

Pharmacy
Benefit
Management

Executive Summary
PBM Purchasers Guide
A Quality Management Toolkit
Evaluating and Managing PBM Services

IN PARTNERSHIP WITH



National Business
Coalition on Health

EMPOWERING CONSUMERS BY PROMOTING
QUALITY HEALTH CARE MANAGEMENT



Message from NBCH and URAC

December 2008

Dear Colleagues:

It was early in 2008 when NBCH and URAC met to discuss the development of this PBM Purchasers Guide. The impetus for this discussion was driven by a comment received after a presentation of URAC's then newly released Pharmacy Benefit Management (PBM) Accreditation Standards. It came from a small employer, who after hearing about the quality standards an organization must meet in order to become PBM accredited, mentioned, "what a great tool it would be to have something that would show me how I could benefit from and better manage my PBM relationship using these standards". This kicked off a series of discussions between our two organizations and ultimately led to our partnership to produce this important "how-to" resource guide for evaluating and managing PBM Services.

PBMs are an integral part of our health care system, and the selection of a pharmacy benefit manager and the management of its services can be a complex issue. Knowing the PBM landscape and understanding the rudiments of how a PBM derives its revenue are important factors when trying to effectively evaluate or manage the services you receive. For employers, large and small, knowing what to ask for and what to be aware of can make all the difference in having a contract that meets your benefit objectives for cost, quality, accessibility, and member satisfaction.

Through the efforts of our Advisory Group, we worked diligently to identify which of the URAC PBM Standards are most relevant to you and then extended our knowledge to show you how to apply these standards as a purchaser of PBM Services. Realizing the intricacies of the subject matter, we have endeavored to make this guide useful without appearing daunting through the manner in which the information is presented and by using summary tables for quick review.

It is our sincere belief that you will find this PBM Purchaser Guide to be a valuable and extremely useful tool. We are pleased to provide this Guide to you and feel it will be an important addition to your resource library.

Sincerely,



Andrew Webber
President & CEO
National Business Coalition on Health



Alan P. Spielman
President & CEO
URAC

Acknowledgements

URAC would like to acknowledge the following industry experts and stakeholders who came together to form the editorial advisory committee for this guide. The committee has worked together to define the basic information that is essential for today's purchaser of PBM services. We recognize that our efforts will not replace the services of a competent consultant nor do we intend to tell you what to buy. Rather, we offer this guide as a tool to assist you in the process of evaluating, purchasing, and managing PBM services. We also hope that the guide assists employers engaged in the movement toward nationwide, value-based health care, by supplying an evaluative tool in support of the Standards.

We hope that you find our efforts useful and that you are able to develop an effective, transparent, and balanced relationship with a PBM. The full Purchasers Guide can be downloaded at WWW.PQM.URAC.ORG.

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This guide is intended to help purchasers of Pharmacy Benefit Management (PBM) services understand some of the issues involved in negotiating and purchasing PBM services, obtaining the best price and highest quality, and ongoing vendor management. Whether you are a purchaser using the services of a consultant, or going through the process alone, you may use this guide to assess the following:

- How Pharmacy Benefit Managers (PBMs) function, operationally and clinically, including various business and service models
- How the URAC Quality Standards embodied in PBM Accreditation can assist the purchasers of PBM services to make decisions based on a set of concise and critical business criteria

Although all the Standards are important to the accreditation of a PBM as a quality organization, the guide summarizes only those Standards that are especially significant to you as a purchaser. These standards are listed in a series of tables at the end of summary. The full guide provides more detail on these selected standards and also provides you with a series of questions to ask your PBM to further compare and evaluate PBM quality and services relative to your needs.

Using the URAC Standards

URAC is an independent, nonprofit organization serving as a national leader in promoting health care quality and efficiency through accreditation, education, and measurement. The Pharmacy Benefit Management (PBM) Accreditation Standards were developed by experts representing a wide range of experience in health care. To earn accreditation, URAC's independent evaluators must certify that a PBM operates efficiently and effectively, demonstrates its commitment to the highest level of standards for care, dedicates resources to quality improvement, and invests in clinical expertise and oversight necessary for managing an effective program.

Purchasers of PBM services can use the URAC Standards in two ways.

