

Pharmacy
Benefit
Management

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



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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
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Dear Employers and other Purchasers

The world of health care and pharmacy benefits is continuously evolving as competition, private initiatives, and federal programs focus efforts toward developing a quality-based and value-driven health care system. The Pharmacy Benefit Management (PBM) industry has kept pace with this growth and has technological capabilities that now place it in an important position of influencing both financial and clinical management for the health care industry and consumers.

To address the need for quality measures in the PBM industry from both organizational and clinical aspects, URAC introduced the first PBM and Drug Therapy Management (DTM) Accreditation standards in 2007 with the objectives of providing an evaluative tool for vendor selection, enhancing patient safety, assuring access to drugs and pharmacies, improving medication management, improving understanding of standard definitions and disclosure, and empowering and protecting consumers. These standards were received enthusiastically by purchasers and the PBM industry, resulting in 20 companies becoming accredited or in-process of accreditation in 2008¹.

Accredited PBMs have voluntarily committed to the highest level of standards for care. Showing a dedication to quality improvement, these organizations have made the necessary investments to clinical and operational expertise and oversight that are crucial to managing an effective program in today's environment. PBM and DTM accreditation has set in place a means of evaluating PBMs within the industry based on nationally-recognized, best practices.

Even with these significant gains in quality management, URAC continues to hear that the employer and business coalition community has difficulty using the standards to evaluate the business issues they address. While the standards require an accredited PBM to document disclosure of the business agreement of the parties in their contract, they don't necessarily help the purchaser ask relevant questions of their prospective PBM partner while in the selection or negotiation phase of their relationship. Although the standards are designed to set quality baselines for operational and clinical requirements that a PBM must meet in order to achieve accreditation, purchasers can still gain more value from using the standards as a tool for PBM evaluation and management.

To address this need, URAC has partnered with the National Business Coalition on Health (NBCH) to offer this guide to purchasing and managing PBM services. A natural partner in this area, NBCH is a national, non-profit, membership organization of employer-based health care coalitions dedicated to value-based purchasing of health care services through the collective action of public and private purchasers. NBCH also participates in URAC governance as a member organization.

URAC has utilized its experience in bringing industry experts and stakeholders 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

¹ Consult www.uran.org for up-to-date information on those organizations that have obtained accreditation or are in-process.

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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.

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Introduction

About this Guide

This guide is intended to help purchasers of Pharmacy Benefit Management (PBM) services understand some of the issues involved in negotiating, purchasing, managing and obtaining the highest quality PBM services. 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

This guide is presented in three sections. Section One covers PBM business models, the essential elements of PBM pricing and contracts, and suggestions to facilitate the contracting process. Section Two covers the URAC organizational standards for PBM services, containing specific benchmarks for excellence in organizational structure, customer service, communications, and disclosures that have been found to be important in well-run, quality-oriented businesses. The organizational PBM standards also present an overview of the different types of pharmacy distribution operations: retail, mail service, and specialty pharmacy. URAC has individual sets of accreditation standards available for mail service and specialty pharmacy, which are not covered in this guide. (See WWW.PQM.URAC.ORG for more information.) Section Three covers the clinical standards. These standards specify benchmarks for quality practices in drug utilization management and formulary development and management.

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. See Tables 1 – 5 below for a list of all the PBM standards. For a quick summary of the key information pertaining to the standards, an overview table is provided at the beginning of each chapter. Finally, the guide provides you with a series of questions to ask your PBM to further compare and evaluate PBM quality and services relative to your needs. The questions are also collected into a table for your use in Appendix B.

The guide also contains a glossary in Appendix A, which has been compiled specifically to help purchasers understand PBM language. Access to the URAC PBM standards themselves can be found at WWW.PQM.URAC.ORG.

Appendix C lists accredited PBMs to date and Appendix D lists sources for articles containing more information on subjects you might find useful in making PBM choices and Value-Based Benefit Design.

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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.

See Appendix C for a list of URAC Accredited PBMs and [WWW.URAC.ORG](http://www.URAC.ORG) for updates.

- Second, purchasers can use the standards themselves as a guide for evaluating the services and operations of the PBM (www.PQM.URAC.com).

The following tables shows all the URAC Pharmacy Benefit Management standards that must be implemented in accredited PBMs and highlights the standards that are especially relevant to the purchasing process.

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Table 1: Pharmacy Benefit Management Standards, Version 1.0 — Pharmacy Core

Highlights indicate standards reviewed in Purchasers Guide

PHARMACY CORE (PHARM CORE)
PC - 1 - PHARM CORE 1 - ORGANIZATIONAL STRUCTURE
PC - 2 - PHARM CORE 2 - ORGANIZATION DOCUMENTS
PC - 3 - PHARM CORE 3 - POLICY AND PROCEDURE MAINTENANCE, REVIEW, AND APPROVAL
PC - 4 - PHARM CORE 4 - JOB DESCRIPTIONS
PC - 5 - PHARM CORE 5 - STAFF QUALIFICATIONS
PC - 6 - PHARM CORE 6 - CREDENTIALING
PC - 7 - PHARM CORE 7 - STAFF TRAINING PROGRAM
PC - 8 - PHARM CORE 8 - STAFF OPERATIONAL TOOLS AND SUPPORT
PC - 9 - PHARM CORE 9 - STAFF ASSESSMENT PROGRAM
PC - 10 - PHARM CORE 10 - SENIOR CLINICAL STAFF REQUIREMENTS
PC - 11 - PHARM CORE 11 - SENIOR CLINICAL STAFF RESPONSIBILITIES
PC - 12 - PHARM CORE 12 - INTER-DEPARTMENTAL COORDINATION
PC - 13 - PHARM CORE 13 - INFORMATION MANAGEMENT
PC - 14 - PHARM CORE 14 - BUSINESS RELATIONSHIPS
PC - 15 - PHARM CORE 15 - DELEGATION REVIEW CRITERIA
PC - 16 - PHARM CORE 16 - DELEGATION REVIEW
PC - 17 - PHARM CORE 17 - DELEGATION CONTRACTS
PC - 18 - PHARM CORE 18 - DELEGATION OVERSIGHT
PC - 19 - PHARM CORE 19 - REGULATORY COMPLIANCE
PC - 20 - PHARM CORE 20 - FINANCIAL INCENTIVE POLICY
PC - 21 - PHARM CORE 21 - COMMUNICATION PRACTICES
PC - 22 - PHARM CORE 22 - CONSUMER COMMUNICATION PLAN
PC - 23 - PHARM CORE 23 - CONSUMER SAFETY MECHANISM
PC - 24 - PHARM CORE 24 - CONFIDENTIALITY OF INDIVIDUALLY-IDENTIFIABLE HEALTH INFORMATION
PC - 25 - PHARM CORE 25 - CONSUMER SATISFACTION

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PC - 26 - PHARM CORE 26 - ACCESS TO AND MONITORING OF SERVICES

PC - 27 - PHARM CORE 27 - COMPLAINT AND APPEAL SYSTEM

PC - 28 - PHARM CORE 28 - APPEAL PROCESS

PC - 29 - PHARM CORE 29 - COMPLAINT AND APPEAL REPORTING

PC - 30 - PHARM CORE 30 - QUALITY MANAGEMENT PROGRAM

PC - 31 - PHARM CORE 31 - QUALITY MANAGEMENT PROGRAM RESOURCES

PC - 32 - PHARM CORE 32 - QUALITY MANAGEMENT PROGRAM REQUIREMENTS

PC - 33 - PHARM CORE 33 - QUALITY MANAGEMENT COMMITTEE

PC - 34 - PHARM CORE 34 - QUALITY MANAGEMENT DOCUMENTATION

PC - 35 - PHARM CORE 35 - QUALITY IMPROVEMENT PROJECT REQUIREMENTS

PC - 36 - PHARM CORE 36 - QUALITY IMPROVEMENT PROJECT GOALS
AND MEASUREMENT

PC - 37 - PHARM CORE 37 - CLINICAL, ERROR REDUCTION, AND CONSUMER SAFETY
REQUIREMENTS

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Table 2: Pharmacy Benefit Management Standards, Version 1.0 — Customer Service, Communications, and Disclosure

Highlights indicate standards reviewed in Purchasers Guide

CUSTOMER SERVICE, COMMUNICATIONS, AND DISCLOSURE (CSCD)
CSCD 1 – POST-ENROLLMENT CONSUMER INFORMATION REQUIREMENTS
CSCD 2 - ON-GOING COMMUNICATION PRACTICES
CSCD 3 - COMMUNICATION SAFEGUARDS
CSCD 4 - DISCLOSURE
CSCD 5 - DISCLOSURE VERIFICATION
CSCD 6 - PROGRAM REPRESENTATIVE AVAILABILITY
CSCD 7 - CALL CENTER OPERATING REQUIREMENTS
CSCD 8 - SCOPE OF TELEPHONIC SERVICES
CSCD 9 - MULTIPLE FORMAT COMMUNICATIONS REQUIREMENT
CSCD 10 - HEALTH LITERACY COMMUNICATION REQUIREMENT
CSCD 11- CULTURAL SENSITIVITY COMMUNICATION REQUIREMENT
CSCD 12 - GENERIC AND MAIL ORDER EDUCATIONAL INFORMATION

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Table 3: Pharmacy Benefit Management Standards, Version 1.0 — Pharmacy Distribution Channels

Highlights indicate standards reviewed in Purchasers Guide

PHARMACY DISTRIBUTION CHANNELS (PHARM-DC) STANDARDS
PHARM-DC 1 SCOPE OF SERVICES
PHARM-DC 2 ACCESS AND AVAILABILITY
PHARM-DC 3 QUALITY AND SAFETY CRITERIA
PHARM-DC 4 OUT OF NETWORK SERVICES
PHARM-DC 5 PARTICIPATING PHARMACY RELATIONS PROGRAM
PHARM-DC 6 PARTICIPATING PHARMACY WRITTEN AGREEMENTS
PHARM-DC 7 WRITTEN AGREEMENT INCLUSIONS
PHARM-DC 8 WRITTEN AGREEMENT SUBCONTRACTING
PHARM-DC 9 OTHER PARTICIPATING PHARMACY AGREEMENT DOCUMENTATION
PHARM-DC 10 PARTICIPATING PHARMACY DISPUTE RESOLUTION SCOPE
PHARM-DC 11 PARTICIPATING PHARMACY SUSPENSION MECHANISM
PHARM-DC 12 CLAIMS PROCESSING
PHARM-DC 13 DISCLOSURE ON REFILLING PRESCRIPTIONS

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Table 4: Pharmacy Benefit Management Standards, Version 1.0 — Drug Utilization Management

