

Risk & Regulatory Consulting, LLC Comments

Draft 11/25/25

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

Chapter XX—Conducting the Pharmacy Benefit Manager Examination

IMPORTANT NOTE:

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

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

Background, Scope and Types of Examinations

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

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

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

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

Definitions:

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

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Biologic Drugs - Biologic drugs are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, and certain vaccines.¹⁶ Biologics are sometimes referred to as “large- molecule drugs.” Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process.¹⁷ Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.¹⁸ A biosimilar drug product may be produced following the expiration of the biologic’s patent and exclusivity period.

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

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

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

Insurers - Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees.⁴ Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management.⁵ In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks.⁶ Ultimately, the scope of the PBM’s role in managing this benefit depends on the insurer.⁷

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

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

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

Pharmacies - A pharmacy chain refers to a third-party entity that engages in a retail business and that owns or operates multiple retail outlets at which an individual consumer may have a prescription drug order filled. Retail

Commented [HH2]: (Capitated contract, Carve Out Contract, Closed Formulary, Open Formulary, Mandatory Generic Enforcement, = All of these components can be modified by the PBM to shift a higher percentage of the cost of expensive therapies to members instead of employer/union/government agency, etc

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outlets may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling.

Independent

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

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

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

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

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

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

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

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

Additional definitions to consider:

Commented [HH3]: Consider - PBMs also perform clinical services like disease management and utilization management services for their clients.

Commented [HH4]: Consider breaking out admin services to clinical services. Admin services: benefit administration, pharmacy network administration, claims adjudication, mail order operations and administration

Commented [HH5]: Consider - Almost without exception, the most heavily advertised and rebated drugs have therapeutic generic alternatives that cost about 90% less than the rebated drugs.

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Administrative Fees – Claim fees paid to the PBM by clients (employers, insurers, etc) for services like claims processing and clinical services (formulary development, utilization management retrospective review). Also used to denote the fees paid by manufacturers to PBMs for administering formulary rebate contracts.

Average Manufacturer Price (AMP) - Defined as the average price paid to the manufacturer for the drug by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. Payments and rebates or discounts provided to certain providers and payers are included in the calculation of AMP.

Average Sales Price (ASP) - Drug price benchmark used for Medicare Part B drugs, primarily injectable drugs administered by physicians' offices and infusion clinics, as part of the Medicare Modernization Act of 2003. ASP = Manufacturer Unit Sales of a Drug to all U.S. Purchasers in Calendar Quarter + Total Number of Units of the Drug Sold by Manufacturer in same quarter. Net of any price concessions such as volume, prompt pay, and/or cash discounts. Reference Section 303(c) of ASP drug payment system (option to insert link to statute). Since January 1, 2005, drugs and biologicals have been paid based on the ASP methodology. Payment to providers will be 106 percent of ASP. The ASP methodology uses quarterly drug pricing data submitted to CMS by drug manufacturers.

AWP Discount Percentage - The negotiated amount a drug plan pays to pharmacies for the ingredient cost of a prescription, commonly expressed as a percentage off average wholesale price.

AWP Spread – The percentage difference between AWP price and WAC price. For brand products, retail pharmacies typically refer to AWP spread as either 16% or 20% referencing a discount off AWP. Manufacturers view AWP spread as 20% or 25%, using WAC as a basis for a markup to arrive at AWP on branded prescriptions. For generics and multi-source medications, there is no standard AWP spread. For non-MAC generics, there is no standard spread across PBMs. The larger the AWP spread – the greater the profit opportunity for the pharmacy on third party prescriptions.

Brand Drug – A product marketed by the original holder of a new drug application or biological license application for a given drug entity.

Average wholesale price (AWP) – The AWP is a drug pricing benchmark used in the US pharmacy and insurance industry. Despite the name, the AWP is not an actual average of wholesale prices. Instead, it is a reference price published by commercial drug pricing organizations (example: Medi-Span, First Databank). The AWP is not currently regulated by any state or federal government agency. The AWP is derived by manufacturer pricing data but can often be inflated to a much higher number. An example is differential contracting where PBMs bill terms to a plan sponsor or insurer client based on AWP price but the reimbursement to the network pharmacy for dispensing the medication is based on MAC, this leaving a difference in price that favors the PBM.

Benefit Administration – The administration of drug benefit design which includes setting up and maintaining the drug coverage and exclusions, setting limits on drug coverages and defining member cost sharing requirements.

Capitated Contract – A very rare type of contract among PBMs, It is often used when a PBM agrees to assume financial risk for an employer client drug spending. Capitation is a set dollar amount established

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by analysis of pharmacy claims data. It is used to cover a member's prescription cost and usually set at a per member per month rate (PMPM) that can be negotiated by employer client and PBM.

Claim Adjudication – The online processing of a prescription drug claim. Most claims are submitted electronically at the point of service (the retail pharmacy or mail order pharmacy).

Client – A managed care organization (MCO) employer, or insurer that contracts with a PBM to administer their drug benefits and numerous cost control programs.

Co-pay – A fixed dollar amount paid for every prescription.

Co-insurance – The fixed percentage members pay of the cost of each prescription.

Deductible – A specific annual dollar amount that a member must pay out-of-pocket for prescription drugs before the drug benefit program benefits is applied.

Disease Management Program – Programs designed and developed by PBMs to identify and categorize patients with chronic conditions and to direct these patients towards specific treatment protocols. These programs apply to medical/surgical and behavioral health, mental health and substance use disorder chronic disease management diagnoses.