- First, by choosing a PBM with URAC accreditation, purchasers are assured that they are dealing with a PBM that has invested in and attained a level of quality that meets or exceeds the national Standards.
- Second, purchaser can use the Standards themselves as a guide for evaluating the services and operations of the PBM.

See WWW.PQM.URAC.ORG for more information and to download copies of this document, the full purchasers guide, or the URAC PBM Standards¹.

¹ A table listing all the URAC Pharmacy Benefit Management Standards that must be implemented in accredited PBMs and highlighting the Standards that are especially relevant to the purchasing process is available within the full guide.

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Purchasing PBM Services

To effectively purchase PBM services you need an understanding of the options for types of services and pricing practices used by PBMs. Although pricing arrangements between you and your PBM are an important aspect of your overall contract, there are other ways that a PBM can help in controlling costs. Formulary Management, Drug Utilization Review, Rebate Negotiations, Pharmacy Network Discounts, the use of Mail Service Pharmacies, and Disease Management Programs are a few methods that should be reviewed and discussed with your PBM during the purchasing process. These topics are reviewed in detail in the full guide.

Next, consider your ability to monitor and pay for pharmacy benefits and what effect the options may have on your members/employees. We have summarized the general steps below as an overview of the process.

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SUMMARY OF STEPS IN PURCHASING PBM SERVICES TO ENSURE HIGH VALUE

STEP ONE: DETERMINE THE OVERALL GOALS OF THE PRESCRIPTION DRUG BENEFIT THAT YOU WANT TO OFFER YOUR EMPLOYEES.

- Define the type of benefit that you are providing for your members/employees. Is it a rich benefit or a lean benefit? Do you want it tightly managed or loosely managed? Are you concerned with low member impact to be competitive in a tight labor market or is your goal to be aggressive at controlling costs with less deference to employee benefit desires?

STEP TWO: EVALUATE YOUR INTERNAL RESOURCES AND PHARMACY EXPERTISE.

- Do you have the expertise in your company to manage the PBM evaluation process and negotiate the PBM contracting process, or do you need to use the services of a consultant? The following steps may be followed with or without a consultant or broker.
- How do you want to be involved in the management of the program after it is set up? Do you have the expertise and resources to manage a pass-through pricing arrangement or do you need to build in the incentives for the PBM to manage your program? For example you could offer incentive payments for specific performance or meeting or exceeding guaranteed pricing, using a spread-pricing arrangement. (See Chapter 1, Comparing Basic Pricing Arrangements.)
- Analyze your purchasing power. If you are an organization that lacks bagaining scale, is there a consortium you can join to increase your leverage? Consult NBCH for information on how to increase your purchasing power (<http://www.NBCH.org>).

STEP THREE: ASSESS YOURSELF AS A PLAN SPONSOR.

- Assess the three key issues: What do you want in terms of cost, quality, and access?
- Be aware of your needs for cash flow. Do you want to share rebates with the PBM and if so, what do you consider a fair division? Can you wait for rebate payments or do you need the PBM to pass these savings to you in a more immediate form?
- What types of disclosures will you need in order to manage your contract? Compare the types of disclosures necessary for different pricing arrangements. How will each of these approaches serve your benefit's goals?

STEP FOUR: SELECT A PBM THAT SUPPORTS YOUR OVERALL GOALS.

- Interview the candidates most likely to meet your needs.
- Ask the PBMs to explain their pricing arrangements that meet your needs.
- Research the PBM's history and get references from others in your industry that have purchased their services. Choose a PBM that has a reputation for integrity and the ability to collaborate and communicate.

STEP FIVE: DEFINE IN WRITING THE TERMS IMPORTANT TO YOUR CONTRACT.

- Make sure you define the contract in terms that reflect your overall goals established in step one, above. It is important to have someone managing the contract process that has an in-depth understanding of PBM language and concepts.

STEP SIX: MONITOR THE PERFORMANCE OF THE PBM .

- Develop and implement an ongoing plan to monitor the performance of the PBM on an ongoing basis to make sure your goals and the terms of the contract are met.

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Comparing Pricing Arrangements

Perhaps the most important question you may ask a PBM is to discuss pricing arrangements that are available to you and how these will affect your overall costs and cash flow. The following discussion compares the pros and cons of the pricing arrangements that are available and summarizes these differences in the table on page 10.