Highlights indicate standards reviewed in Purchasers Guide

DRUG UTILIZATION MANAGEMENT (DRUM) STANDARDS
DRUM 1 - DRUG UTILIZATION MANAGEMENT PROGRAM COMPONENTS
DRUM 2 - COVERAGE DECISIONS BASED ON CLINICAL INFORMATION
DRUM 3 - REVIEW CRITERIA REQUIREMENTS
DRUM 4 - PROSPECTIVE, CONCURRENT AND RETROSPECTIVE DRUG UTILIZATION MANAGEMENT
DRUM 5 - CONSUMER SAFETY
DRUM 6 - GENERAL TRANSITION PROCESS REQUIREMENTS
DRUM 7 - REVIEW SERVICE DISCLOSURES
DRUM 8- PROSPECTIVE REVIEWER QUALIFICATIONS
DRUM 9 - RENDERING OF NON-CERTIFICATIONS
DRUM 10 - AUTOMATED REVIEW
DRUM 11 - OVERSIGHT OF AUTOMATED REVIEW NON-CERTIFICATIONS
DRUM 12 - EXCEPTIONS
DRUM 13 - POLICIES AND PROCEDURES FOR EXCLUDED DRUGS
DRUM 14 - WRITTEN NOTICE OF NON-CERTIFICATION DECISIONS & RATIONALE
DRUM 15 - REVERSAL OF CERTIFICATION DETERMINATIONS
DRUM 16 - SCOPE OF REVIEW INFORMATION
DRUM 17 - PROSPECTIVE AND CONCURRENT REVIEW DETERMINATION
DRUM 18 - RETROSPECTIVE REVIEW DETERMINATIONS
DRUM 19 - LACK OF INFORMATION POLICY AND PROCEDURE
DRUM 20 - APPEALS
DRUM 21 - APPEALS PROCESS CONSUMER RIGHTS
DRUM 22 - NON-CERTIFICATION APPEALS PROCESS
DRUM 23 - APPEALS PROCESS
DRUM 24 - APPEAL PEER REVIEWER QUALIFICATIONS
DRUM 25 - EXPEDITED APPEALS PROCESS TIMELINE
DRUM 26 - STANDARD APPEALS PROCESS TIMEFRAME
DRUM 27 - WRITTEN NOTIFICATION OF UPHELD NON-CERTIFICATIONS
DRUM 28 - APPEAL RECORD DOCUMENTATION

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Table 5: Pharmacy Benefit Management Standards, Version 1.0 — P&T / Formulary Development

Highlights indicate standards reviewed in Purchasers Guide

P&T / FORMULARY DEVELOPMENT (PTFD) STANDARDS
PTFD 1 - P&T / FORMULARY DEVELOPMENT
PTFD 2 - FORMULARY MANAGEMENT DECISION MAKING
PTFD 3 - ECONOMIC FORMULARY CONSIDERATIONS
PTFD 4 - ORGANIZATIONAL SPECIFICATIONS
PTFD 5 - P&T COMMITTEE MEMBERSHIP
PTFD 6 - P&T COMMITTEE CONFLICT OF INTEREST
PTFD 7 - P&T COMMITTEE POLICIES AND PROCEDURES
PTFD 8 - P&T COMMITTEE MEETING ADMINISTRATION
PTFD 9 - P&T COMMITTEE
PTFD 10 - INTERFACE WITH QUALITY IMPROVEMENT & DRUM PROGRAMS
PTFD 11 - TIMELY CONSIDERATION OF NEW DRUGS
PTFD 12 - P&T REVIEW FUNCTION

Purchasing PBM Services

To effectively purchase PBM services you need to first understand the options for types of services and pricing practices used by PBMs. Then consider how these options will influence your ability to monitor and pay for pharmacy benefits and what effect the options will have on your members/employees. While there is no simple formula, we have laid out the general steps for you to take in this discussion and in Table 6 below. These steps are intended to give you an overview of the process; you may need to return to this section after you read through the remainder of the chapter for details and definitions.

Before you begin to negotiate for PBM services, you need a thorough understanding of what you want from your PBM. Although prescription drug benefit design is beyond the scope of this guide, you may first want to ask yourself: What type of benefit am I providing for my members/employees? The choices in benefit design range widely from providing a benefit with increased cost sharing by your employees to an alternative program like Value-Based Benefits Support² with many types of choices in between. The following are a few examples that illustrate this:

- You could be providing an executive benefit program and want to make everything easily available to your members/employees with few or no restrictions. For this program you may want a low level of administrative management for the doctors or the consumers.
- You could be a small business just trying to cover the basics. In this case you might want a tightly managed program that focuses on drug therapy for acute and chronic medical conditions and excludes coverage for lifestyle or cosmetic drugs.
- You might have a large population of aging baby boomers accustomed to richer benefits. They may need services ranging from targeted interventions for employees with diseases such as diabetes or high blood pressure, to strong mail service pharmacy to provide value to employees on medications for chronic diseases.

Once you decide what kind of overall benefit you are seeking for your members/employees, you will be able to determine how the pharmacy benefit should be managed to support your choice. Most PBMs can support the different types of benefit design. However, your costs will be affected by anything special that is written into the contract. So your needs for benefit design should be discussed at the beginning of the negotiation process.

The next step is to take an honest look at your resources and decide if you have the pharmacy expertise in-house to negotiate and maintain this contract, or do you need the services of a consultant or broker. You also need to ask yourself how much involvement you want in the on-going management of your pharmacy benefit. This is an important factor in the type of contract that you set up. While all contracts require management, the amount of management needed can vary greatly with your choice of pricing arrangements. (See Chapter 1, Comparing Pricing Arrangements)

² A program like Value-Based Benefits has very distinct features and will require you to have done your research to identify these before you engage in the purchasing process. See www.NBCH.org for more information.

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If you are an organization that lacks bargaining scale, you can increase your leverage by joining a consortium of purchasers. Consult NBCH for information on how to increase your purchasing power (WWW.NBCH.ORG).

Now you are ready to translate your analysis above into an approach to balance your prescription drug benefits in terms of costs, quality, and access. It is important to remember that in the equation of costs, quality, and access, every component influences the other two components. For example, you may choose a program with the lowest sticker price for a drug but you must also factor in the management of the drug's utilization. This means that at the end of the day, what initially looks like a higher drug price might actually turn out to be a lower price based on how the PBM manages the drug utilization program. (See Chapter 1, Contract Elements, Clinical Programs/Saving Money by Changing the Drug Mix.)

Poor quality in the management of the drug utilization program will increase your costs. Providing greater access will increase your costs but it may be an essential part of your service. You need to understand your members/employees needs before you begin to negotiate.

Another factor to consider with costs is your requirement for cash flow. How long can you wait for rebate payments? Some plan sponsors negotiate for their share of the rebate discounts to come out of their fees for service, lowering their overall payment up front rather than waiting for a rebate check. (See Chapter 1, Contract Elements, Rebates.)

For some plan sponsors, slightly higher costs are not as important as maintaining continuity and consistency of services for their members. Having a good understanding of your priorities will help you to negotiate a balance of services from the PBM that suits you and your members/employees.

Overall, when you are choosing a PBM to partner with, look for a company that has a reputation for integrity. Aim to develop a relationship with your PBM that allows you to collaborate and share information freely. This approach will help you to create a higher quality program at a cost that you know is fair and transparent. Table 6 presents an overview of the steps in purchasing.

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Table 6: Summary of Steps in Purchasing PBM Services to Ensure High Value

SUMMARY OF STEPS IN PURCHASING PBM SERVICES TO ENSURE HIGH VALUE
<p>STEP ONE: DETERMINE THE OVERALL GOALS OF THE PRESCRIPTION DRUG BENEFIT THAT YOU WANT TO OFFER YOUR EMPLOYEES.</p> <ul style="list-style-type: none"> 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?
<p>STEP TWO: EVALUATE YOUR INTERNAL RESOURCES AND PHARMACY EXPERTISE.</p> <ul style="list-style-type: none"> 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 bargaining 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).
<p>STEP THREE: ASSESS YOURSELF AS A PLAN SPONSOR.</p> <ul style="list-style-type: none"> 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?
<p>STEP FOUR: SELECT A PBM THAT SUPPORTS YOUR OVERALL GOALS.</p> <ul style="list-style-type: none"> 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.
<p>STEP FIVE: DEFINE IN WRITING THE TERMS IMPORTANT TO YOUR CONTRACT.</p> <ul style="list-style-type: none"> 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.
<p>STEP SIX: MONITOR THE PERFORMANCE OF THE PBM .</p> <ul style="list-style-type: none"> 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.



Section I: PBM Procurement 101

This section covers PBM business models, the essential elements of PBM pricing and contracts, and suggestions to facilitate the contracting process.

Chapter One: Understanding PBMs

Industry Perspective

Understanding the business models used by Pharmacy Benefit Managers (PBMs) is easier if you understand the evolution of the PBM industry. The PBM industry evolved from a wide variety of origins. In general, most PBMs started out offering processing and adjudication of prescription drug claims. The PBMs' only source of revenue was an administrative fee (considered point of sale fees) charged for each claim they processed.

Later, the PBM industry adopted mechanisms for controlling drug costs by developing pharmacy networks, contracting for branded drug discounts with drug manufacturers (rebates), developing and managing formularies, and promoting generic drugs. These techniques achieved substantial savings for plan sponsors. As the PBM industry evolved and computer systems became more sophisticated, PBMs offered a large range of clinical services including disease management, clinical outcomes measuring and reporting, and interventions to improve prescribing practices and promote appropriate drug use. Some PBMs have also entered the drug distribution channel via direct ownership of retail, mail, or specialty pharmacy facilities.

The Traditional Business Model

These mechanisms allowed the PBMs to spread their operating cost and profit over a wide range of revenue sources and lower their administrative fee. This approach evolved into what is often referred to as the traditional PBM business model. There were benefits to the traditional business model, including lowered administrative costs and market risk. However purchasers found it difficult to understand and compare services and prices between PBMs with this model, since PBMs did not disclose their pricing arrangements.

Transparency

In order to be competitive and to satisfy market demand, most PBMs have offered more transparency in their pricing programs. Transparency does not have a standard definition within the industry. Rather it refers to the ability of the client to clearly see and understand a company's business practices in areas important to achieving the clients' goals. Transparency allows the plan sponsor to more effectively compare services, evaluate the costs, and determine if the PBM is acting in the plan sponsor's best interests. Transparency concepts do not refer to one particular business model.

PBMs today offer a wide range of pricing programs or strategies. Employers who understand how basic pricing programs work, and the pros and cons of each, will be better prepared with information to ask questions thereby achieving greater transparency in their program. (See Comparing Pricing Arrangements below.)

Upon your request, a PBM should be able to provide you with the following information regarding their business practices or policies:

Chapter One: Understanding PBMs

- Appropriate disclosure of pricing structure for PBM services, including rebate structure, administrative fees, existence of pass-throughs on spread pricing in retail network as well as the existence of other revenues related to our account.
- The ability of auditors to follow claims through the system so that appropriate pricing and crediting of rebates can be confirmed.

PBMs will provide transparency and disclosure to a level demanded by the competitive market and generally rely on the demands of prospective clients for disclosure in negotiating their contracts. The best proponent of transparency is informed and sophisticated purchasers of PBM services. The purchaser needs to understand not only what they want to achieve in their relationship with their PBM but also the competitive market and their ability to drive disclosure of details on services important to them. Purchasers of these services can become knowledgeable of PBM business practices through publications such as this one or by contracting with a specialized consultant. Assessing transparency will be more effectively done by a trained eye with personal knowledge of the purchaser's benefit and disclosure goals.

Current Choices

The PBM industry has evolved to meet the demand for almost any type of contract that can be imagined by a plan sponsor. These options range from a more traditional approach with low administrative fees, but with margins on network discounts and sharing of rebates, to a more recent trend toward pass-through pricing, including many choices and combinations of these options. This guide does not recommend one option over the other. The services you choose to purchase should be a reflection of your goals as a health care plan sponsor. Ideally, you will negotiate a contract where the PBM is rewarded as it supports your individual goals.

In the remainder of this chapter, we compare and contrast pricing strategies. We then present a brief overview of the elements of procurement and how these elements are affected by a PBM's basic pricing arrangements.

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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 on Table 3 below.

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. Here is an example of how this works. For prescription drug A:

- Your member/employee pays the PBM Average Wholesale Price (AWP) minus a discount of 15%
- PBM pays the contracted retail pharmacy AWP minus 16%, and
- the PBM retains the 1% difference.