Fee-for-Services Contract – The most common pricing arrangement PBMs have with their clients. Under the contract terms, PBMs are paid for the administrative services they provide, and they do not assume the risk for the cost of the drugs dispensed.

Formulary – An approved list of branded (and generic) drugs developed by the PBM, and/or the client within contractual terms.

- **Open Formulary** – A list of recommended drugs. Under this structure all drugs are reimbursed irrespective of formulary status. A client's plan design may exclude certain drugs such as over the counter, weight loss GLP1, cosmetic and lifestyle drugs.
- **Incented Formulary** – An incented formulary applies differential co-pays or other financial incentives to influence patients to use, pharmacist to dispense, and physicians to write formulary product.
- **Closed Formulary** – A closed formulary limits reimbursement to those drugs listed on the formulary. Non-formulary drugs are reimbursed if the drugs are determined to be medically necessary, AND the member has received prior authorized.

Ingredient Cost – The cost to the pharmacy for dispensed drugs. To calculate the ingredient cost if not provided by the PBM, a regulator can take the AWP subtracted by the discount percentage.

Mail Pharmacy – Mail pharmacies dispense 90-day supply of drugs through the United States Postal Service (USPS) mail, typically for chronic conditions. Some widely prescribed controlled substances can be sent via mail but there are federal compliance standards for stimulants, opioids, benzodiazepines, and certain analgesics if certain conditions are met. Most PBMs offer a mail order pharmacy service to promote cost savings and improve access to drugs in remote and/or rural areas.

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Manufacturer – A company that creates branded and/or generic pharmaceutical medications.

Maximum Allowable Cost (MAC) – The MAC list is a pricing benchmark that a PBMs use to determine the maximum amount they will reimburse pharmacies for certain generic drugs and multisource brand and specialty medications. Instead of paying whatever the pharmacies charges, a PBM set a standardize ceiling price for each drug on the list. The MAC price list helps controls drug costs, applies mainly to generic drugs. Regulators will need to request copies of MAC price lists for the experience/review period under examination. Some states require PBMs to file their MAC price list methodologies, frequency of updates to the MAC price list, appeal of MAC price outcomes, and also complete transparency by requiring the actual MAC list to be public.

Member – A covered individual within a health plan.

WAC – Wholesale Acquisition Cost (WAC) is the manufacturer's list price for a prescription drug when sold to wholesalers or direct purchasers, BEFORE any discounts or rebates are applied. The excluded discounts can be chargebacks, rebates, coupons, and volume-based price breaks. The WAC is used as a pricing benchmark by PBMs, insurers, and government programs like Medicare and Medicaid. The WAC is used in pharmacy invoice reviews, regulatory rate settings and some market conduct examinations that focus on drug price.

Nonformulary Drugs – drugs not included on a client's drug list or formulary.

Nonpreferred Brands – brand name drugs not included on client's preferred drug list.

Orange Book – Authoritative source on therapeutic equivalence ratings of drug products approved by the U.S. Food and Drug Administration (FDA). The official name is the FDA's Approved Drug Product with Therapeutic Equivalence Evaluations. The common name, Orange Book, is a result of original color of the book's color.

Red Book – A commonly used database of pharmaceutical pricing information and clinical content used in the drug benefit industry. Red Book is published by Truven Health Analytics. This company also publishes Micromedex, a commonly used clinical reference database for pharmacists.

Pass thru Pricing – An arrangement in which a plan sponsor pays the exact amount paid to the pharmacy (ie no markup).

Pharmacy Network – Specifies which pharmacies are approved for members, and includes retail, mail order and specialty pharmacies.

Prior Authorization – A prior approval process that allows prescription drugs to be dispensed to members only when specific conditions have been met.

Shared Savings Contract – A contract between a PBM and a client that provides incentives for both sides to collaborate and run the pharmacy benefit effectively and to share in the overall cost savings.

Therapeutic Substitution Program – Mail order pharmacies created the program to encourage physicians and patients to switch from the drug prescribed to a lower cost, comparable drugs. Substitution requires both physician and member permission before processing.

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Rebates – Paid by manufacturers to PBMs for the sale of branded drugs to PBM members. Types of rebates can include, but are not limited to:

- Access Rebates
- Flat Rebates
- Formulary Placement Rebates
- Market Share Rebates
- Performance-Based or Outcome-Based Rebates
- Price Protection Rebates
- Inflation Rebates
- Penalty Rebates
- Administrative Fees (AFL, CAF)
- Data Fees/Data Usage Rebates
- Volume Based Rebates
- Bundled Rebates
- Specialty Drug Rebates
- Line Extension or New Formulation Rebates
- Non-Formulary Access Rebates (also known as Off-Formulary)
- Guarantee Rebate Arrangements
- Prescription Switching Rebates
- Copay Offset or Copay Assistance Linked Rebates

Usual and Customary (U&C) - The price pharmacies charge cash-paying customers for prescription drugs.

Utilization Management Programs – Programs designed to lower drug cost for a client (employer MCO, insurer). Limits physician control of prescribing medications and delays access to critical patient care for worsening chronic conditions which may result in avoidable Emergency Room visits and/or hospitalization. These programs require the use of generics or preferred products (rebate incentives) by using prior authorization, drug utilization review (concurrent and retrospective, academic detailing programs and patient education.

Specialty Drugs – Drugs that treat chronic, complex, or life-threatening conditions, usually manufacturer through biologic processes and/or targeting a specific gene. Typically, these medications are costly and require intensive clinical monitoring, complex patient actions and/or special handling by the dispensing pharmacy. These medications are most commonly injected or infused, they may also be taken orally or inhaled. This important group of drugs and biologicals is not precisely defined, but it includes products based on one or more of the following: (1) how they are made (2) how they are approved by the FDA, (3) conditions they treat (4) how they are used or administered, (5) their cost, and (6) special features (example: refrigeration, light sensitivity, etc).

