Chapter XX—Conducting the Pharmacy Benefit Manager Examination

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

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

Background, Scope and Types of Examinations

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

PBM examinations can be either comprehensive or targeted. A PBM examination can be conducted by one jurisdiction or as a multistate cooperative examination. To the extent that the PBM'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, currently there are generally little, if any, "market analysis" procedures or tools developed to assist in the conduct of PBM examinations. Similarly, PBMs are not regulated for solvency. Rather, PBMs negotiate on behalf of insurers and other PBMs and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related items. PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers. In addition, PBMs contract directly with Pharmacy Services Administrative Organizations (PSAOs), who provide administrative services to independent pharmacies, including, but not limited to, contract negotiations with PBMs.

For additional information on background and scope, please refer to Chapter 12 and Chapter 13 of this handbook.
Key Terms:

Regulators must consider state specific definitions when conducting a PBM Examination.

340B Pharmacy – a pharmacy that dispenses outpatient drugs purchased at significant discounts by eligible "covered entities" such as safety-net hospitals, clinics, and health centers under the federal 340B Drug Pricing Program. These pharmacies are often excluded from additional drug manufacturer rebates for certain drug claims.

Note: The term "340B" is derived from the section of the Public Health Service Act (PHSA), 42 U.S.C. 256b, from which the 340B Program is defined.

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Affiliated Pharmacies – refers generally to pharmacies that are formally connected to or associated with a larger organization, such as a health system, hospital, or a PBM, through ownership, partnership, or contracted arrangement.

Biologic Drugs - are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, certain vaccines, and cell and gene therapies. Biologics are sometimes referred to as "large- molecule drugs." Manufacturers of biologic drug products are also required to receive approval from the U.S. Food & Drug Administration (FDA) to sell their products through a separate application process. 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.

Biosimilar Drugs - are FDA approved as having no clinically meaningful difference from the referenced product and may be produced following the expiration of the biologic's patent and exclusivity period. Biosimilar drugs are listed in the FDA Purple Book and are not considered "generic" of their brand referenced biologic product.

Brand Name Drugs - are medications discovered, developed, and marketed by a pharmaceutical company under a specific, patented, and trademarked name. These original, FDA-approved, or regulatory-approved drugs have exclusive marketing rights for a set period to recoup research costs, often making them more expensive than generic alternatives. Brand name drugs are often designated as the "Reference Listed Drug" in the FDA Orange Book.

Chain Pharmacy – Unless otherwise defined in the state, a chain pharmacy is owned, operated, or controlled by a corporate-owned entity, generally defined as four or more locations, often operating under a shared corporate banner and utilizing centralized management.

Covered Entity – means, as defined in 45 CFR 160.103, a health plan, a healthcare clearinghouse, or a health care provider who transmits health information electronically in connection with covered transactions.

Generic Drugs - are small molecule drugs that are therapeutically equivalent to their reference brand name drug. Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Like brand-name drugs, the FDA must approve a generic drug application called an Abbreviated New Drug Application to ensure its bioequivalence to the brand-name drug before it can be produced. Generic drugs comprise the largest portion of the pharmaceutical market.

Independent Pharmacy – unless otherwise defined in the state, a pharmacy that is privately and independently owned and operated by one or more pharmacists or under common ownership with not more than three pharmacies and whose primary function is to provide direct pharmaceutical care to patients. These services can include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling in a community setting.

Insurers – entities that contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees. Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management. In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including, but not limited to, utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks. Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.

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.

Long-Term Care (LTC) Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses medications and delivers them directly to a licensed long-term care facility, such as a nursing home, group home, or specialized health care facility, and generally does not provide medications to inpatient hospitals.

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Mail-Order Pharmacy – is a licensed "closed door" (i.e. not open to the public) pharmacy that dispenses prescription medications and delivers them directly to a patient's home, workplace, or preferred location through the mail or courier service.

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

Pharmaceutical Manufacturers or Manufacturers - research, develop, produce, market, and sell prescription drugs to treat medical conditions. 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. Pharmaceutical manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Pharmaceutical manufacturers may also purchase prescription drugs developed by other manufacturing companies to market as their own. Pharmaceutical manufacturers may also offer patient assistance programs and direct-to-consumer programs for some of the drugs they market.

Pharmacies - a place licensed by a state Board of Pharmacy in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed. A pharmacy may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling, and other health care related functions, as permitted by the state in which the pharmacy is licensed.

Pharmacists - are licensed and trained health care providers that assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing a medication to a patient to ensure patients do not receive the wrong drug 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 are licensed by a State Board of Pharmacy and are permitted to conduct various levels of health care services in different states, depending on state licensure requirements.

Pharmacy and Therapeutics (P&T) Committee – are expert, multidisciplinary groups, which are usually comprised of physicians, pharmacists, and other health care professionals, that evaluate clinical, safety, and economic evidence for prescription drugs. P&T Committees determine which medications are covered, create formularies, and manage utilization policies, such as prior authorization.

Pharmacy Benefit Managers (PBMs) - provide claims processing services or other prescription drug services on behalf of insurers 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 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 may also develop, negotiate, implement, or administer clinical, formulary, or other preferred lists for prescription drugs, including negotiating and the administration of rebates and drug coverage terms with pharmaceutical manufacturers and other entities. PBMs may be delegated the responsibility of the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (for example ,drug coverage tiers, and utilization management protocols). PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.

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PBMs may also be delegated the adjudication of appeals or grievances related to prescription drug coverage or the performance of drug utilization reviews (DURs).