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 deeper network discount rate to the purchaser and a pharmacy negotiates a less aggressive discount 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. Sometimes a PBM will cross subsidize a particular cost such as the network discount with other revenues in an attempt to achieve a client's business goal. The client achieves the desired network discount and the PBM uses other revenues to offset the loss when paying the pharmacies.

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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 the plan sponsor a smaller administrative fee or none at all. This arrangement is an updated version of the traditional contract described above. In these more current agreements with disclosure agreements, the plan sponsor requests disclosures that enable them to compare services, pricing, and monitor on-going expenditures. For these reasons, it is important to build disclosures into the contract that define where the spread exists.

PROS The spread-pricing arrangement may be the least expensive when PBMs are competing aggressively and the purchaser is comparing similar offerings. The risk of this contract is minimized, as the PBM is usually guaranteeing the rates. Thus, the discounts and rebates guaranteed protect you against increases in costs or decreases in rebates. Determine what your goals are for the pricing for each part of the services. If the PBM is able to achieve your goals for network pricing and access along with rebates, it may serve you best to pay for the PBM's services via 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 your members/employees, it provides incentive to the PBM to promote generics over brand drug dispensing, 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 makes it difficult to compare pricing. 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. The PBM needs to disclose enough information so that the purchaser can understand how their PBM earns revenue and how much it amounts to on a regular basis.

ASK ▶ *the PBM what their contract is with the network pharmacies and how those discounts compare with the contract they offer you.*

ASK ▶ *to see sample financial reports that are provided to clients and data definitions used in developing the elements of the reports.*

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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 per the terms in the contract. The services are contracted on a per member per month (PMPM), per employee per month (PEPM), per service rendered or per claim basis. The plan sponsor pays the price for service in a higher administrative fee and assumes all costs or shares the risks of the costs of drugs with the PBM.

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.

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.

Not having spread pricing may also 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.

ASK ► *the PBM to show you different options for pricing arrangements they propose to use in a contract for services in relationship to your benefits, services, and financial goals.*

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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.

Table 7: 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>

(Chart was adapted from Mercer Human Resource Consulting)

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PBM Revenue Sources

As explained under Contract Elements below, there are many things to consider when purchasing PBM services. Described in more detail below, the following are 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)

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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.

While we provide you with a general definition below (and in the glossary), it is important for you to find out how the PBM defines these terms and transactions when you are comparing offers and contracts across PBMs. Each PBM may define these terms and costs differently. For an in-depth explanation of payment methods and benchmarks, see the AMCP Guide to Pharmaceutical Payment Methods (www.AMCP.org).

We have provided questions below each category to get you started in the process of defining how the PBM operates. Each reference to **ASK ►** notes the questions you should discuss with your PBM. Each question has a symbol beside it to mark it as a highlight. These questions are also provided in a list format, without explanations, in Appendix B.

Benefit Design

Although they are generally very flexible, PBMs can specialize in supporting particular types of prescription drug benefit programs. For example, not all PBMs support the Value-Based Benefit Design³ promoted by NBCH, which is useful in limiting the amount or type of cost-sharing by employees based on drug and medical condition parameters. Another example is a PBM that specializes in designing and supporting Medicare prescription drug benefits. The benefit design will specify the level of coverage or type of services provided. The subject of benefits, especially anything unusual, needs to be discussed immediately so that the cost and timing of implementation can be calculated. Any unusual benefit request is usually a separate line item that costs you time and materials.

ASK ► *the PBM if it supports the type of benefits you wish to provide your employees.*

Pricing and Payment

(Pricing arrangements, spread pricing and pass-through pricing, are discussed above.)

Maximum Allowable Cost (MAC)

MAC is a cost management concept or arrangement that sets upper limits on the payment for generic drugs available from multiple manufacturers. It is the highest unit price that will be paid for a generic drug and is designed to ensure the pharmacy dispenses economically, to prevent a windfall, and to control future cost increases. Not all generic drugs are placed on the MAC list. These may be generic drugs without

³ See www.NBCH.org for more information on Value-Based Benefit Design.

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competition or ones that are first introduced to the market after the innovator drug has lost its patent. Unless otherwise negotiated, a generic non-MAC drug sometimes defaults to the agreed-upon brand AWP discount. There can be a wide range of costs for the items not covered under MAC.

There may also be spread pricing in place here between the price the PBM pays to the pharmacy and the price charged to the plan sponsor. Since the plan sponsor may wish to promote generics and allow the PBM an incentive to promote generics to the network, this spread may be a desirable method of compensation.

- ASK ▶** *the PBM to explain MAC pricing terms in the contractual agreement with its network pharmacies. Ask the PBM if MAC pricing applies to generics dispensed in all pharmacy types, retail, mail, long term care, and specialty.*
- ASK ▶** *what is not covered by MAC pricing (for example single source generic drugs, drugs available over the counter, or branded generics) and negotiate for a competitive discount as close to the MAC discount as possible on these items.*

▶ MANAGEMENT TIP AND INFORMATION

Have the PBMs you are considering take a current list of your claims (e.g., a representative distribution during a 6 month time period at a minimum) and apply their pricing to it. This will demonstrate how each PBM's pricing works in relationship to each other and your member/employee needs.

Dispensing Fees

The dispensing fee, for pharmacy overhead costs, is paid to the pharmacy at the time of service for each prescription dispensed. There may be spread pricing in place here between the fee the PBM pays to the pharmacy and the fee charged to the plan sponsor.

Dispensing fees for generic drugs and brand name drugs are often different. This provides an incentive for the pharmacy to dispense generic drugs.

- ASK ▶** *the PBM to explain the contractual agreement on dispensing fees with its network pharmacies.*

Administrative Fees (Point of sale, others)

This fee was the original, or historic, service fee charged by PBMs for providing pharmacy benefit management services. Under the spread-pricing arrangement (see above), administrative fees may be low or waived in entirety. If the contract has pass-through pricing, the administrative fee may be the primary

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charge for the PBM's services, as all other discounts can be negotiated to pass through to the plan sponsor without retention of the spread. Thus, in a pass-through pricing arrangement, this fee may be much higher than in a spread-pricing arrangement.

Administrative fees can also be charged for other services, for example processing paper claims and specific clinical programs like prior authorization.

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 must be paid adequately for them. Either the administrative fees or other revenue sources need to be allowed for payment, or the services will not be available in administering the benefit.

- ASK ▶** *the PBM what services have associated administrative fees and the pricing schedule for those fees.*
- ASK ▶** *for specific information as to whether fees are charged on a per paid claim basis, across all claims (paid and rejected), per employee, per member, per service rendered, or per clinical intervention.*

Discounts – direct from manufacturer (also called discount off invoice, bulk, or purchase discounts)

This type of discount is especially important in the case of PBMs that also own distribution channels such as mail service, retail, and specialty pharmacies. The PBM negotiates with the manufacturer of a pharmaceutical to purchase the drug at a discounted price, depending on a competitive bid. The products may be dispensed as received or repackaged by the PBM and sold under the re-packager's National Drug Code (NDC) number at an AWP with a higher base value than what was purchased.

- ASK ▶** *the PBM if it owns distribution channels like mail service, retail, and specialty pharmacies.*
- ASK ▶** *if the purchase discounts are passed along to the purchaser or are kept as margin by the PBM.*
- ASK ▶** *if the PBM permits repackaged products in pricing algorithms with the pharmacy network.*

Rebates

Rebates are a discount given by the manufacturer after the drug is dispensed. Rebates are typically only offered for branded pharmaceutical products and not generic products. Rebates are the most common method employed by PBMs to reduce the costs of branded pharmaceuticals for plan sponsors. The PBM may negotiate rebates with the manufacturer of the drug based on the:

- drug being placed on the formulary

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- administration of the formulary
- presence or absence of administrative restrictions
- benefit designs such as co-pay levels, and
- amount of market share it achieves against competing drugs.

Rebates are usually paid by the manufacturer on a quarterly basis but may lag by several quarters. Most manufacturers pay within 90 days of submission by the PBM. The PBM submits rebate claims quarterly so some claims may be paid up to six months after the drug has been dispensed. Your contract should specify a time frame, after the money is received by the PBM, that you want to be paid a rebate. Some plan sponsors negotiate for their share of the rebate discounts to come out of their fees for service, lowering their overall payment up front rather than waiting for a rebate check. Other plan sponsors have negotiated point of sale rebates so members paying a percentage coinsurance copayment may benefit from the rebate at the point of sale.

It is common for plan sponsors to receive either a part or all of PBM rebates. However, PBMs may use different rebate calculations so it may be difficult to compare potential rebate yield between various PBMs. A contract with a spread-pricing arrangement may share some of the rebates by guaranteeing a flat rebate amount per claim or giving a percentage of the actual rebate back to the plan sponsor. In pass-through pricing arrangements, the actual realized rebates are passed through to the plan sponsor and there is no retention by the PBM. The PBM is likely to charge a rebate administrative fee to the plan sponsor to manage the rebate program. Negotiate for the type of rebate that works best for your plan. Also remember, a lowest net cost strategy is the best approach to managing the total cost of the pharmacy benefit and generic drugs typically represent a lower cost than a branded drug with a drug rebate. For more information on types of rebates see the AMCP Concepts in Managed Care Pharmacy Series Document: Maintaining the Affordability of the Prescription Drug Benefit (www.AMCP.org).

ASK ▶ *“What type of rebate agreements do you offer?”*

ASK ▶ *“What is your definition of rebates?”*

ASK ▶ *“How can the rebate agreement be audited?”*

ASK ▶ *“What other services are included in the rebate contract, for example fees, compensation, and discounts?”*

Clinical Programs

PBMs offer a wide array of clinical programs to improve the quality and efficiency of patient care and ensure cost-efficient use of prescription drugs. These may include the following programs:

- Formulary development decision making/administration
- Disease management programs
- Medication therapy management programs

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- Medication evaluation policies and systems such as drug utilization review, prior authorization, step therapies, and quantity and dosage management
- Therapeutic interchange
- Prior authorization using clinical guidelines

The depth and sophistication of the programs offered may vary significantly across PBMs. Fees for these programs also vary widely and must be negotiated. Any unusual benefit requests, information technology time, or other services are usually a separate line item that costs you time and materials for changes to an existing program offered by the PBM. It is wise to ask the PBM to perform a return on investment analysis for clinical programs that are suggested for your members. See the URAC standards in Chapters Five and Six for information on these programs.

ASK ► *the PBM to clearly describe the clinical program offering and associated fees.*

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.

As stated above in Pricing and Payment, and Rebates, 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 since they can affect 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. This is especially true for the treatments involving specialty drugs, like chemotherapies. When you are concerned about subjecting this type of member/employee to a change, you can decide to maintain current treatments for patients currently on therapy (also know as "grandfathering").

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Some plan sponsors are also adopting the philosophy that in the long run, it is better to make a more expensive drug for certain chronic diseases (e.g., asthma or diabetes) available at the lowest member cost-sharing co-payment tier on the formulary. This is a decision to spend more money up front because the health plan believes that having the most effective drug on a lower tier saves the health plan through minimization of member cost-sharing barriers, increased member/employee adherence, and overall health and productivity. One example of this is the Value-based Purchasing design developed by NBCH (WWW.NBCH.ORG). While there is anecdotal evidence for this approach, it is still not known whether tier placement encourages optimal adherence over an extended time period. This is only one step in a complex program that is required for Value-Based Purchasing benefit design. Another, similar approach is to base rewards on compliance with adherence to prevention and treatment programs.