Dispensing Fee - The dispensing fee represents the cost for the pharmacist's services (overhead associated with maintaining the facility and equipment).

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

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“Claw backs” - Occur when a PBM charges or collects from an insured a copayment that exceeds the total submitted charges, by the network pharmacy, for which the pharmacy is paid.

“Gag-clause” contractual provision(s) prohibiting pharmacist, from providing individuals information on the amount of the cost share and clinical efficacy of a more affordable alternative drugs.

Spread Pricing - Is a model of prescription drug pricing in which the pharmacy benefits manager charges a covered entity a contracted price for prescription drugs although the contracted price may differ with the amount the pharmacy benefits manager pays the pharmacist.

340B Federal Drug Discount Program - Is a program that was created in 1992 and expanded in 2010 under American Recovery and Reinvestment Act. This program requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities (340B Entities) at significantly reduced prices.

340B Entities - Means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. §256b, including its pharmacy or pharmacies, or any pharmacy or pharmacies, contracted with the participating entity to dispense drugs purchased through such program.

Affiliated Pharmacy – Is generally refers to a pharmacy that is formally connected to or associated with a larger organization—such as a health system, hospital, or a Pharmacy Benefit Manager (PBM)—through ownership, partnership, or contractual arrangement.

Pharmacy Audit - Is a formal review process conducted by a payer, Pharmacy Benefit Manager (PBM), or regulatory body to verify the accuracy, compliance, and integrity of a pharmacy's claims and operations.

ERISA - Stands for the Employee Retirement Income Security Act of 1974, a foundational federal law that governs employer-sponsored benefit plans in the private sector, including retirement funds (e.g., 401(k), pension plans) and health and welfare benefits such as health insurance or prescription drug coverage.

Biosimilar Drug - Is a biologic medication that is highly similar to an already FDA-approved reference biologic product, with no clinically meaningful differences in terms of safety, purity, and potency.

Qualifications of Examiners

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

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

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Scheduling, Coordination and Planning Scope

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

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

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

Procedural Considerations

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

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

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

Writing the Examination Report

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

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

Use of Examination Standards

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

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

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1)PBM Licensing

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A. Pharmacy Benefit Manager Operations/Management

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

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

Standard 1 – The PBM has an up-to-date, valid internal or external audit program.

Standard 2 – The PBM has appropriate controls, safeguards and procedures for protecting the integrity of computer information.

Standard 3 - The PBM has antifraud initiatives in place that are reasonably calculated to detect, prosecute and prevent fraud.

Standard 4 - The PBM has a valid disaster recovery plan.

Standard 6 - The PBM is adequately monitoring the activities of any entity that contractually assumes a delegated business function or is acting on behalf of the PBM.

Standard 7 - Records are adequate, accessible, consistent and orderly and comply with state record retention requirements.

Standard 9 - The PBM cooperates on a timely basis with examiners performing the examinations.

Standard 11 - The PBM has developed and implemented written policies, standards and procedures for the management of client information.

Standard 12 - The PBM has policies and procedures to protect the privacy of nonpublic personal information relating to its customers, former customers and consumers that are not customers.

Standard 15 - The PBM's collection, use and disclosure of nonpublic personal financial information are in compliance with applicable statutes, rules and regulations.

Standard 16 - In states promulgating the health information provisions of the *Privacy of Consumer Financial and Health Information Model Regulation* (#672), or providing equivalent protection through other substantially similar laws under the jurisdiction of the insurance department, the PBM has policies and procedures in place so that nonpublic personal health information will not be disclosed, except as permitted by law, unless a customer or a consumer who is not a customer has authorized the disclosure.

Standard 17 - Each PBM licensee shall implement a comprehensive written information security program for the protection of nonpublic customer information.

Standard 18 - All data required to be reported to the departments of insurance is complete and accurate.

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

Standard 1 – Spread Pricing

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to PBM's billing with health plans.
- Complete and unredacted contracts between the PBM and health plan.
- Complete and unredacted contracts between the PBM and pharmacy.
- An index of periodic reports, certifications, or real-time systems made available to health plans to monitor services provided and PBM charges.
- A schedule of claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
 - The total reimbursement amount paid to the pharmacy for each prescription drug claim.
 - The total reimbursement amount paid to the pharmacy for each prescription drug claim.
- Documentation of health plan billings during the exam period including a itemized breakdowns.

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

Standard 2

Standard 2

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to PBM's billing with health plans.
- An index of all policies and procedures relating to the PBM's payment to pharmacies.
- Complete and unredacted contracts between the PBM and health plan.
- Complete and unredacted contracts between the PBM and pharmacies.
- Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
 - The total reimbursement amount paid to the pharmacy for each prescription drug claim.
 - The total amount charged to the covered entity or health plan for each prescription drug claim.