Pharmacy Benefit Manager Network –is a contracted, organized group of retail, mail-order, specialty, and other pharmacies established by a PBM to provide covered prescription drug services to health plan members. Pharmacies within the network have specific reimbursement rates, terms, and, in some cases, performance-based quality measures.

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

Rebates or Manufacturer Rebates – are a post-purchase discount or price concession paid by pharmaceutical manufacturers directly or indirectly to rebate aggregators, group purchasing organizations (GPOs), PBMs, covered entities, or health insurers. These payments are typically negotiated in exchange for favorable placement of a drug on a health plans' formulary and may be described as reducing the overall cost of drugs for covered entities or payors.

Note: Rebates may also apply when speaking of wholesaler or pharmacy rebates, which are contractual incentives paid to pharmacies based on specific performance metrics. For purposes of this chapter unless otherwise specified, the term "rebates" includes "manufacturer rebates."

Specialty Drugs - 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 chronic conditions. Because of this, these drugs often dispensing through a specialty pharmacy, rather than traditional retail pharmacies.

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

Specialty Pharmacy – is a type of pharmacy that dispenses specialty medications. Specialty pharmacies often hold limited-distribution contracts with a pharmaceutical manufacturer to be one of just a few pharmacies authorized to dispense a particular specialty medication. Specialty pharmacies may offer in-depth patient support such as clinical patient management.

Utilization Review – which is also known as utilization management or DUR, includes using predetermined criteria for appropriate drug therapy, utilizing patient-specific information to ensure safe and effective use of drug therapy to potentially lower the overall cost of health care. Types of utilization review include prospective, concurrent, and respective utilization review. PBMs and/or payors may develop utilization review standards to evaluate and approve or deny services when compared to clinical need, cost, and established national guidelines.

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. Wholesalers own several of the largest PSAOs used by independent pharmacies.

Qualifications of Examiners

Information on qualifications, please refer to Chapter 14 of this handbook**.** In addition, states might want to include a pharmacist or other PBM-specific qualifications to the examination team.

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Types of Examinations

When planning the examination, it is helpful to first identify which services and products are regulated and the impact on regulated entities. A PBM 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 PBM examination. Because most operations for these entities remain consistent in all states, it is recommended to coordinate examinations or communicate with the NAIC, especially when conducting comprehensive reviews.

Scheduling, Coordination and Planning Scope

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

1. Determine the jurisdiction's requirements for licensing and examining the PBM 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 PBMs operating in the jurisdiction.
3. For those PBMs for which a recent and current examination report has been made public 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 communicating with members of 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 a licensed pharmacist (ideally one with experience with the functions of a PBM or pharmacy operations).
6. Due to the complexity of pharmacy claims data, a comprehensive data dictionary shall be developed for all requested datasets. The data dictionary must clearly define all data fields, formats, and required inputs and shall be reviewed and finalized to ensure mutual understanding and agreement among all parties before data collection begins. The regulator may develop the data dictionary or may work with the PBM to develop the dictionary. The final regulator-approved data dictionary shall be used by the PBM. Any questions, clarifications, or necessary revisions must be addressed and resolved before data extraction occurs in order to minimize discrepancies, ensure data integrity, and prevent delays during the examination process.

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

Procedural Considerations

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

- Scheduling an examination.
- Determining the scope of the examination;
- Calling the examination;

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- Notification of the examination;
- Preexamination procedures;
- On-site coordination, if applicable;
- Data calls;
- Sampling;
- Test procedures;
- Communication management;
- Post-examination procedures; and
- The examination report.

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

Writing the Examination Report
The report preparation elements as outlined in Chapter 19 of this handbook are generally applicable to PBM 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 PBM. The examination plan should indicate which standards for review will be used for each specific examination.

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

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A. PBM 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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B. PBM Pricing and Methodologies

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, payor, or health plan an amount greater than the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

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

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

_____ Complete and unredacted contracts between the PBM and pharmacy.

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

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

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

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

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

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policies regarding PBM pricing.

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

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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, payor, or health plan compared to the reimbursement paid to a pharmacy for a prescription drug as required by applicable statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

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

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

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

_____ Complete and unredacted contracts between the PBM and pharmacies.

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

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

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

Determine if contracts between the PBM and health plans are consistent 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 with contracts between the PBM and the health plan and are consistent with state requirements.

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STANDARDS
PHARMACY BENEFIT MANANGERS
PBM PRICING METHODOLOGIES
(BETWEEN PBM AND PHARMACIES)

Standard 3
The PBM demonstrates it has transparent payment methodologies for reimbursement of all drugs that enable a pharmacy to understand the reimbursement amount for each claim prior to the pharmacy submitting the claim for reimbursement.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted format.

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

_____ Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to the pharmacy reimbursement method being examined. Request documents in an unredacted format.

_____ PBM contracts with pharmacies in an unredacted format.

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

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

____ All contracts between the PBM and any third-party entities that may process prescriptions on behalf of the PBM or the PBM's clients, including but not limited to, any drug discount coupons or programs from manufacturers or drug discount entities.

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

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

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy 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, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment 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

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fee. For example, any claims processing fee applied to the claim.

- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") 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.*

Others Reviewed

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Review Procedures and Criteria

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

- Assess how the PBM determines the drug pricing source it uses to reimburse each drug type including generic, brand and specialty drugs. Confirm the selection of the drug pricing source is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plain language.
- Assess the PBM's ability to change the drug pricing source selection, for example through application of the "lessor of logic" method. 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 this drug pricing source, assess how that change occurs, how often it occurs, how it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.
- Assess whether the PBM applies any "discounts" or other methods of reducing the amount of the selected drug pricing source. If the PBM does reduce the amount of the drug prior to paying the pharmacy, ensure that the "discount" reduction amount 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. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.
- If the PBM does apply "discounts" or otherwise reduce the amount of the drug pricing source, ensure the contract language describes the extent of the PBM's ability to change this "discount," how that change occurs, how often it occurs, how and when it is communicated to the pharmacy, and whether the change can be done with or without the pharmacy's consent.