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

- ASK ▶** *the PBM to see the formulary. Make sure the formulary and data you consider are a good fit for your employee demographics.*
- ASK ▶** *the PBM to show you their data on the effect of these programs and determine whether they are aligned with your benefit goals.*
- ASK ▶** *to see reports showing you information on patient adherence, generic dispensing, and controlled substance utilization.*
- ASK ▶** *the PBM how customizable these programs are and how much they cost as designed and for custom tailoring to your needs.*
- ASK ▶** *"What is the return on investment and how much will this disrupt my membership?"*

Over-the-Counter Drug Support

Many of the highly prescribed drugs of the 1990s are now off-patent and have become available either generically or as non-prescription, over-the-counter (OTC) products (e.g. non-sedating antihistamines and proton pump inhibitors for acid reflux). In consideration of both patient safety and savings, many plan sponsors have restructured their formularies to include OTC medications. With OTC medications, patient safety may be a concern since there is no physician monitoring of drug usage and historically, these medications did not go through the claims processing system. However, the Food and Drug Administration determines when the drugs are safe enough to be moved from prescription to OTC status and be made available to the population without a prescription.

Some PBMs can now support claims processing for OTC products covered under the pharmacy benefit plan. Savings have been shown to be considerable when a plan covers OTC medications. For example, if your employee has the option to pay the full retail cost of \$20 for a 28-day supply of 20 mg Prilosec OTC or pays a \$10 co-pay for a 30 day supply of 20 mg generic omeprazole, the employee may be inclined to

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choose the generic prescription drug. The generic drug will save the employee an out-of-pocket cost of \$10, but cost the plan an estimated \$50 for a 30-day supply. The plan sponsor typically will also incur the cost for a doctor's office visit to obtain the prescription order. A Blue Cross and Blue Shield plan reported projected savings of \$20 million annually after a month of implementing coverage for OTC Prilosec.

While this issue is still being debated, it is important that you know whether your PBM will support an OTC program. The PBM may lose some rebates if OTC medications are substituted for branded medications and may charge a specific administrative fee to offer such a program.

ASK ▶ *"What kind of services can you offer for OTC medications?"*

Pharmacy Distribution Channels

See Chapter Four for information on URAC's accreditation standards that cover pharmacy distribution channels in general. However, URAC also has independent sets of standards that specifically cover Mail Service and Specialty Pharmacy accreditations. See www.urac.org for information on these standards.

Retail Network Pharmacies

PBMs provide drug products to covered members by entering into contracts with chain and independently-owned retail pharmacies to create a network of retail pharmacies accessible to members. These pharmacies are referred to as retail network pharmacies. The large majority of prescriptions in this country are delivered to patients through retail network pharmacies. The PBM does not receive shipments of drugs or take direct ownership of the drugs from the manufacturer. For more information on types of pharmacy networks see the AMCP Concepts in Managed Care Pharmacy Series Document: Maintaining the Affordability of the Prescription Drug Benefit (www.amcp.org).

When considering costs, it is important to realize that the ability of the PBM to provide greater discounts is based on providing a smaller, more select group of pharmacies in the network. Purchasers must balance access and availability of pharmacies against a higher level of discounts achieved by a smaller network. It is important to understand the demographic needs of your members/employees in order to make a balanced selection that provides sufficient access at the lowest cost.

ASK ▶ *the PBM to inform you of state laws requiring that "any willing provider" be a part of a network and how the PBM handles such requirements at the network level.*

ASK ▶ *the PBM to explain their pharmacy network options and offerings.*

ASK ▶ *the PBM to illustrate their ability to offer a restricted network at a more aggressively discounted contracted rate.*

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ASK ► *for a pharmacy access report which tells you how far your membership is from the network pharmacies. You can set access standards. For example, if you are looking for a narrow range for your members/employees you could say, "I want 85% of my members to be within 5 miles of a pharmacy."*

Mail Service Pharmacy

Mail service facilities account for 17 percent of expenditures on outpatient prescriptions. Typically a pharmaceutical manufacturer or wholesaler negotiates and contracts directly with the mail service facility. All products are usually shipped directly to the facility for dispensing to patients who have chosen to use this alternative. The pharmaceutical manufacturer may provide volume discounts to the mail service facility through a discount-off-invoice arrangement. If the PBM does not have a mail service pharmacy within its organization, it contracts for mail services as they would with a retail network pharmacy.

Since mail service pharmacies have invested in technology to automate the dispensing process and leverage their volume purchase discounts, they are able to process prescription orders in a quicker and more cost effective manner than typical retail network pharmacies. As a result, mail service pharmacies generally offer better discounts and no dispensing fees in comparison to retail network pharmacies. Mail service pharmacies may also earn revenue by buying medications and other ingredients in discounted bulk, sometimes repackaging them, and dispensing at a higher prescription product cost. Mail service pharmacies are generally open to a variety of payment methods and will negotiate to meet client needs and meet market competition. While negotiation does not usually involve passing through discounts to plan sponsors, it is common to negotiate aggressive discounts on branded and generic drugs as well as very low or zero dispensing fees. Still, acquisition costs may be discussed and negotiated, if necessary to get your preferred contract terms.

The typical prescription filled at a mail service pharmacy is used to treat a chronic disease or condition and is filled for a 90 day supply. These types of prescriptions are also known as maintenance medications. Traditionally retail prescriptions have only been filled with a 30 day supply. However, recent industry trends have resulted in select retail pharmacies offering 90 day supplies at discounts comparable to the mail service discounts. Mail service pharmacy is an important component of access for your employees with chronic diseases like diabetes, asthma, or high blood pressure. Some members/employees with chronic diseases prefer mail service pharmacy because they are generally only paying one (or two) co-pay(s) for the 90 day supply versus the three co-pays they must pay for the same amount of medication from the retail pharmacy. Some plan sponsors have objected that the loss of the co-pay reduces the expected savings they might have had with the mail service program, so it is important to work with the PBM on modeling mail service benefit designs to meet your financial goals.

Mandatory Mail

Some plan sponsors are requiring that members/employees with chronic diseases on maintenance medications use mail service pharmacies. Plan sponsors seem to agree that the savings is substantial for consumers and/or the sponsor. Whether mandatory mail service saves money for the plan sponsor must be evaluated with your PBM, taking your needs into account.

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- ASK ▶** *which pharmacy provides the mail services, whether the pharmacy accepts MAC pricing for generic drugs and the typical turn around to fill mail service prescription orders.*
- ASK ▶** *about the option to fill 90 day supplies within the retail network.*

Specialty Pharmacy

A Specialty Pharmacy is one that dispenses low-volume, high-cost medications to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life threatening (e.g., multiple sclerosis, cancer, rheumatoid arthritis, HIV/AIDS, growth hormones, hepatitis, hemophilia, transplants). These therapies often require specialized delivery and administration. The average prescription is for a 30 day supply and costs around \$1,700. Specialty pharmacies have a patient case management component and special drug handling that is not present in a more general mail service pharmacy; otherwise they are somewhat similar to mail service operations.

- ASK ▶** *“What specialty pharmacies do you expect to have available for my employees and for which conditions will these services apply?” You need to have a thorough understanding of what access options the PBM can provide and how this will fill the needs of your members/employees.*
- ASK ▶** *which pharmacy provides the specialty pharmacy services and how the first fill of specialty drugs is handled when members require immediate access. Most specialty pharmacies use overnight delivery carriers but may direct members to the retail pharmacy network if same day service is required.*

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Prescription Claims Processing and Data

Data Access

Your PBM should inform you as to if or how they use the prescription data collected while processing your members' claims. Some plan sponsors expect to be paid for utilization of their data for revenue generating activities undertaken by the PBM or chose to omit their data from any sales arrangements. See Chapter Two for URAC standards that address data access issues.

ASK ▶ *the PBM how they plan to use your data and if they are compensated for data sharing. Include a paragraph in your contract to address whether your data is sold and how you would be notified of the sale.*

E-Prescribing

E-Prescribing is an electronic system used by prescribers to send prescriptions directly to the pharmacy. E-prescribing brings many benefits to both consumers and the health care system by increasing consumer safety through reduction of human errors and the ability to check the formulary status of drugs, patient medication history, eligibility, and prior authorization requirements before the prescription is written at the point of care. E-prescribing also reduces paper work, time delays, call-backs, and can provide an overall medication management process through programs for drug utilization review (DUR). URAC accredited PBMs are required to have the capability to support e-prescribing by accepting and transmitting data.

In 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) authorized the Centers for Medicare & Medicaid Services (CMS) to pay a bonus to physicians for e-prescribing of Medicare prescriptions beginning in 2009. Physicians who do not use e-prescribing will receive a penalty beginning in 2012. (See Overview at www.cms.hhs.gov/eprescribing for more information.)

ASK ▶ *"What are your capabilities for processing e-prescriptions?"*

Customer Service and Call Center

For many plan sponsors, customer service is one of the most significant components. Customer service is usually defined in the contract by an extensive list of performance measures for the PBM. For example, these may include call response time, complaint resolution, average speed of answer, blockage rates, first call resolution rates, and turn-around times. PBMs that are accredited by URAC are required to meet specific standards for customer service. See Chapter Three for URAC standards on Customer Service, Communications, and Disclosure (CSCD).

Often contracts include penalties for not meeting the specified performance standards. Generally the PBM will guarantee a certain level of customer service performance. Remember, you can always negotiate for a higher level of performance.

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ASK ▶ *“What are your performance standards for customer service and the call center?”*

ASK ▶ *“How are these performance standards measured and reported?” Make sure you specify your desires in your contract.*

Account Management

As a purchaser, you are making a large investment in contracting with the PBM and it is important that you can work well with the account team. Often a plan sponsor requests the resumes and background information of the account managers that will handle their account within the PBM.

ASK ▶ *to meet with the account management and the clinical pharmacy teams and make certain that they are responsive to your needs for help and information.*

Reports from the PBM

Many plan sponsors utilize reports from the PBM in order to verify and assess trends in drug cost and utilization. Reports are also used to monitor potential fraud and abuse by consumers and network pharmacies. PBMs usually offer a set of standard reports. It may cost you more to request additional, customized or ad hoc reports; however, it may save you money in the long run since they are tailored to your needs and those of your membership. Know your data requirements before you negotiate with the PBM. You may want the PBM to provide reports to support performance measures, clinical management, drug utilization/ drug mix, financial reporting, generic utilization, financial and clinical trending, and ad hoc reporting unique to the plan.

ASK ▶ *“What standard, customized, and ad hoc reports do you provide and how will these reports show me significant information?”*

ASK ▶ *“What is the typical turn-around-time for custom report requests?”*

ASK ▶ *“What are your charges for standard and additional, customized reporting?”*

ASK ▶ *“Is there a reporting tool that clients can use to generate their own reports?”*

Performance Standards

All of your performance standards need to be outlined carefully in your contract. In general you will pay more for the PBM to meet higher/more comprehensive performance standards and the ability to audit them.

ASK ▶ *the PBM to show you their quality metrics for your performance goals. These metrics may be in the areas of claims processing, customer service, financial guarantees, and network accessibility standards.*

Chapter One: Understanding PBMs

Incentives

Building incentives into your contract is a recommended strategy for achieving high performance from your PBM. Incentives are also recommended as a successful approach for pass-through pricing arrangements and Value-Based Health Care (see www.nbch.org). Incentives are more successful at building a positive relationship with the PBM than penalties for failure to meet a goal. Determine what goals are important to your membership for promoting value and consider which incentives are necessary for the PBM to achieve those goals.