For purposes of this discussion, we describe these pricing arrangements as opposites. In reality the options are almost endless, with many possible combinations. We take this approach to illustrate the possible effects of each choice, not to limit the purchaser to an either/or situation.

Pricing arrangements defined below include:

- spread pricing (also called differential pricing, guaranteed rebates/network discounts or product and service margin/mark-up), and
- pass-through pricing

The key to making any combination of these choices work for you is to ensure that you have defined exactly what the PBM is offering, that it has disclosed its combination of pricing strategies, and that you are properly comparing the effects of these arrangements as it applies to your program.

Spread Pricing Arrangement

Spread pricing is a common way for PBMs to generate incremental revenue from each transaction. Spread is the difference or margin between the price charged to the plan sponsor for an item and the cost the PBM pays for the item. For example, the PBM may negotiate one discount off the average wholesale price (AWP) to the plan sponsor, but pays the contracted retail pharmacy at a different discount rate.

When the price difference is a positive number, this generates revenue for the PBM. When the price difference is a negative number, this is a loss absorbed by the PBM. The PBM may have to absorb a loss from the spread pricing if it has guaranteed a network rate to the purchaser and a pharmacy negotiates a higher rate with the PBM. In this case the PBM will lose the difference in the guaranteed versus the negotiated rates. Often the PBM is making up this loss with another element of pricing, referred to as cross-subsidizing.

THE CONTRACT In a typical approach to a contract with spread pricing the PBM is calculating the rebates, discounts, and costs and presenting the plan sponsor with the costs for service in the form of guaranteed rates and administrative fees. The PBM earns revenue through the spread pricing on discounts and services and thus usually charges a smaller administrative fee or none at all. This arrangement is an updated version of the traditional contract, where the plan sponsor may request disclosures that enable them to compare services and pricing. Since spread pricing can exist in almost every transaction with the PBM, it is important to build disclosures into the contract that define where and to what extent the spread exists.

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PROS The spread pricing arrangement may be the least expensive. If you have negotiated an aggressive rate for network discounts, it may put the PBM at risk for any pharmacies that charge a higher rate. The pricing guarantees protect against fluctuations by region, chain or population density. Determine what your goals are for the pricing and payment for each part of the services. If the PBM is able to achieve your goals for network pricing and access, it may serve you best to pay for at least part of the PBM's services through the spread.

Allowing spread pricing provides incentives for the PBM to negotiate aggressively with the network providers. It also allows the PBM to offer a better price in the areas where the plan sponsor demands price competition. Spread pricing may also act as an incentive to dispense lower cost drugs such as generics. If spread is built into a contract for the generic drugs dispensed to beneficiaries, it provides incentive to the PBM to promote generics over brand drug dispensing thus bringing down the benefit expense. This reasoning also applies to rebates and other negotiated discounts. Taken together, having these incentives built into the contract with defined market competitive discounts means that the PBM will continue to negotiate the best pricing, so that the plan sponsor is not required to continuously manage these strategies.

CONS The cons in spread pricing are associated with a lack of disclosure which make it difficult to compare pricing or know whether or not the PBM is aggressively pursuing the client's quality and performance goals or just its own bottom-line goals. Understanding the costs, comparison shopping, and ensuring your PBM is really providing the lowest net cost is only possible with the appropriate transparency in the communication of pricing arrangements. Further, to protect the plan sponsor, a spread contract must have market competitive pharmacy network discount guarantees in place at the drug category level covering branded products, generic products covered under a Maximum Allowable Cost (MAC) list, generic products not covered under a MAC list, and the associated dispensing fees for each drug category type.

Pass-through pricing arrangement

Pass-through pricing generally means that the PBM passes the discounts, rebates, other revenues and actual costs charged by the pharmacy or paid by a pharmaceutical company in the form of rebates directly on to the plan sponsor. In actual use, it can have various definitions according to the understanding of the parties. The term must be carefully defined in the contract in every instance it is used since there is no industry-accepted definition.

THE CONTRACT In a pass-through pricing arrangement the costs, discounts, and savings negotiated by the PBM are passed through to the plan sponsor as agreed to and fully disclosed in a contract. The services are contracted on a per member per month (PMPM), per employee per month (PEPM), per service rendered or per claim basis. Often, the plan sponsor pays the price for services solely through administrative fees and assumes the risks of the costs of drugs.