Review contracts between the PBM and the insurer or employer group to determine whether the pricing methodologies described to pharmacies are consistent with the PBM's requirements described in the insurer's or employer group's contract with the PBM.

Review a sample of (or all) claims to ensure the PBM follows its own policies and procedures regarding reimbursement of pharmacies. Review claims data to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, LTC, 340B, specialty or affiliate. Review "discount" amounts applied

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for claims to assess whether the PBM's description of the "discounts" to pharmacies is consistent with the actual reimbursement amounts. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment should be consistent across pharmacies within the same network.

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

Standard 4
The PBM demonstrates it has transparent effective rate reconciliation methods for all drugs that enable a pharmacy to understand the reimbursement amount for each claim that is part of the reconciliation process.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

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

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

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

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

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

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

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

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category;
- 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 drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment 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.

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- 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 or batch of claims.
- The total final reimbursement amount for each drug claim or batch of claims after reconciliation. This should not include the dispensing fee amount.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each drug. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO.
- The type of health coverage being reimbursed. For example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim. For example, paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Request a listing of all network pharmacies or PSAOs that have an effective rate contract and all pharmacies or PSAOs that do not have one. Ensure the PBM is offering contracts to all similarly situated pharmacies and that it provides a reasonable explanation for why it does not offer an effective rate contract to any specific pharmacies or pharmacy types, such as independent pharmacies. Understanding which pharmacies have an effective rate contract will assist the regulator in ensuring the PBM is compliant with state laws. For example, if a state requires NADAC payment for each drug, the regulator will not expect to see any effective rate contracts in that state.

Assess how the PBM determines which claims will be part of the reconciliation process, including categories of claims that are included and excluded in accordance with contract language. Confirm the selection of the claims is communicated to the pharmacies in clear and concise language.

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

- If PBM provides any reports or charts to the pharmacy, ensure the document explains all use of acronyms and claims categories through use of a key.
- Review all documents describing the final reconciliation amount that may be owed to or from pharmacies or

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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.

- Does the PBM provide pharmacies with the ability to inquire about or appeal the PBMs final determination? Is the process reasonable in that it 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 sample of (or all) claims to ensure the PBM follows its own policies and procedures regarding reconciliation process. Compare the original "discount" and price paid to the pharmacy to the reconciled "discount" and price to determine if the reconciled "discount" applied to each claim or batch of claims is within the contractually stated "discount" amounts. In addition to the PBM's own "discounts," other discounts may include drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment.

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

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

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

Standard 5
The PBM demonstrates it has transparent payment methodologies for the dispensing fees of all drugs that enable a pharmacy to determine the dispensing fee amount paid for each claim.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all policies and procedures relating to pharmacy dispensing fees.

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

_____ PBM contracts with pharmacies in an unredacted format.

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

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

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

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

- Pharmacy information including but not limited to name, NPN, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy claims with clear indication of each category.
- The drug pricing source used for reimbursement of each claim at the time of adjudication.
- The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source drug copay copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment 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 ingredient cost 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.

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- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when the PBM reimbursed the pharmacy, to ensure the PBM is timely when paying clean claims.
- If the claim was rejected or is under appeal, provide reasons, including applicable rejection codes. *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. However, pharmacy and network information is important to assess whether the PBM is reimbursing dispensing fees consistently across pharmacies in a network.*

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language.

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

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

Review a sample 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, LTC, 340B, specialty or, if the pharmacy is affiliated or not affiliated with the PBM. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example. Payment of dispensing fees should be consistent across pharmacies within the same network.

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C. Contracts

STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS
(BETWEEN PBMS AND PHARMACIES)

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.

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

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

_____ All documentation and correspondence, including but not limited to emails and red-lined documents, between pharmacies and the PBM that pertain to the contact and contact amendments. The documentation should provide examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses.

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, independent, mail order, LTC, 340B, specialty, or affiliate. Review all exclusionary criteria which may include but not be limited to, placing limits on the number of pharmacies in a geographic location. Standards should be applied in a non-discriminatory manner such that the PBM does not favor affiliate over non-affiliate pharmacies, for example.

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Review policies and procedures for providing information to pharmacies about the contracting and contract negotiation processes. Examples include 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 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 the PBM's review, how the PBM provides feedback to pharmacy negotiation requests, how pharmacy may request or provide additional information.

Review the documentation to assess whether the PBM is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with pharmacies.

Review the 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 the PBM's communications to pharmacies to assess if the PBM is following its own policies and procedures for contracting and contract negotiations with pharmacies. Determine whether the PBM appears to contract with certain pharmacy types and not others. For example, does the PBM frequently negotiate with chain pharmacies and rarely with independent pharmacies? If so, request the PBM to provide an 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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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

_____ An index of all contracts with vendors that provide pharmacy benefits management services on behalf of the PBM and that interact with the pharmacy. The index should include a description of the 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 the pharmacies being examined. Request documents in an unredacted format.

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, independent, mail order, LTC, 340B, specialty, or affiliate. Standards should be applied in a non-discriminatory manner such that the PBM does permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example.