Other Contract Elements

Other contract elements may include⁴:

- Maintaining current eligibility
- Invoicing
- Contract termination
- Penalties
- Indemnification
- HIPAA Obligations
- ERISA, Medicare Part D, or other regulatory requirements
- Audit rights

⁴ These elements are not all addressed here.

Section II: URAC Organizational Quality Standards

This section covers the URAC organizational standards for PBM (Pharmacy Benefit Management) services, containing specific benchmarks for excellence in organizational structure, customer service, communications, and disclosures that have been found to be important in well-run, quality-oriented businesses. The organizational PBM standards also present an overview of the different types of pharmacy distribution operations: retail, mail service, and specialty pharmacy. URAC has individual sets of accreditation standards available for mail service and specialty pharmacy, which are not covered in this guide.

(See www.PQM.URAC.org for more information.)

Chapter Two: URAC's Core Standards

Introduction

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 the URAC standards (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.

The table below presents an overview of the standards that are especially important for purchasers to consider. Below each table are more detailed explanations that include examples, questions for you to ask the PBM, and how to take full advantage of accreditation.

Chapter Two: URAC's Core Standards

Organizational Quality

STANDARD
ORGANIZATIONAL QUALITY
PHARM CORE 1 - ORGANIZATIONAL STRUCTURE
PHARM CORE 2 - ORGANIZATION DOCUMENTS
PHARM CORE 3 - POLICY AND PROCEDURE MAINTENANCE, REVIEW, AND APPROVAL
PHARM CORE 4 - JOB DESCRIPTIONS
PHARM CORE 5 - STAFF QUALIFICATIONS
PHARM CORE 6 - CREDENTIALING
PHARM CORE 7 - STAFF TRAINING PROGRAM
PHARM CORE 8 - STAFF OPERATIONAL TOOLS AND SUPPORT
PHARM CORE 9 - STAFF ASSESSMENT PROGRAM
PHARM CORE 10 - SENIOR CLINICAL STAFF REQUIREMENTS
PHARM CORE 11 - SENIOR CLINICAL STAFF RESPONSIBILITIES
PHARM CORE 12 - INTER-DEPARTMENTAL COORDINATION
ACCREDITATION SUMMARY

The PBM has:

- 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 standards 1 through 12 contain specific benchmarks for excellence in organizational structure that have been found to be important in well-run, quality-oriented businesses:

Rigorous Information Management Required

STANDARD
<p>RIGOROUS INFORMATION MANAGEMENT REQUIRED</p> <p>PHARM CORE 13 - INFORMATION MANAGEMENT</p>
<p>ACCREDITATION SUMMARY</p> <ul style="list-style-type: none"> • Data integrity • Data confidentiality and security • Disaster recovery

This standard discusses the requirements of the PBM's information management system. It outlines the need for information systems to provide for data integrity, data confidentiality and security. Core 13 also defines the necessary components of the disaster recovery plan. These capabilities form the core of PBM service and should not be taken for granted. Good information systems management helps to maintain confidentiality and consistent information flow, supporting an organization's ability to provide appropriate and timely services. A PBM's information management system must also comply with the Health Insurance Portability and Accountability Act (HIPAA).

In discussing a PBM's information management system, you also want to remember to think about your ability to get useful information from their data systems. Establish a plan for reporting according to your needs and ask specific questions as to how the reports work. See Chapter 1, Contract Elements, Reports.

- ASK ►** *"What is your application platform for data management, homegrown or outsourced? What plans are in place for your system stability, security, and disaster recovery?" Have someone who is technically qualified rate these data capabilities in detail.*
- ASK ►** *"What level of detail can I receive from the data?" Evaluate whether this level of detail will suit your needs for analysis of clinical programs and creation of ad hoc reports, especially regarding the interface with the claims history.*

Chapter Two: URAC's Core Standards

Communication Practices Monitored

STANDARD
COMMUNICATION PRACTICES MONITORED
PHARM CORE 22 - CONSUMER COMMUNICATION PLAN
ACCREDITATION SUMMARY
PBM informs consumers and clients how to obtain services and submit a complaint or appeal

The PBM should inform consumers and clients of their rights and responsibilities, including how to obtain services and submit a complaint or appeal for service that has been denied. These practices should also be documented. If this is not the organization's responsibility, it must still communicate how the consumer can find the right information.

- ASK ▶** *"How do you inform consumers and clients of their rights and responsibilities, including obtaining services and submitting a complaint or appeal?"*
- ASK ▶** *someone to go through the process steps and show you the documentation.*
- ASK ▶** *for the complaint and appeal rate.*

Chapter Two: URAC's Core Standards

Consumer Safety Promoted

STANDARD

CONSUMER SAFETY PROMOTED

PHARM CORE 23 - CONSUMER SAFETY MECHANISM

ACCREDITATION SUMMARY

PBM can identify and react to situations that could create potential harm to members/employees

The PBM must be able to respond quickly to situations that pose an immediate threat to the health and safety of your members/employees (consumers). This standard is important in situations where there may have been a drug prescribed that will interact with a patient's other medications, a patient is in danger of taking a duplicate drug, there is a drug that is not appropriate for a patient's age or gender, or there is a regulatory drug recall.

- ASK ▶** *"How do you identify situations that could create potential harm to my members/employees?"*

- ASK ▶** *"How do you notify members/employees and or prescribers when you have an adverse event or a drug recall?"*

Chapter Two: URAC's Core Standards

Confidentiality Maintained

STANDARD
<p>CONFIDENTIALITY MAINTAINED</p>
<p>PHARM CORE 24 - CONFIDENTIALITY OF INDIVIDUALLY-IDENTIFIABLE HEALTH INFORMATION</p>
ACCREDITATION SUMMARY
<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

The PBM must use a procedure to protect the confidentiality of individually-identifiable health information that addresses all aspects of storing and handling the individual's information, including all forms of wireless communication, internet, fax, and HIPAA requirements.

- ASK ▶** *"How do you maintain the confidentiality of an individual's health information?"*
- ASK ▶** *"Do you address the oral, written, or electronic communication and records that are transmitted or stored?"*
- ASK ▶** *"Do all your employees understand their responsibility to preserve confidentiality?"*
- ASK ▶** *"Show how the PBM ensures that an individual's health information is used only for purposes necessary for conducting the business of the organization, including evaluation activities?"*
- ASK ▶** *"Do you have credit protection in place for those times in which personal health information is accidentally or inappropriately disclosed?"*

Consumer Satisfaction Promoted

	STANDARD
CONSUMER SATISFACTION PROMOTED	
PHARM CORE 25 - CONSUMER SATISFACTION	
	ACCREDITATION SUMMARY
PBM collects and evaluates information about consumer satisfaction with services	

The PBM collects information about consumer satisfaction with services provided by the organization. For example, the PBM may use surveys, focus groups, complaints or grievances. See the CAHPS® program, managed by the Agency for Healthcare Research and Quality for information on consumer satisfaction with services provided by an organization. CAHPS® refers to a family of surveys that ask consumers to evaluate the interpersonal aspects of health care in which consumers are the best or an important source of information.

ASK ▶ *“Show me an example of how you assess consumer satisfaction and some recent findings.”*

Chapter Two: URAC's Core Standards

Consumer and Client Services Accessible

STANDARD

CONSUMER AND CLIENT SERVICES ACCESSIBLE

PHARM CORE 26 - ACCESS TO AND MONITORING OF SERVICES

ACCREDITATION SUMMARY

Consumers or clients have access to the PBM via telephone, mail, and internet

The PBM must have standards to assure that consumers or clients have access to services. This standard refers to access to network services and access to the PBM via telephone, mail, and internet.

Note that while URAC requires that these services are in place, Pharm Core 26 does not require a particular performance standard. Rather it requires that the PBM establishes quality standards and monitors its performance. This means it is up to you as a purchaser to evaluate the program the PBM has in place and determine if it is performing up to the specific standard that you desire. Each purchaser of PBM services may emphasize quality standards that are important to its specific membership. It is wise to first define quality goals that will most benefit your covered members. This will make asking questions concerning quality more productive.

ASK ► *“What are your standards for access to your services? Show me your performance metrics.”*

Rigorous Complaints and Appeals Process Defined

STANDARD
RIGOROUS COMPLAINTS AND APPEALS PROCESS DEFINED
PHARM CORE 27 - COMPLAINT AND APPEAL SYSTEM
PHARM CORE 28 - APPEAL PROCESS
PHARM CORE 29 - COMPLAINT AND APPEAL REPORTING
ACCREDITATION SUMMARY

PBM has a process in place to handle complaints and appeals

The PBM must have procedures to receive complaints and, when appropriate, inform consumers of their rights and how to submit an appeal. The PBM must respond to complaints and appeals in a timely manner.

The PBM must have a formal appeal resolution process that includes notifying the consumer in writing of the final decision on the appeal and why it was decided in that way. The PBM should also notify the consumer of how to seek further review, if available. The PBM should have a reasonable, specified time frame for resolution and response.

Since managing complaints and appeals is considered an important component of maintaining a quality organization, the PBM should report all the information concerning complaints and appeals to the quality management committee.

- ASK ►** *"What is your process to handle complaints and appeals in your organization? How do you handle appeals that are categorized as "urgent" by the member or prescriber?"*
- ASK ►** *"Are your statistics on appeals and grievances reviewed by a quality committee?"*

Chapter Two: URAC's Core Standards

Quality Management Program Defined

STANDARD
QUALITY MANAGEMENT PROGRAM DEFINED
PHARM CORE 30 - QUALITY MANAGEMENT PROGRAM
PHARM CORE 31 - QUALITY MANAGEMENT PROGRAM RESOURCES
PHARM CORE 32 - QUALITY MANAGEMENT PROGRAM REQUIREMENTS
PHARM CORE 33 - QUALITY MANAGEMENT COMMITTEE
PHARM CORE 34 - QUALITY MANAGEMENT DOCUMENTATION

ACCREDITATION SUMMARY

Quality improvement program includes:

- Performance measures on activities
- Monitoring of performance measures
- Efforts to improve performance measures

Chapter Two: URAC's Core Standards

Quality Improvement Projects Implemented

STANDARD
QUALITY IMPROVEMENT PROJECTS IMPLEMENTED
PHARM CORE 35 - QUALITY IMPROVEMENT PROJECT REQUIREMENTS
PHARM CORE 36 - QUALITY IMPROVEMENT PROJECT GOALS AND MEASUREMENT

ACCREDITATION SUMMARY

Quality improvement projects include:

- Quantifiable performance measures
- At least annual measure of baseline performance
- Established strategies, goals, documentation, and analysis

These standards convey the importance of the quality management process to the PBM. They are also a part of monitoring compliance with the URAC standards for which the PBM is accredited. These standards provide guidance to the organization on how to establish a quality improvement program and performance measures on activities within the program, the monitoring of these measures, and efforts to improve when these measures are not met. These standards further define the quality management program scope, operations and the activities of the quality management committee. (See the URAC standards for details.)

While you can expect all accredited PBMs to have this program in place, the accreditation will not tell you how well the quality program functions. To see how it really works you need to analyze the organization's process and look at examples.

- ASK ▶** *"How do you define a process error? When do you start measuring a process error, when do you stop measuring the process?" This tells you how the error reporting really works and allows you to make comparisons between PBMs.*
- ASK ▶** *"How do you track and trend data so that you know when you have a problem related to consumer and client services?"*
- ASK ▶** *"How do you communicate quality goals to your staff as a whole?"*
- ASK ▶** *"Show me the outcome of a recent quality improvement project. How was this value added back into your processes/business?"*

▶ MANAGEMENT TIP AND INFORMATION

- ASK ▶** *"What is the stability of the management team?" This shows the level of quality beyond accreditation. Management does not have to come exclusively from the PBM industry; it could come from health care in general. You want to know that you have a stable, experienced team leading the way.*

Chapter Three: Customer Service, Communications, and Disclosure

Introduction

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.