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

Standard 3

Standard 3

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- PBM to provide an index of all policies and procedures relating to the effective rate reconciliation process.
- Based on information submitted with the policies & procedures index, all policies and procedures that are applicable to effective rate reconciliation process being examined if the regulator is not examining the entire process. For example, all generic effective rate (GER) policies or all brand effective rate (BER) policies. Request documents in an unredacted format.
- PBM contracts with pharmacies or PSOs in an unredacted format.
- All notices, amendments, updates, or other informative documents describing any changes to the PBM's effective rate reconciliation process that it sends to pharmacies.
- All documents provided to pharmacies that support or describe the PBM's effective rate reconciliation process to specific pharmacies, including but not limited to mail order, specialty, or affiliate pharmacies.
- All reports or accounting documents provided to pharmacies or PSOs showing the PBM's quarterly and annual reconciliation amounts. This should include but not be limited to summary reports and claims data.
- Request all claims data for a specified time period and in a standardized template showing how each claim was 'reconciled' by the PBM. Claims detail may include but not be limited to:
 - Pharmacy information including but not limited to name, NPN, and address.
 - Pharmacy network name associated with each claim.
 - Retail, mail order, and specialty drug claims;
 - The drug pricing source used for reimbursement of each claim when
 - The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its initial payment to the pharmacy when the pharmacy submitted the claim.

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- The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
- The total initial drug reimbursement amount of each claim (meaning the amount the PBM paid the pharmacy when it submitted the claim; the amount should not include the dispensing fee).
- The total initial reimbursement of any dispensing fee;
- The reconciled percentage of 'discount' applied to each claim.
- The total final reimbursement amount for each drug claim after reconciliation. This should not include the dispensing fee amount.
- The difference between the total initial drug reimbursement amount and the final reconciled amount for each drug. Request the dollar amount and percentage differences.
- The total reconciled amount owed to or from each pharmacy group or PSAO.

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

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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

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

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

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

Standard 4

Standard 4

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- PBM to provide an index of all policies and procedures relating to pharmacy dispensing fees.
- All policies and procedures that are applicable to pharmacy dispensing fees being examined. Request documents in an unredacted format.
- PBM contracts with pharmacies in an unredacted format.
- All notices, amendments, updates, or other informative documents describing any changes to the PBM's dispensing fees that it sends to pharmacies.
- All documents provided to the pharmacy that support or describe the PBM's dispensing fee amounts to specific pharmacies including but not limited to mail order, specialty, or affiliate pharmacies.
- Contracts with the PBM and the carrier or employer group that include any references to the requirements for PBM's payment of dispensing fees to pharmacies and that describe the carrier or employer group's oversight of the processes. Request the entire contract in an unredacted format.
- Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
 - Pharmacy information including but not limited to name, NPN, and address.
 - Pharmacy network name associated with each claim.
 - Retail, mail order, and specialty drug claims;
 - The drug pricing source used for reimbursement of each claim
 - The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
 - The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
 - The final reimbursement amount of each claim for the drug.
 - The final reimbursement of any dispensing fee;
 - The type of health coverage being reimbursed, for example, commercial vs. Medicare and self-

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funded vs. fully insured;

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

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

Others Reviewed

Review Procedures and Criteria

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

Assess how the PBM determines the dispensing fee amount it pays for each drug type including generic, brand and specialty drugs. Confirm the dispensing fee amount is communicated to the pharmacies in clear and concise language that is easily understandable and cannot be misinterpreted to mean more than the plain 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 plain language. If the PBM contract language gives the PBM authority to change the dispensing fee amount, assess how that change occurs, how often it occurs, how and when it is communicated to the pharmacies, and whether the change can be done with or without the pharmacies' consent.

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

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

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

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- PBM to provide an index of all policies and procedures for the pharmacy contracting and contract amendment and negotiation process.
- From the indices provided, request all policies and procedures that are applicable to contracting or the contract negotiation processes with pharmacies that are being examined. Request documents in an unredacted format.
- A listing of all pharmacies in the PBM's network. The listing should also require the PBM to provide a listing of all contracts (including provider manuals) and contract amendments the PBM has in place with each pharmacy. For each contract and amendment, request a listing of the effective dates and summaries of the content of each contractual document.
- All documentation and correspondence, including but not limited to emails and red-lined documents, between pharmacies and the PBM that pertain to the contact and contact amendments. The documentation should provide examples of pharmacies' requests to change or amend contract terms and should show the PBM's responses. The Examiner should review the documentation to assess whether the PBM is willing to negotiate contractual terms (or not) and whether there are any concerning trends in the PBM's dealings with pharmacies.

Others Reviewed

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for contracting and contract negotiations with pharmacies. Review criteria to assess if there are differing standards based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Review all exclusionary criteria which may include but not be limited to, placing

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limits on the number of pharmacies in a geographic location. Standards should be applied in a non-discriminatory manner such that PBM does not favor affiliate over non-affiliate pharmacies, for example.

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

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

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

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

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

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

STANDARDS PHARMACY BENEFITS MANAGERS PROVIDER/PHARMACY RELATIONS

Standard 2

Standard 2

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

Apply to: All PBMs

Priority: Essential
Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- PBM to provide an index of all contracts with vendors that provide pharmacy benefits management services on behalf of the PBM including a description of those services provided by each vendor and how the services impact pharmacies.
- From the index provided, review all policies and procedures that are applicable to the practices with pharmacies being examined. Request documents in an unredacted format.
- Unredacted PBM contracts from vendors that provide pharmacy benefit management services on behalf of the PBM.

Others Reviewed

Review Procedures and Criteria

Review policies and procedures regarding PBM requirements for implementing the terms of its contracts with its vendors. Review to assess if there are differing standards for the vendor's conduct that may, for example, be based on the type of pharmacy: chain, retail, mail order, specialty or affiliate. Standards should be applied in a non-discriminatory manner such that PBM does not permit the vendor to favor an affiliate over a non-affiliate pharmacy, for example.