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

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

Assess whether the PBM effectively implements its own contractual obligations with its vendors and pharmacies that interact with the vendor. The PBM should implement requirements in a non-discriminatory manner that is consistent with state law. For example, the PBM should not implement its contracts in a manner that favors its

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affiliate pharmacies over non-affiliated pharmacies.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PROVIDER/PHARMACY RELATIONS

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

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

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

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

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Review contracts and manuals for details provided to pharmacies about the dispute resolution process. Review how the 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), the PBM's obligation to provide a justification for the final determination and timeframes for PBM response and resolution of the dispute.

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

Assess whether the PBM's requirements for pharmacies are convenient and accessible or whether the requirements create such a burden to seemingly dissuade a pharmacy from initiating or following through with a dispute.

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

Assess whether the PBM has staffing models to effectively resolve disputes.

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D. Pharmacy Claims

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY CLAIMS

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format

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

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

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

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

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

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

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

- Pharmacy information including but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy 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.

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- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") 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

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Review Procedures and Criteria

Review policies and procedures related to the 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 applicable NCPDP standards.

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:

- The PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any "discount" the PBM may apply to reduce the reimbursement amount paid to the pharmacy
- The PBM should have clear criteria for claims approvals, denials or rejections at the point of sale.
- The PBM should have clear timeframes for claims adjudication either through payment or rejection of the claim.
- The PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is rejected, which may include providing reject codes that can be reviewed by the pharmacy.
- The PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or appeals for example, about any claims that are rejected or denied. *This would not include coverage appeals initiated by a consumer.*

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

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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 Maximum Allowable Cost (MAC) list, 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 applies a "discount" or other type of reimbursement reduction to the drug pricing source it uses to pay pharmacies, is that discount reasonably described in documentation to pharmacies such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a "discount" and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, is that process clearly described to pharmacies? Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Can the pharmacy "opt-in" 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*** claims being examined, including a specific description of the claims being requested, including distribution channels (chain, independent, mail-order, LTC, 340B, or specialty), as well as lines of business (e.g. fully insured, Medicare, Medicaid, self-insured—ERISA, self-insured non-ERISA, etc.). In addition, consider including the scope of claims in the description (e.g. all pharmacies with physical locations in the state, member claims filled in the state, claims filled for members covered by health plans situsedin the state, or some other criteria). 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 a dispensing fee. Ensure the 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 plans.

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

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E. Pharmaceutical Manufacturer Rebates

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 1
The PBM demonstrates all rebate payments provided by pharmaceutical manufacturers to PBMs (including rebates paid by or to aggregators, group purchasing organizations, or affiliated entities), administrative fees, credits, incentives and penalties are passed through to health plans, payors, patients, or covered entities as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

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

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ All policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans, payors, or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request document in unredacted format.

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

_____ A listing of all health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____ Complete and unredacted contracts between the PBM and all applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ 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.

_____ All standard rebate reports provided to health plans during the examination period, including data

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dictionaries and field definitions.

_____ All claims data and rebate data for a specified time period in a standardized template sufficient to link:

- Pharmacy information including, but not limited to name, NPI, and address.
- Pharmacy network name associated with each claim.
- Chain, independent, mail order, LTC, 340B, and specialty drug pharmacy 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, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment that the PBM applied as part of its payment to the pharmacy.
- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The final reimbursement amount of each claim for the drug.
- The final reimbursement of any dispensing fee.
- The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-funded vs. fully insured.
- The status of the claim, for example paid, rejected, adjusted, under appeal, etc.
- The dates of when the claim was submitted (generally referred to as "Date of Service") and when it was paid (if applicable) to ensure the PBM is timely when paying clean claims.
- The percentage *and* actual amount of any "discount" or other price reduction from the drug pricing source, drug copay discount program, copay accumulator or maximizer program, or any other discount/price adjustment 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 NDC and units are integral parts of the rebate transaction and must be included in the data dictionary.
- The rebate eligibility of the claim/drug.
- The rebate amount invoiced of the drug/claim.
- The rebate amount collected of the drug/claim.
- The rebate amount retained by the PBM.
- The rebate amount remitted to the health plan.
- The timing of each rebate transaction (claim versus rebate invoicing versus collection).

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 governing the identification, invoicing, collection, accounting, allocation, and remittance of manufacturer rebates, fees, and discounts, and whether those standards comply with state requirements.

Review contracts between the PBM and health plans, carriers, or employer groups to determine:

- Whether rebates are required to be passed through in full, in part, or retained by the PBM;
- If rebates are to be passed through in full or in part, are they allocated to the health plan, payor, and/or patient as authorized by law or contract;
- Whether administrative fees or other retained amounts are expressly permitted; and

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- Whether spread pricing or other pricing methodologies are authorized under the contract.

Review contracts between the PBM and pharmaceutical manufacturers or rebate aggregators to determine the types of remuneration received, the methodology used to calculate rebate amounts, and the timing of rebate payments.

Assess whether the PBM's descriptions of rebate practices in its contracts with health plans are consistent with its contractual arrangements with pharmaceutical manufacturers and affiliated rebate entities.

Determine whether the PBM has established processes to ensure that all rebate-eligible claims are accurately identified and included in manufacturer rebate submissions. Evaluate whether the PBM maintains controls to prevent the omission or misclassification of rebate-eligible claims.

Review all rebate transactions and associated pharmacy claims to verify that:

- The units for each NDC is applied appropriately and rebates are invoiced timely and appropriately in accordance with contractual and statutory requirements;
- Rebate amounts invoiced to manufacturers are supported by underlying claims data;
- Rebate amounts collected from manufacturers are consistent with contractual terms; and
- Rebate amounts remitted to health plans are calculated and transmitted in accordance with contractual and statutory requirements.