PROS: Some plan sponsors feel that pass-through pricing simplifies the choices and that they are better able to examine the total costs and ultimately the impact on net cost to the plan. Many believe it is better to pay a reasonable fee for program administration. Cost savings can be realized by plan sponsors who are willing to use the greater level of information gained through the disclosures of passed-through arrangements to actively manage their plan to drive utilization of lower cost channels of distribution.

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CONS: Pass-through pricing may not give you the lowest possible cost. Because the prices are passed through, you will incur the same risks the PBM is taking. Risk comes from two areas. The first is that you may have a higher volume of prescriptions from retail pharmacies that give less favorable discounts. This means your costs will depend on which pharmacy your members/employees choose. The second is that a drug manufacturer's rebate may decrease over the course of the contract if a generic is introduced to replace the blockbuster brand. You will also have a higher program administration fee since it is the sole payment for the PBM's services.

Not having a spread may reduce the incentive for a PBM to negotiate aggressively for network discounts and rebates. Auditing and management of the account with pass-through pricing may be more expensive and may require a national accounting firm or more internal resources to manage. The auditing costs are generally paid by the party requesting the audit.

The table below summarizes the key differences between pricing arrangements in PBM contracts.

It is important to realize that the PBM can provide a number of services which are designed to increase quality, improve outcomes and decrease expenses. In order to provide these services, the PBM will want to be paid adequately for them. Either the administrative fees or other revenue sources will need to be allowed for payment or the services will not be available in administering the benefit.

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Comparison Criteria: Spread Pricing vs. Pass-Through Pricing?

The choice of pricing strategies varies by plan sponsor. The following table summarizes the key differences between pricing arrangements in PBM contracts. Showing these choices in a table is a means to help you compare and contrast the differences. In reality, these are not always either/or choices.

Key Considerations in Pricing Arrangements

KEY CONSIDERATIONS	SPREAD PRICING	PASS-THROUGH PRICING
Financial Structure	<p>PBM guarantees pricing to plan sponsor for individual financial components.</p> <p>PBM experiences profit or loss on each component.</p>	<p>PBM passes through actual costs to each plan.</p> <p>PBM earns profit through administrative fees.</p>
Plan Sponsor's Role	<p>PBM manages the program with limited active management by the plan sponsor.</p>	<p>PBM serves as administrator</p> <p>Plan sponsor must allocate resources to devote to PBM network discounts and rebate oversight.</p> <p>Fewer incentives for PBM to optimize rebate performance</p>
Risk Sharing	<p>PBM at risk for achieving guaranteed pricing.</p> <p>Plan sponsor has limited liability if guarantees are set at market competitive rates.</p> <p>Plan sponsor has liability if guarantees are not set at market competitive rates.</p>	<p>PBM has little risk; serves more as an intermediary.</p> <p>Plan sponsor has potential for greater liability.</p>
Incentives	<p>PBM has incentives through participation in rebates and network discounts to aggressively negotiate the best pricing.</p>	<p>Fewer incentives for PBM to optimize rebate performance</p> <p>Plan sponsor needs to create incentives or performance requirements via administrative payments or other means for the PBM to assure market competitive discounts and rebates.</p>
Disclosure/Reporting	<p>Reports and audits needed to provide detailed evidence that the plan sponsor is receiving discounts guaranteed by the PBM.</p>	<p>Auditing may be complex and expensive for the plan sponsor, often requiring substantial internal resources or a national accounting firm.</p>

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PBM Revenue Sources

The following is a brief summary of common sources of revenue for a PBM:

- Access Rebates
- Market Share Rebates
- Rebate Administrative Fees
- Data Sales
- Pricing Spreads (e.g. charging the client one price and paying a different price to the network pharmacy)
- Disease Management Programs
- Claims Processing Fees/Mail Service Margin
- Calculating payment on a standard Package Size (100s vs. quantity purchased)
- Product Margin
- Aggregator for Rebates (small PBMs combine rebate power with large PBMs)
- Therapeutic Interchange Program Fees
- Other service fees (prior authorization, network audit, etc)

Contract Elements

There are many elements that should be carefully considered for your contract with a PBM. After considering each element separately, you must take into account how the mix of these elements will affect your relationship and give you the service you desire from the PBM. Not all PBMs offer the same services and contracts may vary from purchaser to purchaser and vendor to vendor. Or, you may be offered a standard services contract that you will want to customize.