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

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

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

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

STANDARDS PHARMACY BENEFITS MANAGERS PROVIDER/PHARMACY RELATIONS

Standard 3

Standard 3

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- PBM to provide a data dictionary or list (and definitions) of all types of disputes that it considers 'disputes.' This may include but not be limited to complaints, independent third-party reviews, and arbitration.
- PBM to provide an index of all policies and procedures relating to the PBM's dispute resolution process for pharmacies.
- From the index provided, request all policies and procedures that are applicable to dispute resolution process being examined. Request documents in an unredacted format.
- PBM documentation of showing how disputes are addressed and finalized. PBM should provide examples of actual disputes and provide all documentation sent to or received by a pharmacy showing how the dispute was initiated, the correspondence between the PBM and pharmacy, any documentation that is exchanged, and documentation showing how the dispute is resolved.

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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

Assess whether PBM has staffing models to effectively resolve disputes.

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**STANDARDS
PHARMACY BENEFITS MANAGERS
PHARMACY CLAIMS**

Standard 1

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

Apply to: All PBMs

Priority: Essential
Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format
- PBM to provide an index of all policies and procedures for pharmacies to submit *and* adjudicate claims to the PBM.
- PBM to provide an index of all policies and procedures for the pharmacies to inquire about or contest the PBM's adjudication of pharmacy claims.
- Based on information submitted with the indices provided, request all policies and procedures that are applicable to the PBM's practices with pharmacies that are being examined. Request documents in an unredacted format.
- Other than contracts and manuals, request all documents provided by the PBM to pharmacies relating to claims processes including but not limited to claims forms with instructions, bulletins, PBM newsletters, pharmacy updates, other mass communications and time stamped screenshots and URLs of the PBM's website showing where information concerning its claims submission and appeals processes are communicated to pharmacies. Request documents be provided in an unredacted format.
- All internal PBM reports used by management regarding claims and claims processing. Request documents be provided in an unredacted format.
- All contacts with carriers or employer groups in an unredacted format.
- Request all claims data for a specified time period and in a standardized template to capture all required claims information that may include but not be limited to:
 - Pharmacy information including but not limited to name, NPN, and address.
 - Pharmacy network name associated with each claim.
 - Retail, mail order, and specialty drug claims;
 - The drug pricing source used for reimbursement of each claim
 - The percentage *and* actual amount of any 'discount' or other price reduction from the drug pricing source that the PBM applied as part of its payment to the pharmacy.
 - The amount of any fees or amount of any other price reduction that is not related to the drug or dispensing fee. For example, any claims processing fee applied to the claim.
 - The final reimbursement amount of each claim for the drug.

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

_____ Regulatory actions

Others Reviewed

Review Procedures and Criteria

Review policies and procedures for pharmacy requirements to be able to submit claims that may include but are not limited to the following:

- Claims processing software requirements
- Claims form information that must be submitted with the claim such as the prescriber identification number, claim codes, and reject codes.

Review policies and procedures relating to the requirements for pharmacies to submit claims that may require additional information, for example claims that include but may not be limited to the following:

- Dispensed as written codes
- Over-the-counter products
- Multi-ingredient compound processing
- Override
- Coordination of benefits
- Reversals
- Submission timeframes

Review policies and procedures relating to the PBM's adjudication of the claims. The policies and procedures should include, but not be limited to, the following:

- PBM should have clear criteria for how it arrives at the payment level and dispensing fee for each claim. This should include how it determines which drug pricing source is used and how it determines any 'discount' the PBM may apply to reduce the price paid to the pharmacy
- PBM should have clear criteria for claims approvals, denials or rejections.
- PBM should have clear timeframes for claims adjudication either through payment or denial/rejection of the claim.
- PBM should have processes describing how it provides pharmacies with reasonably sufficient detail to justify any claim that is denied or rejected.
- PBM should have clear criteria, including timeframes, describing processes for pharmacies to submit inquiries or appeals for example, about any claims that are rejected or denied.

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

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

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

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

- If the PBM publishes a MAC list, is the list readily available and useful to pharmacies? Does the listing provide a 'search' function to find a specific drug or is the list formatted in a way that requires the pharmacy to scroll through thousands of drugs to find a specific drug? The latter would not be reasonable.
- If the PBM applies a 'discount' to the drug pricing source it uses to pay pharmacies, is that discount reasonably described in documentation to pharmacies such that pharmacies will understand the final payment amount prior to submitting a claim? Use of opaque language that does not expressly identify use of a 'discount' and the applicable discount amount should not be allowed; the regulator should require the PBM make changes to any opaque language.
- If the PBM uses a third-party vendor for processing and/or payment of any claims, is that process clearly described to pharmacies? Does the PBM expressly describe the criteria for when a claim will be diverted to a third party? Does it describe which specific drugs will be run through a third-party? Does the pharmacy have the ability to '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. *Regulators have had challenges getting mail order and specialty drug claims from some PBMs.* Ensure the PBM clearly identifies the payment amount and assess whether it is consistent with any state law, such as requiring payment at the NADAC rate or a required amount of dispensing fee. Ensure PBM is compliant with any state law prohibiting fees or claw backs of clean claims.

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

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

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**STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES**

Standard 1

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to the PBM's rebates.
- An index of all training manuals relating to the PBM's rebates.
- Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.
- A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).
- Complete and unredacted contracts between the PBM and manufacturers.
- An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates received by the PBM and/or amounts remitted to health plans.

Others Reviewed

Review Procedures and Criteria

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

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

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

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**STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES**

Standard 2

Standard 2

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to the PBM's rebates, fees and discounts.
- An index of all training manuals relating to the PBM's rebates.
- Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.
- A listing of all health plans or covered entities with which the PBM provides services in the state (for the applicable examination period).
- Complete and unredacted contracts between the PBM and health plans or covered entities.
- An index of periodic reports, certifications, or real-time systems made available to health plans to monitor rebates fees and discounts received by the PBM and/or amounts remitted to health plans.