Assess whether rebates are remitted to health plans within required contractual or statutory timeframes and whether any delays are supported by documented reconciliation or dispute processes.

Where spread pricing is permitted under the contract between the PBM and the health plan, review claims and rebate data to determine whether the PBM's retention of spread or rebate amounts is consistent with the express terms of the contract and is accurately disclosed in required reporting to the health plan.

Review claims payment, pharmacy reimbursement, and rebate data collectively to ensure that drug ingredient cost, dispensing fees, administrative fees, alternative payment programs, discounts, accumulators, maximizers, spread pricing (if applicable), and manufacturer rebates are applied and reported in a consistent and transparent manner across all PBM financial transactions associated with a claim.

Assess whether the PBM provides health plans with reasonably sufficient detail in its reporting to enable the health plan to independently verify rebate calculations, collections, and remittances. Reports should allow reconciliation from manufacturer payment to claim-level utilization.

Determine whether the PBM applies differing rebate allocation methodologies across lines of business (e.g., fully insured, self-funded, independent, chain, LTC, specialty pharmacy) and verify that any such differences are permitted under applicable contracts and law.

Evaluate whether 340B pharmacies are included in rebate allocation and determine if permitted under applicable contracts and law.

Evaluate whether any affiliated pharmacies, specialty pharmacies, or PBM-owned entities are treated differently in rebate attribution or allocation and verify that such practices are disclosed and permitted under contract.

Where point-of-sale rebate crediting is used, review system logic, claims adjudication rules, and financial settlement processes to verify that rebate amounts applied at the point of sale are accurately calculated and reflected in both member cost sharing and health plan financial reporting.

Determine whether the PBM maintains adequate internal controls, audit trails, and reconciliation processes to ensure completeness and accuracy of rebate invoicing, collection, and remittance.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES

Standard 2
The PBM demonstrates all pharmaceutical manufacturer rebates are correctly reported to the commissioner/department as applicable to current statutes, rules and regulations.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ An index of all training manuals relating to the PBM's rebate administration, accounting, and reporting processes.

_____ All policies and procedures related to rebate negotiation, rebate processing, rebate invoicing, rebate collection, rebate crediting at the point of sale, and rebate remittance to health plans or covered entities as well as other affiliated entities that may administer rebate negotiations on behalf of the health plan, payor, or covered entity. Request documents in unredacted format.

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

_____ A listing of all health plans, insurers, employer groups, or covered entities for which the PBM provided services in the state during the examination period.

_____ Complete and unredacted contracts between the PBM and pharmaceutical manufacturers, rebate aggregators, group purchasing organizations, or affiliated entities involved in rebate negotiation, administration, or collection.

_____Complete and unredacted contracts between the PBM and all applicable health plans, insurers, employer groups, and covered entities. Contracts should include all rebate-related provisions, including but not limited to:

- Definitions of rebates, administrative fees, and other manufacturer remuneration;
- Pass-through or retention provisions;
- Reporting requirements; and
- Audit rights.

_____ 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.

_____ All standard rebate reports provided to health plans during the examination period, including data dictionaries and field definitions.

_____ All claims data and rebate data for a specified time period in a standardized template sufficient to link:

- National Drug Code (NDC);
- Claim identifier;
- Dispensing date;
- Rebate eligibility;

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- Rebate amount invoiced;
- Rebate amount collected;
- Rebate amount retained by the PBM;
- Rebate amount remitted to the health plan; and
- Timing of each rebate transaction.

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 to the regulator were complete, accurate, and timely filed.

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F. Pharmacy Network Adequacy

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

Standard 1
The PBM demonstrates its credentialling process for all pharmacies in its network and is able to demonstrate its credentially criteria from the beginning of the process to the end.

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

_____ Pharmacy contracts and manuals in an unredacted format.

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

_____ An index of all internal policies and procedures for the credentialing process.

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

_____ Any complaints from the network enrollment/credentialing Department.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for assessing licenses, credentials, accreditations, provider ID (including but not limited to NPI and NCPDP) and other qualifications for all pharmacies and pharmacy staff including but not limited to the pharmacist in charge (designated in different states as Supervising Pharmacist or Pharmacy Manager, etc), staff pharmacists, nationally certified and non-certified pharmacy technicians, and any customer service representatives/pharmacy clerks. Scope of practice and licensure are governed by the laws and regulations of each State Board of Pharmacy and should be reviewed as it pertains to that particular state. 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.

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

Review policies and procedures for providing information to pharmacies about the credentialing process, including how the 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, and any credentialing fees required.

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

Review contracts and manuals for details provided to pharmacies about the credentialing process. The PBM should provide clear and concise information that is consistent with its own policies and procedures and should follow any applicable state or federal law for credentialing and recredentialing. 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 the 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. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

Request *all correspondence* between the PBM and a pharmacy as part of the credentialing process. Consider whether to request information from all entities/persons or just a sample 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, any emails, notes from phone conversations, and any other communications about the credentialing process that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format. Ensure all correspondence from the PBM is clear and concise and provides reasonably sufficient information to pharmacies regarding the credentialing process and any decisions made by the PBM.

In any Summary of the PBM Network Adequacy that proceeds these standards, consider describing 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 chain/independent), or geographic location and will likely have differing reimbursement levels.

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STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

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

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

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

_____ A listing of all the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, specialty, LTC, or 340B 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). Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ A state map or geo-maps identifying the location of each pharmacy.