The table below presents an overview of the standards that are especially important for purchasers to consider. Below each table are more detailed explanations that include examples, questions for you to ask the PBM, and how to take full advantage of accreditation.

Consumer Information Disclosed

STANDARD	
CONSUMER INFORMATION DISCLOSED	
CSCD 1 – POST-ENROLLMENT CONSUMER INFORMATION REQUIREMENTS	
CSCD 2 - ON-GOING COMMUNICATION PRACTICES	
ACCREDITATION SUMMARY	
<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 	

These standards describe in detail what the PBM needs to inform consumers about regarding available information resources and assistance. This includes information on the options and implications of prescription benefits for consumers who are making decisions.

The PBM must also make sure that the communications are updated to inform consumers about currently participating pharmacies, formulary design, formulary changes, and their costs; and benefit design, benefit changes, and their costs.

While the standards are very specific about the requirements of information to communicate, the purchaser must make sure that the PBM has chosen communication methods that suit the needs of their employee/retiree population.

ASK ► *“Show me your communication materials and the update schedule on each of them.” Check to make sure that everything on the list (in the main text) is covered.*

Business Information Disclosed

STANDARD
BUSINESS INFORMATION DISCLOSED
CSCD 4 - DISCLOSURE
ACCREDITATION SUMMARY

PBM discloses business model including:

- Potential conflicts of interest that affect clinical or financial decisions
- Sources of revenue
- Pricing structure for PBM services

This standard specifies that, if included in the client contract, the PBM discloses its basic business information to their clients, including pricing arrangements. The PBM must also disclose the existence of organizational arrangements that could potentially create a conflict of interest that affects clinical or financial decisions, sources of revenue, and pricing structure for PBM services (e.g., rebate structure) and administration fees.

This URAC standard is very clear about financial information to be disclosed. However, the purchaser should be careful to include all disclosure requirements in the contract with the PBM. This financial information is available to you upon request. For accredited PBMs the client contract includes a description of pricing structure and how it is defined and updated. This includes the source of the price updates and pricing update time cycle. For example, whether drugs are priced using average wholesale price (AWP) and how AWP is defined and updated. Other possible descriptions of pricing structure are: spread pricing, straight pass-through pricing, maximum allowable cost (MAC), and usual and customary (U&C) charge. Any administrative charges should be defined and included.

Your first step should be to define how you want to pay your PBM, perhaps from a menu of options, and what services you want. When these are clearly defined, you can compare offerings from various PBMs based on your business needs, not on the PBM's standard contract. The key to a successful relationship with a PBM is to make sure these are defined in your contract.

See the discussion in Chapter 1, comparing pricing arrangements.

ASK ► *"Can you provide me references of other clients with similar business needs whom you have served?" This will give strong insights to the disclosure experiences the PBM's clients have had and whether they were memorialized in the contract.*

Client Audit Rights Maintained

STANDARD

CLIENT AUDIT RIGHTS MAINTAINED

CSCD 5 - DISCLOSURE VERIFICATION

ACCREDITATION SUMMARY

PBM provides verification so that the client can ensure disclosures are comprehensive and accurate

The PBM must have a mechanism to allow its clients to verify the organization's records and ensure that the disclosures in CSCD 4 are comprehensive and accurate. Again this must be specified in the terms of the client contract.

- ASK ▶** *"Who may conduct audits?"*
- ASK ▶** *"How often are audits performed and what is the depth and breadth of information available to the audit team?"*
- ASK ▶** *"Who pays for audits?"*
- ASK ▶** *"How many audits are allowed?"*
- ASK ▶** *"What are the restrictions placed on an audit team selected by the client?"*

Call Center Operations Defined

STANDARD
CALL CENTER OPERATIONS DEFINED
CSCD 6 - PROGRAM REPRESENTATIVE AVAILABILITY
CSCD 7 - CALL CENTER OPERATING REQUIREMENTS
CSCD 8 - SCOPE OF TELEPHONIC SERVICES

ACCREDITATION SUMMARY

Call center provides consumers, physicians, and other prescribers:

- 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

These standards specify that the PBM operates a call center for enrolled consumers, physicians, and other prescribers. Enrolled consumers should be able to call seven days a week, from 8 am to 8 pm.

For pharmacies, the call center should be available during the same hours that network pharmacies are open and provide information on claims processing, benefit coverage, claims submission and claims payment. For physicians and other prescribers, call center hours should cover at least 8 am to 6 pm. All calls should be answered within 30 seconds on average, with an average abandonment rate for all incoming calls not to exceed 5 percent.

The standards do not specify how you want the calls answered. The purchaser needs to agree on the performance measures for this area of the contract. Include your desires for quality and accuracy in the performance measures in the contract.

ASK ▶ *"Is your customer service outsourced?" Make sure you specify your desires in your contract.*

ASK ▶ *"How do you measure call performance?"*

ASK ▶ *"How do you handle calls after the normal business hours?"*

▶ MANAGEMENT TIP AND INFORMATION

ASK ▶ *"What is the PBM's ability to answer a consumer's question accurately on the first point of contact? How does the PBM measure this activity?" This is a key differentiator for good customer service.*

Multiple Communication Formats Required

STANDARD
MULTIPLE COMMUNICATION FORMATS REQUIRED
CSCD 9 - MULTIPLE FORMAT COMMUNICATIONS REQUIREMENT
ACCREDITATION SUMMARY
PBM provides information to consumers in multiple formats and media so that all consumers have access to relevant information

This standard specifies that the PBM provide information to consumers in multiple formats and media (e.g. internet, print, live oral presentation, audio, video, e-mail, telephonic, interactive) such that all consumers have access to relevant information.

However, you must include in your contract the details of which communication formats and media you want used and when, as not all formats are required.

ASK ► *“Show me examples of your formats and materials for communicating with my members/employees.”*

Health Literacy and Cultural Sensitivity Encouraged

STANDARD**HEALTH LITERACY AND CULTURAL SENSITIVITY ENCOURAGED**

CSCD 10 - HEALTH LITERACY COMMUNICATION REQUIREMENT

CSCD 11- CULTURAL SENSITIVITY COMMUNICATION REQUIREMENT

ACCREDITATION SUMMARY

PBM provides health care information in a format (or language) that is understandable by the layman and helps consumers understand health care decisions

These standards specify that the PBM provide health care information in a format that is understandable by the layman and helps consumers understand what effect a health care decision may have for their daily lives.

As a purchaser, you need to specify your requirements for reading level, multiple languages, and any other performance measures you find important to customer service.

ASK ► *“How can you meet the specific needs of my consumers for reading level, multiple languages, and other performance measures? Do you have multi-lingual communication in printed material options and at the customer service call center?”*

Chapter Four: Pharmacy Distribution Channels

Introduction

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.URAC.org.

The table below presents an overview of the standards that are especially important for purchasers to consider. Below each table are more detailed explanations that include examples, questions for you to ask the PBM, and how to take full advantage of accreditation.

Chapter Four: Pharmacy Distribution Channels

Scope of Distribution Channels Defined

STANDARD
SCOPE OF DISTRIBUTION CHANNELS DEFINED
PHARM-DC 1 SCOPE OF SERVICES
PHARM-DC 2 ACCESS AND AVAILABILITY

ACCREDITATION SUMMARY

PBM clearly defines the:

- 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

These standards require that the PBM clearly defines the scope of its services. This includes distribution channels offered (e.g. retail pharmacy network, mail service pharmacies, long term care or specialty pharmacies), the types of pharmacy services offered within each distribution channel, and the geographic area served by each distribution channel.

As a purchaser, you must evaluate whether the access is appropriate for your member/employee population.

- ASK ▶** *“What are the number and types of pharmacies necessary to meet the needs of eligible persons within the network? How should these pharmacies be distributed in the service area?”*
- ASK ▶** *“Is a mail service pharmacy available? Are their multiple mail service distribution centers established regionally?”*
- ASK ▶** *“How many retail pharmacies are in-network?”*
- ASK ▶** *“Can you show me on a geographic access report indicating how close my members are to your network of pharmacies?”*
- ASK ▶** *“Do you have adequate network coverage for my rural members?”*

Chapter Four: Pharmacy Distribution Channels

Quality and Safety Criteria Articulated

STANDARD

QUALITY AND SAFETY CRITERIA ARTICULATED

PHARM-DC 3 QUALITY AND SAFETY CRITERIA

ACCREDITATION SUMMARY

PBM can identify and address concerns related to quality and safety of drug distribution, quality of service

This standard requires that, for each distribution channel, the PBM maintains a mechanism to identify and address concerns related to quality and safety of drug distribution and quality of service. As a purchaser, you must specify the criteria and performance measurement in your contract.

ASK ▶ *“Show me your definitions of errors, what is the process for finding errors.”
This will allow you to compare error rates.*

▶ MANAGEMENT TIP AND INFORMATION

Look for a PBM that encourages networks to go through an audit, or uses some other type of incentive to increase pharmacy quality.

ASK ▶ *“How do you audit network pharmacies? How do you resolve audit issues and recoupment of funds from an audit?”*

ASK ▶ *“How do you address issues of fraud?”*

ASK ▶ *“How many pharmacies have you audited annually in the area where my members reside?”*

Chapter Four: Pharmacy Distribution Channels

Network Access and Availability Articulated and Out of Network Criteria Articulated

STANDARD
NETWORK ACCESS AND AVAILABILITY ARTICULATED
AND OUT OF NETWORK CRITERIA ARTICULATED
PHARM-DC 4 OUT OF NETWORK SERVICES
ACCREDITATION SUMMARY
PBM ensures that members have access to prescriptions when their pharmacies don't have them, or when members are traveling

This standard requires that the PBM implements written policies and procedures that offer consumers a process to obtain covered services that are not available from participating pharmacies; and/or obtain covered services outside the network service area.

This could include access to covered medications when the contracted network pharmacy does not have the medication readily available or when the consumer is traveling outside of the network service area. Make sure you specify these agreements in your contract.

ASK ▶ *"Do you have any policies and procedures for making sure my members have access to prescriptions when your pharmacies don't have them, or when they are traveling?"*

Chapter Four: Pharmacy Distribution Channels

Robust Pharmacy Relations Maintained

STANDARD

ROBUST PHARMACY RELATIONS MAINTAINED

PHARM-DC 5 PARTICIPATING PHARMACY RELATIONS PROGRAM

ACCREDITATION SUMMARY

PBM maintains a participating pharmacy relations program that includes:

- 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

This standard specifies that the PBM implements a participating pharmacy relations program that includes a participating pharmacy communications plan with updated network information for new and on-going programs and processes. This information should also include assistance for participating pharmacies and their staff regarding pharmacy network issues; and suggestions and guidance from participating pharmacies about how the pharmacy network can best serve consumers.

ASK ▶ *“Show me a copy of your provider manual.”*

ASK ▶ *“How often does your provider relations committee meet?”*

▶ MANAGEMENT TIP AND INFORMATION

Look for a PBM that has a positive, quality relationship with a pharmacy network that will be willing to assist the consumers with their needs at the pharmacy counter.

ASK ▶ *“How do you encourage a positive relationship with your pharmacy network?”*

A group of four business professionals in a meeting room. One man is standing and leaning over a table where three others (two men and one woman) are seated. They appear to be in a collaborative meeting. The scene is overlaid with a blue tint.