Others Reviewed

Review Procedures and Criteria

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

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

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

Risk & Regulatory Consulting, LLC Comments

**STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES**

Standard 3

Standard 3

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to the PBM's rebates.
- An index of all training manuals relating to the PBM's rebates.
- Policies and procedures related to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.
- A listing of all pharmacies that the PBM utilizes to pass rebates through to patients at the point of sale (for the applicable examination period).
- Complete and unredacted contracts between the PBM and pharmacies.
- An index of periodic reports, certifications, or real-time systems made available to health plans or patients to monitor rebates received by the PBM and/or amounts passed through directly to patients.

Others Reviewed

Review Procedures and Criteria

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

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

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

Risk & Regulatory Consulting, LLC Comments

**STANDARDS
PHARMACY BENEFIT MANAGERS
PHARMACEUTICAL MANUFACTURER REBATES**

Standard 4

Standard 4

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- An index of all policies and procedures relating to the PBM's reporting requirements to the commissioner/department.
- An index of all training manuals relating to the PBM's reporting requirements to the commissioner/department.
- An index of all policies and procedures relating to rebate processing, rebate crediting at the point of sale, as well as other affiliated entities that may administer rebate negotiations on behalf of the Company.
- A listing of all manufacturers with which the PBM receives rebates or has received rebates (for the applicable examination period).
- Complete and unredacted contracts between the PBM and manufacturers.
- An index of internal reports, certifications, or real-time systems used by employees in the preparation of statutorily required reports.

Others Reviewed

Review Procedures and Criteria

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

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

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

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**STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY**

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- Pharmacy contracts and manuals for PBM's language relating to credentialing.
- PBM to provide an index of all internal policies and procedures for the credentialing process.
- All policies and procedures that are applicable to credentialing practices being examined. Request documents in an unredacted format.
- Any complaints from the network enrollment/credentialing Department.

Others Reviewed

Review Procedures and Criteria

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

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

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

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Review policies and procedures for providing information to pharmacies about the credentialing process. Including how PBM informs pharmacies of required documentation, timeframes for submission of information, processes for submission of information such as via email, web portal or postal mail, any credentialing fees required.

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

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

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

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

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

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**STANDARDS
PHARMACY BENEFITS MANAGERS
NETWORK ADEQUACY**

Standard 2

Standard 2

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

Applicable statutes, rules and regulations.

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

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

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

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

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

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

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

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

Others Reviewed

Review Procedures and Criteria

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

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

- Requirements for pharmacy location. This should include requirements to address pharmacy shortage areas (or pharmacy 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.

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

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

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

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

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

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

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STANDARDS PHARMACY BENEFITS MANAGERS NETWORK ADEQUACY

Standard 3

Standard 3

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- PBM policies and procedures for providing information to covered persons about pharmacy directories.
- PBM policies and procedures for addressing inquiries or complaints from covered persons about pharmacy directories or access. This should include policies and procedures for how covered persons may access emergency pharmacy services when necessary.
- The PBM will demonstrate how it makes its provider directory (that lists all providers who participate in its network) available to covered persons. It also makes available, on a timely and reasonable basis, updates to its directory.
- All documentation to inform covered persons how and where they may fill their prescriptions. Documentation should provide details of how the covered persons may contact the PBM with inquiries.
- PBM to provide a listing of all the pharmacies it contracts with. The listing should require PBM to identify each pharmacy's location or identify if it is a mail order pharmacy, the types of business it serves (commercial, Medicaid or Medicare), the types of drugs it dispenses (generic, brand, specialty), the unique pharmacy network each pharmacy participates in, and whether the pharmacy is an affiliate pharmacy or not.
- PBM to provide a state map or geo-maps identifying the location of each pharmacy in relation to consumers.

Others Reviewed

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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

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has complied with this provision, the regulator should consider the relative availability of pharmacies in the service area.

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

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

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H. Utilization Review

Overview

1. Purpose

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

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

2. Techniques

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

- a. Examiners should request a written overview of the pharmacy benefit managers' utilization review program. The overview should include the names and positions of individuals responsible for overseeing the program, along with the qualifications of the utilization review director and staff. Examiners may request an interview of appropriate personnel, to supplement information obtained in the written overview. During this process, examiners should also determine how the pharmacy benefit manager maintains corporate oversight of the utilization review process. Where applicable, the examiner should obtain copies of any required utilization review licenses or certifications. Review the scope of the utilization review program. Utilization review functions for some specialized services are occasionally delegated to other entities. Examiners should request copies of applicable reports required for regulatory purposes.
- b. Examiners should also obtain the program materials and scripts to ascertain the source of guidelines used, how frequently the materials are updated and whether they are supported by reliable sources of data and medical protocol. In addition, obtain standards used by applicable accreditation entities, if any. A review of the time guidelines for responding to utilization review and reconsideration requests should be conducted. An evaluation of the methods used to communicate utilization review decisions to medical providers, subscribers and other applicable divisions within the company should be completed.
- c. Evaluate the availability of, and access to, the utilization review program to plan members or subscribers. Review adequacy of staffing and hours of operation.
- d. Ascertain whether utilization review requirements are consistent with and supported by language the contractual agreement with the insurer and the insurer's policy, certificate of coverage and marketing materials.
- e. Obtain listings of utilization review approvals or certifications, denials and requests for reconsideration. Use sampling techniques to review specific cases. Evaluate handling for adherence to written guidelines and standards.