_____ 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 chain/independent), 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 the PBM does not favor affiliate over non-affiliate pharmacies, for example.

_____ A list of all insurers and employer groups and each plan for the entity for which the PBM administers prescription drug benefits. Require the PBM to identify every network associated with each plan. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

_____ 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.

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Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Review the PBM's internal policies and procedures to assess how the PBM creates, maintains and changes pharmacy networks. Ensure the PBM has clear and concise requirements. The 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 deserts) and describe how the PBM utilizes out-of-network pharmacies when necessary.
- Requirements for how the PBM may update or change network requirements or network participation for a pharmacy. This should include procedures for the PBM to provide *notice* of changes to the pharmacies and its carrier/employer group clients.
- Requirements for pharmacy network reimbursement levels. Ensure these are applied consistently among all pharmacies in each network.
- Conditions under which a pharmacy may be terminated, including requirements on how the pharmacy is notified of the termination and payment for all unpaid claims at the time of the termination.

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

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

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

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

- Does the PBM have networks that are comprised solely of affiliate pharmacies?
- Does the 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 when compared to networks without affiliates?

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 BENEFIT MANAGERS
PHARMACY NETWORK ADEQUACY

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations

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

_____ 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.

_____ Documentation regarding how the PBM makes its provider directory (that lists all providers who participate in its network) available to covered persons and how it makes available, on a timely and reasonable basis, updates to its directory.

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

_____ A listing of all the pharmacies with which the PBM contracts. The listing should require the PBM to identify each pharmacy's location, pharmacy type (for example, chain, independent, mail-order, LTC, or 340B pharmacy), the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand name, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

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

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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.

Review all consumer complaints submitted to the PBM and the regulator to assess whether consumers have issues with pharmacy access.

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G. Utilization Review

1. Purpose

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

The areas to be considered in this kind of review include the insurer's or payor's 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.

DUR is conducted in three primary forms: prospective, concurrent, and retrospective. Prospective DUR occurs prior to dispensing and is designed to identify potential issues such as drug–drug interactions, therapeutic duplication, or inappropriate dosing before the medication is provided to the patient. Concurrent DUR takes place during the course of treatment and is used to monitor ongoing therapy, such as reviewing refill patterns or emerging safety concerns while a patient is actively receiving a medication. Retrospective DUR is performed after dispensing and involves analyzing historical claims data to identify patterns of inappropriate prescribing, potential overutilization, or opportunities for provider or patient education.

2. Techniques

The analysis of utilization review activities should include an overview of the PBM'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 PBM's 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. The overview should also include if the PBM utilizes artificial intelligence (AI) in its utilization review, and if so, the extent of what is being reviewed by AI and what criteria determines that it moves from AI to PBM 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 PBM 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 determinations, including approvals or certifications, denials, and requests for

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reconsideration. Using appropriate sampling methodology, select a representative sample of cases for detailed review. For each sampled case, obtain the clinical criteria and review guidelines applied in the determination and evaluate whether the PBM's actions were consistent with its written policies, clinical standards, and established review procedures. Ensure that the examiner assigned to this review possesses sufficient clinical expertise to interpret the applicable criteria, understand the clinical context of the request, and assess whether determinations were made in accordance with the PBM's documented guidelines and utilization review protocols.

f. Obtain annual reporting by the PBM of its utilization review. Minimum standards should include:
- Number of requests by type (prior authorization, maximum unit, appeal, etc.).
- Number approved of each type.
- Number denied of each type.
- Number appealed of each type.
- Number approved after appeal of each type.
- Timeframe of each response of each type.
- Whether or not each of the above was derived from AI, clinical staff, or non-clinical staff.

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 PBM.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 1
The PBM 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 or payor.

Priority: Essential

Documents to be Reviewed

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

_____Utilization review policies and procedures.

_____Utilization review program or plan documentation.

_____Medical criteria used to make utilization review determinations.

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

_____Minutes of the PBM's board of directors.

_____Minutes of the PBM's utilization review committee.

_____Documentation of clinical staff credentialing maintenance and education requirements.

_____Program assessment reports.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

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

Verify that a PBM 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 PBM's written utilization review program document describes all the following:
  - Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of pharmacy 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 pharmacy services;
  - Provisions for ensuring confidentiality of clinical and proprietary information;
  - If AI is used and in what capacity;
  - The organizational structure (e.g., utilization review committee, quality assurance or other committee) that periodically assesses utilization review activities and reports to the insurer's or payor's governing body; and
  - The staff position functionally responsible for day-to-day program management.

- Verify that the PBM ensures that appropriate personnel have operational responsibility for conducting the insurer's or payor's utilization review program.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 2
The PBM 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 or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

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

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM utilization review program uses documented clinical review criteria that are based generally accepted, independently-developed clinical standards published by the federal government or professional organizations and evaluated periodically to assure ongoing efficacy.

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

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

Verify that the PBM ensures that qualified pharmaceutical professionals administer the utilization review program and oversee review decisions. Verify that the PBM has appointed clinical peers to evaluate the clinical appropriateness of adverse determinations.

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

Verify that the PBM conducts routine assessments of the effectiveness and efficiency of its utilization review program.

Verify that the PBM's data systems are sufficient to support utilization review program activities and to generate management reports to enable the PBM to monitor and manage pharmacy services effectively.

If a PBM delegates any utilization review activities to a utilization review organization, verify that the PBM 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 PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the utilization review organization.

If a PBM delegates any utilization review activities to AI, a AI program, or a AI vendor, verify that the PBM maintains adequate oversight, to include all the following:

- A written description of the AI/AI organization's activities and responsibilities, including reporting requirements;
- Evidence of formal approval of the AI program by the PBM or respective insurer; and
- A process by which the PBM evaluates the performance of the AI functionality.