It is important for you to find out how each PBM defines the terms and conditions within its client contracts when you are comparing offers and contracts across PBMs. PBMs may define these terms and costs differently.

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The following list summarizes the different elements that should be considered in a contract for PBM services:

- Definitions and Terminology
- Benefit Design
- Pricing and Payment
 - Pharmacy Network Discounts – by network and drug category type
 - Maximum Allowable Cost (MAC) pricing for generic drugs
 - Dispensing Fees
 - Administrative Fees (By type of claim, clinical programs, administrative edit support, plus many others)
 - Discounts – direct from manufacturer (also called discount off invoice or bulk discounts)
 - Rebates
- Formulary
- Clinical Programs (Member and prescriber level programs)
- Over-the-Counter Drug Support
- Pharmacy Distribution Channels
 - Retail Network Pharmacy
 - Mail Service Pharmacy
 - Specialty Pharmacy
 - Long Term Care Pharmacy
- Prescription Claims Processing and Data
- Data Access and Ownership
- E-Prescribing
- Customer Service and Call Center
- Account Management
- Reporting from the PBM
- Performance Standards
- Incentives
- Other Contract Elements
 - Maintaining eligibility
 - Invoicing
 - Termination rights
 - Guarantees
 - Penalties
 - Indemnification
- HIPAA Obligations
- ERISA, Medicare Part D, or other regulatory requirements (This element not addressed here.)
- Audit rights

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Saving Money by Changing the Drug Mix

While purchasers of PBM services have historically focused on comparing prices for rebates, discounts, and fees, a newer approach encourages plan sponsors to achieve substantial savings through changing the drug mix. The drug mix refers to the types and amounts of drugs covered under the drug benefit. The drug mix is controlled by clinical programs which focus on formulary and prescribing practices that are aimed at achieving high quality therapy at the lowest cost.

This approach targets less expensive drugs and cost savings through programs such as tiered formularies, drug utilization review, prior authorization, step therapies, quantity and dosage limits, and patient and doctor education projects. For example, one approach is to reduce the co-pay on generic drugs to encourage the use of generic drugs and save money. It is important that these programs be monitored through reports and adjusted as necessary over time.

It is also important to understand that a rebate is paid for placement of a drug on the formulary and administration of the formulary. This underlines the importance of having the URAC Standards in place to ensure that formulary decisions are based primarily on therapeutic practices before financial consideration of rebates.

These clinical programs will also affect your benefit design and can influence physician and member/employee behavior. When you chose a clinical program, you have to weigh the cost these programs may have in member disruption and dissatisfaction. Disrupting the membership costs you in member and physician customer service expenses, and can add overhead costs for the physicians. For example, even though a less expensive drug may become available, some plan sponsors do not like to make their members/employees change drugs once they have started on a treatment program. When you are concerned about subjecting members/employees to a change, you can decide to maintain current treatments.

Overall, the drug mix is an important driver of cost and an updated, well-managed program can show significant savings over time.

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URAC's Pharmacy Benefit Management Standards, Version 1.0

Although the selection of an appropriate pricing arrangement is important as you negotiate for PBM services, the operational performance and quality of services you receive from your PBM is also critically important, especially when considering member satisfaction. The tables below highlight URAC's quality, operational, and clinical standards that are important in the purchasing or management of PBM services. A more detailed review of these standards is provided in the full PBM Purchasers Guide and a complete set of the standards can be downloaded at WWW.PQM.URAC.ORG.

Core Standards

The URAC Core Organizational Quality Standards (Module 1) are the foundation of URAC accreditation. These Standards address key organizational functions that are important for any health care organization or successful business. All URAC Pharmacy Quality Management® Accreditation Products (e.g., Drug Therapy Management, Mail Service Pharmacy, and Specialty Pharmacy Standards) begin with the essential Standards found in this module. This module also contains Standards addressing data management, consumer protection and safety, consumer information and communications, and consumer complaints and appeals processes.