Section III: Clinical Quality Standards

This section covers the URAC PBM clinical standards. These standards specify benchmarks for quality practices in drug utilization management and formulary development and management.

Chapter Five: Drug Utilization Management

Introduction

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.

The table below presents an overview of the standards that are especially important for purchasers to consider. Below each table are more detailed explanations that include examples, questions for you to ask the PBM, and how to take full advantage of accreditation.

Chapter Five: Drug Utilization Management

Coverage Decisions Clinically-Based

STANDARD
COVERAGE DECISIONS CLINICALLY-BASED
DRUM 1 - DRUG UTILIZATION MANAGEMENT PROGRAM COMPONENTS
DRUM 2 - COVERAGE DECISIONS BASED ON CLINICAL INFORMATION
ACCREDITATION SUMMARY

- PBM has policies and procedures for identifying the optimal drug and evaluating the available data to address discrepancies and misuse of drugs.
- PBM bases formulary system decisions on a thorough evaluation of the benefits, risks, and potential outcomes for consumers

When conducting drug utilization management, the PBM must develop and comply with written policies and procedures that address criteria for identifying the optimal drug and evaluating the available data to address discrepancies and misuse of drugs. The PBM should coordinate intervention when treatment alternatives are warranted and evaluate the effectiveness of the drug utilization management program.

The PBM's coverage decisions should be based on clinical information. It is very important that the PBM base formulary system decisions on a thorough evaluation of the benefits, risks and potential outcomes for consumers. This standard is based upon the Academy of Managed Care Pharmacy, Concepts in Managed Care Pharmacy Series Document: Drug Use Evaluation (www.AMCP.org).

Purchasers should look at the process rather than the coverage decisions. You want to know if there is clarity around clinical decisions versus financial decisions. Are the consumers getting the right drugs and are they not getting the wrong drugs?"

ASK ► "How do you influence prescribing behavior and what are the outcomes?"

► MANAGEMENT TIP AND INFORMATION

You have to figure out how much you expect to manage prescribing practices; in other words, ask yourself whether or not you want a tightly managed pharmacy program. Generally, managed programs focus on the use of appropriate drugs and reducing drug costs while improving program quality but have more limitations and exclusions of particular drugs. These limitations may lead to dissatisfaction in your membership. Then you must also ask how do you put this type of clinical program in place, and how do you assess its effectiveness. (See Chapter 1, Saving Money by Changing the Drug Mix.)

Chapter Five: Drug Utilization Management

Clinical Review Criteria Defined

STANDARD
CLINICAL REVIEW CRITERIA DEFINED
DRUM 3 - REVIEW CRITERIA REQUIREMENTS
DRUM 4 - PROSPECTIVE, CONCURRENT AND RETROSPECTIVE DRUG UTILIZATION MANAGEMENT
DRUM 7 - REVIEW SERVICE DISCLOSURES
DRUM 17 - PROSPECTIVE AND CONCURRENT REVIEW DETERMINATION
DRUM 18 - RETROSPECTIVE REVIEW DETERMINATIONS
DRUM 19 - LACK OF INFORMATION POLICY AND PROCEDURE
ACCREDITATION SUMMARY
<ul style="list-style-type: none"> • PBM has qualified prescribers and other clinicians develop and use clinical review criteria that are based on current clinical principles • Clinical review criteria is annually evaluated and updated by qualified personnel • Review determinations are based solely on the clinical information available to the PBM at the time of the review

These standards require the PBM to have qualified prescribers develop and use clinical review criteria that are based on current clinical principles and processes. The clinical review criteria should be (at least) annually evaluated and updated by the medical director, working with the senior clinical staff person, or P&T (Pharmacy and Therapeutics) Committee.

For prospective review and concurrent review, the organization bases review determinations solely on the clinical information available to the organization at the time of the review determination. For retrospective review, the organization bases review determinations solely on the clinical information available to the prescriber or the organization at the time the medical care was provided.

ASK ► *“What is the foundation on which you build your utilization management programs including prior authorization?”*

ASK ► *“What’s the timing for authorization requirements? How do you communicate the findings? How do you manage this process?”*

Chapter Five: Drug Utilization Management

Non-Formulary Exceptions Communicated

STANDARD
NON-FORMULARY EXCEPTIONS COMMUNICATED
DRUM 12 - EXCEPTIONS
ACCREDITATION SUMMARY
PBM informs consumers of how to request coverage of a non-covered prescription drug

The intent of this standard is to enable consumers to request coverage of a prescription drug if the drug is not covered, prior to submitting a formal appeal.

ASK ► *“How do you inform consumers of how to request coverage of a non-covered prescription drug? How does your exceptions process work?”*

Chapter Five: Drug Utilization Management

Decision Notice Required

STANDARD

DECISION NOTICE REQUIRED

DRUM 14 - WRITTEN NOTICE OF NON-CERTIFICATION DECISIONS & RATIONALE

ACCREDITATION SUMMARY

PBM issues a written notification of the non-certification decision to the consumer and prescriber

When a PBM denies coverage of a drug (non-certification), this standard requires the PBM to issue written notification of the non-certification decision to the consumer and prescriber. The written notification should include the reasons for non-certification. The written notification should also explain that the consumer or prescriber can obtain a written description of the clinical rationale and directions for how to do this.

ASK ► *“How do you inform consumers of the reasons for clinical decisions? Show me examples of written notification.”*

Chapter Five: Drug Utilization Management

Consumer Friendly Appeals Process Defined

STANDARD
CONSUMER FRIENDLY APPEALS PROCESS DEFINED
DRUM 20 - APPEALS
DRUM 22 - NON-CERTIFICATION APPEALS PROCESS
DRUM 23 - APPEALS PROCESS
DRUM 27 - WRITTEN NOTIFICATION OF UPHELD NON-CERTIFICATIONS
ACCREDITATION SUMMARY
<ul style="list-style-type: none"> • PBM provides access to an appeal process, may be only a referral to the plan administrator who makes the decision. • Written information on rights to appeal are available to the consumer and prescriber, including the process involved • 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 • 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

It is important that you take the time to consider the appeals process. These standards are required to ensure that consumers have the right to appeal a decision to deny drug coverage (non-certification). Standard DrUM 20 ensures that the PBM provides access to an appeal process, even if that is only a referral to the plan administrator who makes the decision. The remaining appeals standards address the need to provide the consumer (and usually the consumer's doctor/prescriber) with the information on how to request an exception and appeal.

The non-certification appeals process is defined in terms of the standard appeal (non-urgent case) and the expedited appeal (urgent case). Each case should have written information on rights to appeal available to the consumer and prescriber, the appropriate time frames, and the process involved. The consumer and prescriber have the opportunity to submit information relating to the case and the case should be evaluated by a qualified, clinical peer. If the review of the denial is judged in favor of the consumer, then the PBM must act on the decision and reverse the coverage determination.

After the decision, the consumer and prescriber should be notified in writing if a non-certification decision was upheld. The notification should contain information on rights to further appeal available to the consumer and prescriber (if any), and the process involved, and reasons for non-certification.

Often this service is retained by the health plan/employer. However, if you wish to have the PBM perform this service, you may ask the following question.

Chapter Five: Drug Utilization Management

- ASK ▶** *“Do you have the capability to perform appeals? Do you delegate the appeals function? Show me your documentation for the appeals process and some recent cases as well as any appeals delegation agreements.”*

▶ MANAGEMENT TIP AND INFORMATION

If the PBM is engaged in Medicare Part D, and they use the same process, then they more than likely have a structured approach to the appeals and appeals management process.

Chapter Six: P&T/Formulary Development

Introduction

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.

The table below presents an overview of the standards that are especially important for purchasers to consider. Below each table are more detailed explanations that include examples, questions for you to ask the PBM, and how to take full advantage of accreditation.

Chapter Six: P&T/Formulary Development

Effective Formulary Development Required

STANDARD
EFFECTIVE FORMULARY DEVELOPMENT REQUIRED
PTFD 1 - P&T/FORMULARY DEVELOPMENT
PTFD 2 - FORMULARY MANAGEMENT DECISION MAKING
ACCREDITATION SUMMARY
<ul style="list-style-type: none"> • 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

These standards ensure that the PBM has a process to promote clinically appropriate, safe, and cost-effective drug therapy. The process should include a P&T Committee, a formulary management decision-making process, and a process for regular evaluation and review.

The PBM's formulary management process must be clearly defined, consider safety and efficacy when selecting formulary drugs, and assure appropriate drug review and inclusion.

As a purchaser, you need to realize that the scope of the standard and the P&T Committee's decisions about safety and efficacy do not mean that the committee makes a coverage decision. Once the P&T Committee rates a drug clinically, then the drug may be placed in the formulary based on the PBM's financial considerations. However the purchaser may decide whether to accept this service or provide it themselves.

ASK ► *"What is your process for promoting clinically appropriate, safe, and cost-effective drug therapy? Describe your Pharmacy and Therapeutics Committee process."*

Formulary Decisions Therapeutically-Based

STANDARD

FORMULARY DECISIONS THERAPEUTICALLY-BASED

PTFD 3 - ECONOMIC FORMULARY CONSIDERATIONS

ACCREDITATION SUMMARY

Formulary decisions based on cost factors only after safety, efficacy and therapeutic need have been established

The PBM must base formulary system decisions on cost factors only after the safety, efficacy and therapeutic need have been established. After that, the PBM evaluates equivalent alternative drug products and therapies in terms of their impact on health care costs.

The purchaser needs to make sure that their contract stipulates the choice of alternative drug products and therapies is decided in their favor, and is not solely to benefit the PBM. See Chapter 1, Clinical Programs, Saving Money by Changing the Drug Mix for information on the costs of the drug mix.

ASK ▶ *“How are formulary products selected? What place does price have in the placement of drugs on the formulary?”*

ASK ▶ *“What does the PBM do to promote optimal drug mix considering my members’/employees’ needs?”*

Chapter Six: P&T/Formulary Development

Formulary Stakeholders Informed

STANDARD

FORMULARY STAKEHOLDERS INFORMED

PTFD 4 - ORGANIZATIONAL SPECIFICATIONS

ACCREDITATION SUMMARY

- 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

This standard requires the PBM to disclose the existence of formularies and have copies of the formulary readily available and accessible.

The PBM must have a process for informing physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions, including: 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.

The PBM must also provide consumer education that explains how formulary decisions are made and the roles and responsibilities of the consumer.

ASK ► *“What is your process for informing physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions?”*

ASK ► *“Is the formulary readily available on the Internet for both prescribers and members? Can the prescriber and member easily identify utilization restrictions, or formulary alternatives for non formulary or high cost formulary products?”*

P&T Committee Membership Defined

STANDARD
P&T COMMITTEE MEMBERSHIP DEFINED
PTFD 5 - P&T COMMITTEE MEMBERSHIP
PTFD 6 - P&T COMMITTEE CONFLICT OF INTEREST
PTFD 7 - P&T COMMITTEE POLICIES AND PROCEDURES
ACCREDITATION SUMMARY
Needs of the consumers are represented by the appropriate clinical specialties and specialists who are practicing physicians or practicing pharmacists

These standards describe the members of the Pharmacy and Therapeutics Committee to ensure that the needs of the consumers are represented by the appropriate clinical specialties and specialists who are practicing physicians or practicing pharmacists. This must include at least one expert who is independent and free of conflict (health plan and pharmaceutical manufacturers).