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

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

Verify that PBM staff conducting each type of utilization review are qualified to make clinical determinations, i.e. non-clinical staff should not be making determinations on drug coverage based on detailed clinical criteria from information based on patient-specific laboratory or clinical findings when compared to national guidelines or predetermined criteria.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 3
The PBM 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 or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Member materials.

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Determine whether the PBM makes its utilization review criteria publicly available, including whether such criteria are posted on a website or otherwise maintained in a manner that allows covered persons and providers to easily access and obtain them upon request.

Verify that the PBM 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 BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 4
The PBM 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 or payor.

Priority: Essential

Documents to be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Activity reports.

_____Provider manual.

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM maintains written procedures, pursuant to applicable state statutes, rules and regulations, for making standard utilization review and benefit determinations on requests submitted to the PBM 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.

State and federal law may contain specific criteria outlining mandates related to communication from the PBM to the patient or prescriber, such as time limitations of response, manner of communication (written notice, portal, etc.), and may contain different criteria related to different types of insurers/payors. The evaluation should take all state and federal guidelines for any/all types of insurers/payors.

For prospective review determinations, verify that the PBM makes the determination and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether the PBM 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 the time as required by state or federal law after the date the PBM receives the request.

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

Verify that if the PBM 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 the time required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the PBM has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the PBM 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 PBM 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 by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Whenever the PBM receives a prospective review request from a covered person, or, if applicable, the covered person's authorized representative, that fails to meet the insurer's or payor's filing procedures, verify that the PBM 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 PBM as soon as possible, but in no event later than the time required by state or federal law following the date of the failure.

Verify that the PBM 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 insurer'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 PBM 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 pharmaceutical service, treatment, or provider for which certification is being requested.

For concurrent review determinations, if a PBM 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 PBM 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 PBM shall notify the covered person, or, if applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state or federal statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the covered person's authorized representative, to file a grievance to:

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- Request a review of the adverse determination pursuant to state or federal 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 pharmaceutical service or treatment that is the subject of the adverse determination is continued by the PBM 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 PBM makes the determination within a reasonable period of time, but in no event later than the time as required by state or federal law after the date of receiving the benefit request.

If the retrospective review determination is an adverse determination, verify that the PBM 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 PBM determination.

Verify that if the insurer 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 the time as required by state or federal law pursuant to applicable state or federal statutes, rules and regulations, the insurer has:

- Determined that the extension was necessary due to matters beyond the PBM's control; and
- Notified the covered person, or, if applicable, the covered person's authorized representative, prior to the expiration of the initial time period as required by state or federal law, of the circumstances requiring the extension of time and the date by which the insurer 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 PBM 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 by the time as required by state or federal law from the date of receipt of the notice to provide the specified information.

Verify that the PBM 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 PBM in accordance with the insurer's procedures established pursuant to applicable state or federal 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 PBM calculates the time period for making the determination to begin on the date on which the PBM 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 BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 5
The PBM 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 or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed

_____ _____
_____ _____

Review Procedures and Criteria

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

- The specific reason or reasons for the adverse determination;
- Reference to the specific plan provisions on which the determination is based;
- A description of any additional material or information necessary for the covered person, or, if applicable, the covered person's authorized representative, to perfect the benefit request, including an explanation of why the material or information is necessary to perfect the request;
- A description of the PBM's grievance procedures established pursuant to applicable state statutes, rules and regulations, including any time limits applicable to those procedures;
- If the PBM 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;
- The PBM's policy on level of professional clinical license that is appropriate to conduct the adverse determination and if any secondary clinical staff was consulted prior to making an adverse determination;
- 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

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- 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 PBM'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 PBM provides the notice in writing or electronically, when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

Standard 6
The PBM 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 or payor.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Form letters.

_____Utilization review files.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the PBM 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.

Verify that the PBM, in the case of a failure by a covered person, or, if applicable, the covered person's authorized representative, to follow the PBM'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 PBM's notice regarding a covered person's, or, if applicable, the covered person's authorized representative's, failure to follow the PBM'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 the time as required by state law 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 PBM's procedures for filing an urgent care request apply only in the case of a failure that:

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

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- Is a communication that refers to a specific covered person, a specific medical condition or symptom, and a specific pharmaceutical 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 PBM to determine whether, or to what extent, the benefits requested are covered benefits or payable under the insurer's or payor's health benefit plan, verify that the PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of the PBM's determination with respect to the request, whether or not the determination is an adverse determination, as soon as possible, taking into account the medical condition of the covered person, but in no event later than the time as required by state or federal law after the receipt of the request by the PBM.

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

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

Verify that the PBM 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 the time as required by state or federal law 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 PBM notifies the covered person, or, if applicable, the covered person's authorized representative, of its determination with respect to the urgent care request as soon as possible, but in no event more than 48 hours after the earlier of:

- The PBM'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 PBM's determination is an adverse determination, verify that the PBM 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 by the time as required by state law prior to the expiration of the prescribed period of time or number of treatments, verify that the PBM makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the covered person's medical condition, but in no event more than the time as required by state or federal law after the PBM's receipt of the request.

