.

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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 if required by state law.

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**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 if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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~~ PBM maintains a complaint register.

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

**Commented [A74]:** Recommend removal because this is unclear.

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.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**COMPLAINTS, GRIEVANCES, AND APPEALS**

Commented [A75]: Timeframes vary by state laws.

**Standard 3**
**The pharmacy benefit manager must resolve and respond to complaints, grievances, and appeals within prescribed timeframes required by applicable statues, rules and regulations.**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**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.

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**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~~applicable statutes, rules and regulations.**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to Be Reviewed**

_____Applicable statutes and regulations

_____~~Contracts, including provider~~ Complaint, grievance, and appeal procedure manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____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.

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**STANDARDS**
**PHARMACY BENEFITS MANAGERS**
**AUDITS**

**Standard 1**
**The PBM demonstrates that it has ~~reasonable and uniform criteria~~ documented policies and procedures for pharmacy audits and demonstrates that it ~~follows those reasonable standards~~conducts the pharmacy audit in compliance with its policies and procedures and in compliance with appliable statutes, rules, and regulations. .**

**Apply to:** All PBMs if services are delegated by the health plan.

**Priority:** Essential if required by applicable state law.

**Documents to be Reviewed**

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts or applicable material amendments thereto and manuals in an unredacted format to the extent needed to confirm compliance with state law.

_____ 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 to the extent needed to confirm compliance with state law.)

_____ Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format to the extent needed to confirm compliance with state law.)

_____ 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* within scope 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 final and fully executed documents and communications sent by the PBM to the pharmacies and~~, all documents sent~~ by the pharmacies to the PBM ~~and any emails, notes from phone conversations, and any other communications about~~ as part of the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format to the extent needed to confirm compliance with state law.)

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_____ ~~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~~and concise. ~~*While the details of the audit process are important, the information must be provided in a manner that will be easily understood by pharmacies.*~~

**Commented [A76]:** Remove language as standard of "easily understood" is unclear (i.e. who makes this determination?)

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 pharmacy audit requirements ~~for pharmacies are reasonable~~are compliant with state law 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~~compliant with state law, 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.

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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.~~

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