3. Tests and Standards

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

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listed here does not indicate priority of the standard.

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**STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW**

Standard 1

Standard 1

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

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

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations, including those related to mandated benefits and services
- Utilization review policies and procedures
- Utilization review program or plan documentation
- Medical criteria used to make utilization review determinations
- Job description of the staff position functionally responsible for day-to-day management
- Minutes of the Pharmacy Benefit Managers' board of directors
- Minutes of the Pharmacy Benefit Managers' utilization review committee
- Documentation of clinical staff credentialing maintenance and education requirements
- Program assessment reports

Others Reviewed

Review Procedures and Criteria

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

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

- The filing of benefit requests;

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

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**STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW**

Standard 2

Standard 2

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

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

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Utilization review policies and procedures
- Form letters
- Activity reports
- Provider manual
- Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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regulations.

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

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

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

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

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

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

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

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

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**STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW**

Standard 3

Standard 3

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

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

Priority: Essential

Documents to be Reviewed

Applicable statutes, rules and regulations

Member materials

Others Reviewed

Review Procedures and Criteria

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

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

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**STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW**

Standard 4

Standard 4

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

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

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Utilization review policies and procedures
- Form letters
- Activity reports
- Provider manual
- Files with utilization review requests (Verify that all levels of authorized, appealed and disapproved requests are reviewed)

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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- Any reduction or termination by the Pharmacy Benefit Manager during the course of treatment before the end of the period or number of treatments, other than by health benefit plan amendment or termination of the health benefit plan, constitutes an adverse determination; and
- The Pharmacy Benefit Manager shall notify the covered person, or, applicable, the covered person's authorized representative, of the adverse determination in accordance with applicable state statutes, rules and regulations regarding procedures for standard utilization review and benefit determination at a time sufficiently in advance of the reduction or termination to allow the covered person, or, if applicable, the covered person's authorized representative, to file a grievance to:
 - Request a review of the adverse determination pursuant to state statutes, rules and regulations; and
 - Obtain a determination with respect to that review of the adverse determination before the benefit is reduced or terminated.

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

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

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

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

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

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

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

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

If the time period for making a prospective or retrospective determination is extended due to the covered person's, or, if applicable, the covered person's authorized representative's, failure to submit the information necessary to

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make the determination, verify that the Pharmacy Benefit Manager calculates the time period for making the determination to begin on the date on which the Pharmacy Benefit Manager sends the notification of the extension to the covered person, or, if applicable, the covered person's authorized representative, until the earlier of:

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

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STANDARDS PHARMACY BENEFITS MANAGERS UTILIZATION REVIEW

Standard 5

Standard 5

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

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

Priority: Essential

Documents to Be Reviewed

Applicable statutes, rules and regulations

Utilization review policies and procedures

Form letters

Utilization review files

Others Reviewed

Review Procedures and Criteria

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

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

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adverse determination;

- The written statement of the scientific or clinical rationale for the adverse determination; and
- A statement explaining the availability of and the right of the covered person, or, if applicable, the covered person's authorized representative, as appropriate, to contact the insurance commissioner's office at any time for assistance or, upon completion of the Pharmacy Benefit Manager's grievance procedure process as provided under state statutes, rules and regulation, to file a civil suit in a court of competent jurisdiction. The statement shall include contact information for the insurance commissioner's office.

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

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STANDARDS PHARMACY BENEFITS MANAGERS UTILIZATION REVIEW

Standard 6

Standard 6

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

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

Priority: Essential

Documents to Be Reviewed

Applicable statutes, rules and regulations

Utilization review policies and procedures

Form letters

Utilization review files

Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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apply only in the case of a failure that:

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

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

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

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

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

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

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

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

For concurrent review urgent care requests involving a request by the covered person, or, if applicable, the covered person's authorized representative, to extend the course of treatment beyond the initial period of time or the number of treatments, if the request is made at least 24 hours prior to the expiration of the prescribed period of time or number of treatments, verify that the Pharmacy Benefit Manager makes a determination with respect to the request and notifies the covered person, or, if applicable, the covered person's authorized representative, of the determination, whether it is an adverse determination or not, as soon as possible, taking into account the

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covered person's medical condition, but in no event more than 24 hours after the Pharmacy Benefit Manager's receipt of the request.

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

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

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

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

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

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

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following the oral notification.

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**STANDARDS
PHARMACY BENEFITS MANAGERS
UTILIZATION REVIEW**

Standard 7

Standard 7

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

Apply to: PBMs contracting out utilization review services.

Priority: Essential

Documents to Be Reviewed

- Applicable statutes, rules and regulations
- Utilization review policies and procedures
- Contracts with organizations or entities
- Reports of entity reviews and audits (if any) by health carrier
- Periodic reports from the organization or entity
- Minutes of the Pharmacy Benefit Manager's board of directors
- Minutes of the Pharmacy Benefit Manager's utilization review committee
- Policies and procedures for oversight

Others Reviewed

Review Procedures and Criteria

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

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

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

STANDARDS PHARMACY BENEFITS MANAGERS DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 1

Standard 1

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

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

Priority: Essential

Documents to Be Reviewed

Applicable statutes, rules and regulations

Formularies and Formulary Templates used during the examination period.

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

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

Others Reviewed

Review Procedures and Criteria

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

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

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

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

Standard 2

Standard 2

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

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

Priority: Essential

Documents to Be Reviewed

Applicable statutes, rules and regulations.