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

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Verify that the PBM calculates the time period within which a determination is required to be made pursuant to applicable state or federal statutes, rules and regulations, to begin on the date the request is filed with the either the insurer or PBM in accordance with the insurer's procedures established pursuant to applicable state or federal 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 PBM's notification of an adverse determination pursuant to an expedited utilization review and benefit determination is set forth in a manner calculated to be understood by the covered person, or, if applicable, the covered person's authorized representative, to include all the following:

- The specific reason(s) 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 insurer's internal review procedures established pursuant to applicable state or federal statutes, rules and regulations including any time limits applicable to those procedures;
- A description of the PBM expedited review procedures established pursuant to applicable state statutes, rules and regulations;
- If the PBM 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 or federal statutes, rules and regulations; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the health carrier's grievance procedure process as provided under applicable state or federal 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 PBM provides the notice orally, in writing or electronically.

If the PBM provides the notice of adverse determination orally, verify that the PBM also provides written or electronic notice of the adverse determination within the time as required by state or federal law following the oral notification when required by state or federal law.

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STANDARDS
PHARMACY BENEFIT MANAGERS
UTILIZATION REVIEW

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

Apply to: PBMs contracting out utilization review services.

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Utilization review policies and procedures.

_____Contracts with organizations or entities.

_____Reports of entity reviews and audits (if any).

_____Periodic reports from the organization or entity.

_____Minutes of the PBM's board of directors

_____Minutes of the PBM's utilization review committee

_____Policies and procedures for oversight

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

Whenever a PBM contracts to have a utilization review organization or other entity perform the utilization review functions required by the *Utilization Review and Benefit Determination Model Act (#73)* or applicable state statutes, rules and regulations, the PBM is responsible for monitoring the activities of the utilization review organization or entity with which the PBM contracts and for ensuring that the requirements of the *Utilization Review and Benefit Determination Model Act (#73)* and applicable state statutes, rules and regulations are met.

Verify that the PBM 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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H. Drug Formulary, Placement, and Specialty Drug

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 PBM.

STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 1
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations.

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

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period.

_____All (P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

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

Others Reviewed

_____ _____

_____ _____

Review Procedures and Criteria

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

Verify that the PBM formularies utilized during the examination period are appropriate to all applicable state statutes, rules and regulations.

Verify that the PBM P&T Committee or other committee(s) decisions and statements are in compliance with all applicable state and federal statutes, rules and regulations.

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

Standard 2
The PBM establishes and maintains a formulary program in compliance with applicable statutes, rules and regulations regarding access to medications.

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

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

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

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

_____Any and all list(s) of 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 PBM's formularies utilized during the examination period allow drugs to be dispensed at locations required and appropriate to comply with all applicable state and federal statutes, rules and regulations.

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

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STANDARDS
PHARMACY BENEFIT MANAGERS
DRUG FORMULARY, PLACEMENT, AND SPECIALTY DRUG

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

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

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Formularies and formulary templates used during the examination period. Utilization review policies and procedures.

_____Specialty drug list(s)

_____All P&T Committee meeting minutes with identified P&T Committee members, including their affiliation and specialty.

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

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

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

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

Verify that the PBM P&T Committee or other Committees decisions and statements use and apply the correct definition of specialty drug in compliance with all applicable state statutes, rules and regulations.

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I. 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, providers, or pharmacies; 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, contracts, provider manuals, and final resolutions to determine whether proper steps were taken.
- **Communication Verification:** Ensuring that members, consumers, providers, and pharmacies 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, providers, and pharmacies.
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law.
- **Compliance and Fairness:** Determine that responses:
  - Fully address the issue(s) that was raised.
  - Include adequate supporting documentation.

[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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- 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 BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes, rules and regulations.

_____Regulated entity register.

_____Insurance department records.

_____Direct consumer or pharmacy 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, or in accordance with applicable state or federal law, whichever is longer.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

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

_____Member evidence of coverage.

Others Reviewed
_____ _____

_____ _____

Review Procedures and Criteria

Verify that the company maintains a complaint register.

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

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

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

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

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____PBM register.

_____Test Sample.

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

_____Supporting documentation (claim files, extension requests, etc).

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 in accordance with state and/or federal law. *Note:* Timing is measured from the date the issue is received.

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STANDARDS
PHARMACY BENEFIT MANAGERS
COMPLAINTS, GRIEVANCES, AND APPEALS

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

_____Applicable statutes and regulations.

_____Contracts, including provider manuals.

_____PBM register.

_____Test Sample.

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

_____Supporting documentation (claim files, extension requests, etc).

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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J. Pharmacy Audits

STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACY AUDITS

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

_____ Applicable statutes, rules and regulations.

_____ Pharmacy contracts and manuals in an unredacted format.

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

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

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

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

_____ A listing of parties who perform pharmacy audits on behalf of the PBM, including third-party vendors and credentials of auditor staff.

_____ A listing of all audits initiated or that were ongoing during the examination period. (As part of this request, the 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 and supporting documentation 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. Consider creating a spreadsheet to use to collect this information in a format that is helpful for the regulator.

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

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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 applicable state and federal law to ensure PBM policies and audits are compliant.

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 the PBM has clear protocols, timeframes, documentation collection and review processes, requirements for on-site audits including processes for documenting observations during the on-site audit, and requirements for addressing pharmacy questions. The PBM should have internal policies and procedures for all aspects of the audit, including but not limited to processes for initiating, conducting, and resolving each type of audit.

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

Review contracts and manuals for details provided to pharmacies about the audit process. Review how the 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, the PBM's obligation to provide a justification for the draft audit report and final determination, timeframes for PBM responses to pharmacies throughout the audit, and timeframes for resolution of the audit.

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

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

If the regulator feels the PBM's policies and procedures are reasonable, ensure the PBM also follows and implements its own policies and 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 pharmacies 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 the 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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