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Important Core Standards

STANDARDS	AREA AFFECTED	RESULTS OF ACCREDITATION
Core 1-12	Organizational Quality	The PBM has: <ul style="list-style-type: none"> • Organizational Structure Defined • Policies and Procedures Articulated • Staff Qualifications Defined • Staff Credentialing Enforced • Robust Staff Training • Rigorous Regulatory Compliance • Delegation to Business Partners Monitored
Core 13	Rigorous Information Management Required	<ul style="list-style-type: none"> • Data integrity • Data confidentiality and security • Disaster recovery
Core 22	Communication Practices Monitored	PBM informs consumers and clients how to obtain services and submit a complaint or appeal
Core 23	Consumer Safety Promoted	PBM can identify and react to situations that could create potential harm to members/employees
Core 24	Confidentiality Maintained	<ul style="list-style-type: none"> • PBM maintains confidentiality of individual health information • Addresses oral, written, or electronic communication and records that are transmitted or stored
Core 25	Consumer Satisfaction Promoted	PBM collects and evaluates information about consumer satisfaction with services
Core 26	Consumer and Client Services Accessible	Consumers or clients have access to the PBM via telephone, mail, and internet
Core 27 Core 28 Core 29	Rigorous Complaints and Appeals Process Defined	PBM has a process in place to handle complaints and appeals
Core 30 Core 31 Core 33 Core 34	Quality Management Program Defined	Quality improvement program includes: <ul style="list-style-type: none"> • Performance measures on activities • Monitoring of performance measures • Efforts to improve performance measures
Core 35 Core 36	Quality Improvement Projects Implemented	Quality improvement projects include: <ul style="list-style-type: none"> • Quantifiable performance measures • At least annual measure of baseline performance • Established strategies, goals, documentation, and analysis

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Customer Service, Communications, and Disclosure

The Customer Service, Communications, and Disclosure (CSCD) Standards (Module 2) address several key issues related to customer service and disclosure of interest to consumers and purchasers of PBM services. While these are not core Standards, they are essential to responsible organizational functioning in the health care industry to meet the needs of your members/employees.

Important Customer Service, Communications, and Disclosure (CSCD) Standards

STANDARD	AREA AFFECTED	RESULTS OF ACCREDITATION
CSCD 1 CSCD 2	Consumer Information Disclosed	<p>PBM informs consumers about available information resources and assistance including:</p> <ul style="list-style-type: none"> • How to access pharmacy directory • Covered benefits and coverage guidelines • Consumer's costs; including deductibles, co-pays, co-insurance, annual and lifetime co-insurance limits, and changes that could occur during the enrollment period • Consumer's benefit options and implications of these decisions • Evidence-based health information and content for common conditions, diagnoses, treatment diagnostics, and interventions • Information and tips to assist in interactions, such as "Financial decision-making for pharmacy benefits" • Instructions on how to receive assistance via e-mail, telephone, or in person • Monitor and update existing communication materials
CSCD 4	Business Information Disclosed	<p>PBM discloses business model including:</p> <ul style="list-style-type: none"> • Potential conflicts of interest that affect clinical or financial decisions • Sources of revenue • Pricing structure for PBM services
CSCD 5	Client Audit Rights Maintained	PBM provides verification so that the client can ensure disclosures are comprehensive and accurate
CSCD 6 CSCD 7 CSCD 8	Call Center Operations Defined	<p>Call center provides consumers, physicians, and other prescribers:</p> <ul style="list-style-type: none"> • Information on claims processing, benefit coverage, claims submission, and claims payment • Assistance during hours of working pharmacists • Call answering time 30 seconds on average • Call abandonment not to exceed 5 percent
CSCD 9	Multiple Communication Formats Required	PBM provides information to consumers in multiple formats and media so that all consumers have access to relevant information
CSCD 10 CSCD 11	Health Literacy and Cultural Sensitivity Encouraged	PBM provides health care information in a format (or language) that is understandable by the layman and helps consumers understand health care decisions

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Pharmacy Distribution Channels

The Pharmacy Distribution Channels (Pharm DC) Standards (Module 3) address several key issues related to access, availability, quality and safety regardless of which pharmacy distribution channel is addressed. For specific Standards relating to mail service or specialty pharmacies, see WWW.PQM.URAC.ORG.