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

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

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

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

Others Reviewed

Review Procedures and Criteria

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

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

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STANDARDS PHARMACY BENEFITS MANAGERS DRUG FORMULARY, PLACEMENT AND SPECIALTY DRUG

Standard 3

Standard 3

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

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

Priority: Essential

Documents to Be Reviewed

- Applicable statutes, rules and regulations
- Formularies and Formulary Templates used during the examination period. Utilization review policies and procedures
- Specialty drug list(s)
- All Pharmacy and Therapeutics (P&T) Committee meeting minutes and identify all P&T Committee members, including their affiliation and specialty
- A list of any other committee or group that makes drug placement suggestions or determinations.

Others Reviewed

Review Procedures and Criteria

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

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

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

Commented [WY9]: When there are no state statutes, rules, or regulations governing formulary development it is our experience that the states rely on federal regulations.

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J. Complaints, Grievances, and Appeals

Overview

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 regulations¹, including:
 - Determining whether complaints, grievances or appeals were resolved according to the laws in place;
 - Establishing whether violations were committed; and
 - Monitoring future conduct for compliance;
- Verifying that the entity has policies and processes in place to properly manage and timely resolve issues raised by consumers or providers; and
- Identifying problem areas that may indicate broader operational issues.

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

2. Techniques

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

- **Register Reconciliation:** Compare the entity's internal register of issues with those received by the insurance department.
- **Sampling:** Selecting a random sample of complaints, grievances or appeals for detailed review.
- **Trend Analysis:** Identifying patterns or recurring issues to detect systemic problems. Identifying differences in processes or outcomes based on pharmacy types (e.g., Independent vs Chain).
- **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, and providers are informed of the procedures and their rights.

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

3. Tests and Standards

Key Standards for Complaints, Grievances and Appeals include:

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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- **Accurate Logging and Documentation:** Ensuring that all cases are properly recorded in a clear, accessible register and include sufficient detail (type of issue, dates, actions taken, and 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
- **Escalation:** Confirming escalation processes are in place
- **Timely Resolution:** Confirming that the regulated entity responds to concerns within the time frames established by law
- **Compliance and Fairness:** Determine that responses:
 - Fully address the issue(s) that was raised.
 - Include adequate supporting documentation.
 - Are compliant with policy statutes and regulations.
 - Provide appropriate remedies when necessary.

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

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

Standard 1

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

Applicable statutes, rules and regulations

Regulated entity register

Insurance department records

Direct consumer complaint, grievance, or appeal

Member evidence of coverage

Others Reviewed

Review Procedures and Criteria

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

Verify that the register includes enough detail to support regulatory review

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

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

Standard 2

Standard 2

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

- Applicable statutes and regulations
- Complaint, grievance, and appeal procedure manuals, including manuals specific to the credentialing and/or auditing departments.
- Member evidence of coverage

Others Reviewed

Review Procedures and Criteria

Verify that the company maintains a complaint register.

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

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

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

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

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

Standard 3

Standard 3

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

- Applicable statutes and regulations
- PBM register
- Test Sample
- Complaint, grievance, or appeal letter or email and PBM response
- Supporting documentation (claim files, extension requests, etc)
- PBM response

Others Reviewed

Review Procedures and Criteria

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

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

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STANDARDS PHARMACY BENEFITS MANAGERS COMPLAINTS, GRIEVANCES, AND APPEALS

Standard 4

Standard 4

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

Apply to: All PBMs

Priority: Essential

Documents to Be Reviewed

- Applicable statutes and regulations
- Contracts, including provider manuals
- PBM register
- Test Sample
- Complaint, grievance, or appeal letter or email and PBM response
- Supporting documentation (claim files, extension requests, etc)
- PBM response

Others Reviewed

Review Procedures and Criteria

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

For reviewing responses:

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

Document potential violations.

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**STANDARDS
PHARMACY BENEFITS MANAGERS
PHARMACY AUDITS**

Standard 1

Standard 1

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

Apply to: All PBMs

Priority: Essential

Documents to be Reviewed

- Applicable statutes, rules and regulations
- Pharmacy contracts and manuals in an unredacted format.
- Index of all policies and procedures relating to the PBM's audits conducted on pharmacies.
- Listing of all types of audits that may include but not be limited to, on-site, investigational, or desktop audits. (PBM should have policies and procedures for each audit type.)
- From the index and listing provided, all policies and procedures that are applicable to auditing process being examined. (Request documents in an unredacted format.)
- Documentation to pharmacies describing how audits are initiated, conducted and finalized. (Documentation should be provided in an unredacted format.)
- Listing of all audits initiated or that were ongoing during the examination period. (As part of this request, require a timeline of when each audit was initiated, the reason for the audit, the type of audit (on-site, desktop, etc.), a copy of the draft audit report, verification of when the draft audit report was sent to the pharmacy, whether the pharmacy provided additional information after the draft report, when the final report was sent to the pharmacy, whether the audit resulted in a corrective action plan for the pharmacy, whether the audit resulted in any recoupment from the pharmacy (including the amount), whether the audit resulted in any remittance to the pharmacy (including the amount), whether the pharmacy disputed or appealed the findings in the final audit report and the results of any dispute or appeal. *It may be helpful to create a spreadsheet to use to collect this information in a format that is helpful for the regulator rather than letting the PBM send this information in its format.*)
- 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 and any emails, notes from phone conversations, and any other communications about the audit that occurred between the PBM and the pharmacy. Require documents to be provided in an unredacted format.)
- Summary of any use of artificial intelligence (AI) that it may use as part of auditing a pharmacy.
- Policies and procedures associated with the use of AI.

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Others Reviewed

Review Procedures and Criteria

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

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

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

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

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

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

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

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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.