Important Pharmacy Distribution Channels (Pharm DC) Standards

STANDARDS	AREA AFFECTED	RESULTS OF ACCREDITATION
Pharm DC 1 Pharm DC 2	Scope of Distribution Channels Defined	PBM clearly defines the: <ul style="list-style-type: none"> • Distribution channels offered (e.g. pharmacy network, mail service pharmacies, or specialty pharmacies) • Types of pharmacy services offered within each distribution channel • Geographic area served by each distribution channel
Pharm DC 3	Quality and Safety Criteria Articulated	PBM can identify and address concerns related to quality and safety of drug distribution, quality of service
Pharm DC 4	Network Access and Availability Articulated and Out of Network Criteria Articulated	PBM ensures that members have access to prescriptions when their pharmacies don't have them, or when members are traveling
Pharm DC 5	Robust Pharmacy Relations Maintained	PBM maintains a participating pharmacy relations program that includes: <ul style="list-style-type: none"> • A participating pharmacy communications plan with updated network information for new and on-going programs and processes • Assistance for participating pharmacies and their staff regarding pharmacy network issues • Suggestions and guidance from participating pharmacies about how the pharmacy network can best serve consumers

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Drug Utilization Management

The Drug Utilization Management (DrUM) Standards (Module 4) address several key issues related to drug use management which are increasingly important in today's health care environment. These Standards emphasize the importance of basing drug management decisions on clinical information and offering the consumer alternatives to decisions if they should be needed.

Important Drug Utilization Management (DrUM) Standards

STANDARDS	AREA AFFECTED	RESULTS OF ACCREDITATION
DrUM 1 DrUM 2	Coverage Decisions Clinically-Based	<p>PBM has policies and procedures for identifying the optimal drug and evaluating the available data to address discrepancies and misuse of drugs.</p> <p>PBM bases formulary system decisions on a thorough evaluation of the benefits, risks, and potential outcomes for consumers</p>
DrUM 3 DrUM 4 DrUM 7 DrUM 17 DrUM 18 DrUM 19	Clinical Review Criteria Defined	<p>PBM has qualified prescribers and other clinicians develop and use clinical review criteria that are based on current clinical principles</p> <p>Clinical review criteria is annually evaluated and updated by qualified personnel</p> <p>Review determinations are based solely on the clinical information available to the PBM at the time of the review</p>
DrUM 12	Non-Formulary Exceptions Communicated	PBM informs consumers of how to request coverage of a non-covered prescription drug
DrUM 14	Decision Notice Required	PBM issues a written notification of the non-certification decision to the consumer and prescriber
DrUM 20 DrUM 22 DrUM 23 DrUM 27	Consumer-Friendly Appeals Process Defined	<p>PBM provides access to an appeal process, may be only a referral to the plan administrator who makes the decision.</p> <p>Written information on rights to appeal are available to the consumer and prescriber, including the process involved</p> <p>The consumer and prescriber can submit information relating to the case and the case is evaluated by a qualified, clinical peer. If the case is judged for the consumer, then the PBM must act on the decision</p> <p>Consumer and prescriber are notified in writing of the decision with information on rights to further appeal, the process involved, and reasons for non-certification</p>

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P&T/Formulary Development

The Pharmacy & Therapeutics/Formulary Development (PTFD) Standards (Module 5) address several key issues related to formulary management and pharmacy and therapeutics (P&T) committees. Having these Standards in place ensures that the consumer is protected by formulary decisions that are clinically appropriate and that the plan sponsor is protected from high costs of drugs when it is not necessary.

Important Pharmacy & Therapeutics/Formulary Development (PTFD) Standards

STANDARDS	AREA AFFECTED	RESULTS OF ACCREDITATION
PTFD 1 PTFD 2	Effective Formulary Development Required	PBM has a process to promote clinically appropriate, safe, and cost-effective drug therapy Process should include a P&T Committee, a formulary management decision making process, and a process for regular evaluation and review
PTFD 3	Formulary Decisions Therapeutically-Based	Formulary decisions based on cost factors only after safety, efficacy and therapeutic need have been established
PTFD 4	Formulary Stakeholders Informed	PBM has a process to inform all stakeholders of formulary decisions and rationale PBM discloses the existence of formularies and has copies of the formulary readily available Information includes: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs PBM provides consumer education that explains how formulary decisions are made and the roles and responsibilities of the consumer
PTFD 5 PTFD 6 PTFD 7	P&T Committee Membership Defined	Needs of the consumers are represented by the appropriate clinical specialties and specialists who are practicing physicians or practicing pharmacists
PTFD 11	Formulary Kept Current	P&T Committee will establish a policy and procedure for considering new drugs released onto the market