Members of the P&T Committee must sign a conflict of interest statement, updated annually, revealing economic interests or relationships that could influence committee decisions. The P&T Committee does not include product sponsor representatives.

- ASK ►** *“Show me a list of the P&T member qualifications (i.e. credentials and affiliations). Describe the various disciplines represented and how long each member has been serving on the committee. Are any of the voting members employees of the PBM?”*
- ASK ►** *“How often do you validate potential conflicts of interest and review the committee for its independence and areas of specialization?”*

Chapter Six: P&T/Formulary Development

Formulary Kept Current

STANDARD

FORMULARY KEPT CURRENT

PTFD 11 - TIMELY CONSIDERATION OF NEW DRUGS

ACCREDITATION SUMMARY

P&T Committee will establish a policy and procedure for considering new drugs released onto the market

This standard stipulates that the P&T Committee will establish a policy and procedure for considering new drugs released onto the market.

ASK ▶ *“What is your policy and procedure for review and recommending pharmacy updates?”*

▶ MANAGEMENT TIP AND INFORMATION

It is important for the purchaser of PBM services to understand the formulary development and maintenance process. It is also important to understand how the clinical decisions are supported by the organization and how business decisions are integrated without jeopardizing the clinical decision making process. A purchaser should develop a level of comfort by spending time understanding the workings of the PBM in determining drug selection and choice for its members.

ASK ▶ *“What is the default standard for member cost-sharing requirements for a newly released drug that has not yet been reviewed by the P&T Committee?”*

ASK ▶ *“How do you communicate formulary decisions to the prescriber network and plan membership?”*

ASK ▶ *for a copy of minutes of quarterly meetings.*

ASK ▶ *to sit in on a P&T meeting or conference call.*

Appendix A: Glossary-Understanding PBM Purchasing Language

Note: The definitions provided here tend to be generalizations that must be defined specifically in your contract. In every case, include calculations and specifics in your definitions as these terms may vary widely in meaning. For an in-depth discussion of benchmarks and purchasing terms see both text and glossary in AMCP Guide to Pharmaceutical Payment Methods, (www.AMCP.org).

Actual Acquisition Cost (AAC) Final cost of the pharmaceutical to the pharmacy or other health care provider after all discounts, rebates, and other price concessions are taken into account. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org)

Access A patient's ability to obtain prescription drug services determined by the availability of those services, their acceptability to the patient, the location of pharmacies and/or their ease of use, transportation, hours of operation, and cost of care.

Administrative Fee/ Costs The fee the PBM charges to the plan sponsor for administrative services such as claims processing, billing, and clinical services. This fee varies widely and can be attached to every transaction and service or as an aggregate fee for all services based upon membership (listed in the contract with the purchaser).

Average Manufacturer Price (AMP) Average price paid to a pharmaceutical manufacturer by wholesalers for drugs distributed to retail pharmacies or retail class trade, net of prompt-pay (called cash) discounts.

AMP was a benchmark created by Congress in 1990 in calculating rebates owed Medicaid by pharmaceutical manufacturers. The Federal Supply Schedule (FSS) and 340B prices, as well as prices associated with direct sales to health maintenance organizations (HMOs) and hospitals, are excluded from AMP under the Medicaid rebate program. The Office of Inspector General (OIG) in June 2005 estimated the median AMP to be approximately 77% of the average wholesale price (AWP) for single-source brand drugs, 72% of AWP for multiple-source brand drugs, and 30% of AWP for generic drugs. Prior to the enactment of the Deficit Reduction Act of 2005 (DRA), AMP data were used by the Centers for Medicare and Medicaid Services (CMS) primarily for purposes of the Medicaid drug rebate program, and disclosure of AMP data was forbidden except in certain narrow circumstances. The DRA stipulated that AMPs were to be made available to state Medicaid programs, that they were to be used to calculate federal upper limit (FUL) amounts for certain multiple-source drugs, and that states could use them to help set other reimbursement rates. In July 2007, CMS issued final regulations addressing the AMP provisions of the DRA. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org)

Average Sales Price (ASP) Is a new reference price system negotiated in drug pricing litigation settlements by federal and state government prosecutors and included in corporate integrity agreements with pharmaceutical manufacturers TAP and Bayer to ensure more accurate price reporting. ASP is the weighted average of all nonfederal sales to wholesalers and is the net price after subtraction of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether paid to the wholesaler

or retailer. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org)

ASP background and discussion As a result of the Medicare Modernization Act (MMA), Average Sales Price (ASP) replaced AWP as the basis for payment for most drugs covered under Medicare's medical benefit—Medicare Part B, as of January 1, 2005. Unlike AWP, ASP is based upon manufacturer-reported actual selling price data and includes the majority of rebates, volume discounts, and other price concessions offered to all classes of trade. Because ASP is an "average," some providers may be able to obtain pharmaceuticals below this "average" selling price, while others are able only to purchase the drugs at a price that is above the average. Historically, small physician offices buy at the least favorable prices and are unable to purchase some drugs at prices at or below the payment amounts. Generally, large physician groups and hospitals are able to negotiate the best discounts and price concessions and are better positioned under the ASP payment system. Because ASP values are publicly available on the Centers for Medicare and Medicaid Services (CMS) website, private payers are able to use ASP for payment of medical benefit drugs. Uptake beyond Medicare has been slow but steady. This trend is likely to continue and accelerate in upcoming years. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org)

Average Wholesale Price (AWP) Is a reference price calculated by drug pricing data resource vendors and is based on the manufacturer reported Wholesale acquisition cost. It represents the list prices for drugs reported by pharmaceutical manufacturers and published in commercial clearinghouses such as Red Book, Medi-Span, and First DataBank. Each price is specific to the drug, strength, dose form, package size, and manufacturer or (re)labeler. There is an AWP value for each 11-character national drug code (NDC) number that is comprised of the first 5 characters for the manufacturer or labeler, 4 characters for the drug and strength, and 2 characters for the package size. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC) Background and discussion Historically, Average Wholesale Price (AWP) was the generally accepted drug payment benchmark for many payers because it was readily available. However, AWP is now thought of as a "sticker price," in that it rarely if ever reflects the true average wholesale price actually paid prior to or after discounts (such as prompt pay, quantity or promotional discounts) have been subtracted. Related to AWP is Wholesale Acquisition Cost (WAC), which is the "reported list price" set by manufacturers for each product. AWP is typically set at approximately 20% to 25% above WAC. However, like AWP, WAC frequently does not represent what a wholesaler actually pays for the drug because the WAC does not contain many of the discounts and price concessions that are offered by manufacturers, there are significant differences in the reliability of this price as reported by branded and generic manufacturers. In fact, WAC serves as the basis for negotiated discounts and rebates between manufacturers (primarily for branded products) and private payers (i.e., discounts and rebates are subtracted from WAC) for both medical and pharmacy benefit drugs. While most payers base provider payment rates on AWP or WAC for drugs covered under the pharmacy

Appendix A: Glossary—Understanding PBM Purchasing Language

and medical benefits, this is starting to change. Given the growing recognition that neither AWP nor WAC represents the true cost of the product to purchasers, particularly for generic drugs, several new drug payment benchmarks have been created that will likely result in a discontinuation of the use of these benchmarks. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org)

Benchmark (also: benchmark price) Government and other payers generally establish their payment for prescription drugs through formulas that start with a benchmark price. Some benchmarks are proprietary and not publicly available. For example, a state may set its Medicaid reimbursement rate at a benchmark price, such as average wholesale price (AWP) or wholesale acquisition cost (WAC), minus a percentage. Some payment rates are subject to limits, such as through a maximum allowable cost (MAC) mechanism. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Best Price (BP) Lowest price available to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity, or the government. BP excludes prices to the Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), 340B-covered entities, Federal Supply Schedule (FSS) and state pharmaceutical assistance programs (SPAPs), depot prices, and nominal pricing. BP includes cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates.

Bundled (also: packaged, bundling) Packaging of drugs of different types for the purpose of provider payment, sometimes including provider services. For example, in the context of drug sales to providers from manufacturers, the net price of individual drugs in the bundle may be contingent on the sales volume of other drugs included in the bundle. In another use of the term, a bundle of services may be combined at a designated price, as in the case of ambulatory payment classifications (APCs) or diagnosis related groups (DRGs). (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Carve-Out Pharmacy Benefit The prescription coverage benefit that is removed from the primary health care coverage plan and handled by another company (e.g., a Pharmacy Benefits Manager [PBM]). Within a capitation environment, a type of service not included as an agreed service to be provided within the contract, therefore carved out within the per member per month (PMPM) or pricing structure for certain categories of health care services (typically high-volume, high-cost, or areas where specialty expertise can reduce costs for that segment, such as behavioral, lab, podiatry, X-ray, or transplants), not subject to discretionary utilization, and not included within the capitation rate; may also be created when a provider cannot or will not provide some segment of care, or is unavailable during periods of time when care may still be needed; normally a carve out is warranted because there is special expertise and improved cost-effectiveness in a segment of care, versus lumping the segment in with an overall pricing. (Taken from Glossary, www.AMCP.org.)

Cost sharing (also: see co-payment, coinsurance) Method of reimbursement for health care services that holds the patient responsible for a portion or percentage of the charge, with an attending strategy to serve as a means of reducing utilization; normally includes an annual deductible amount.

Maximum Allowable Cost (MAC) A cost management program that sets upper limits on the payment for equivalent drugs available from multiple manufacturers. It is the highest unit price that will be paid for a drug and is designed to increase generic dispensing, to ensure the pharmacy dispenses economically, and to control future cost increases. (Taken from Glossary, www.AMCP.org.)

Maximum Allowable Cost (MAC) list A List of prescription medications established by a health plan and distributed to pharmacies for which reimbursement will be provided at a generic price level only, regardless of what is dispensed.

Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations, 27th Edition (U.S. Department of Health and Human Services and Food and Drug Administration, 2007)), commonly referred to as the “Orange Book.” A publication that identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. Patent listings can be found in this online book, which is updated daily. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Pass Thru Pricing The PBM passes the discounts, rebates, other revenues and actual costs charged by the pharmacy pharmaceutical company 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.

Plan Sponsors PBM services are purchased by many different types of plan sponsors. Plan sponsors include employers, business coalitions, unions, trust funds, associations, and government agencies. Also called payors. (Taken from Glossary, www.AMCP.org.)

Rebates A post provider payment discount paid by the manufacturer after purchase of the drug from a provider such as a network pharmacy. Rebate discounts are the most common method employed by the PBMs to reduce the costs of pharmaceuticals for plan sponsors. The PBM may negotiate rebates with the manufacturer of the drug based on whether the drug is placed on the formulary, administration of the formulary, and for market share gain. Rebates are usually paid by the manufacturer at the end of the year. It is common for plan sponsors to receive a share of PBM rebates. However each PBM uses a different rebate calculation so it can be difficult to compare rebate agreements between them. PBMs using a traditional contract may share some of the rebates; a flat guarantee per claim, or give a percent of the actual rebate. In a transparent contract the actual realized rebates are passed through to the plan sponsor and there is no retention by the PBM. (Taken from Maintaining the Affordability of the Prescription Drug Benefit: How Managed Care Organizations Secure Price Concessions from Pharmaceutical Manufacturers. www.AMCP.org.)

Reference Price (RP) Limits reimbursement for a group of drugs with similar therapeutic application but different active ingredients to the price of the lowest-cost drug within the group (the reference standard). Patients may purchase drugs other than the reference product, in which case they pay the difference between the retail price and the RP. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Appendix A: Glossary—Understanding PBM Purchasing Language

Single-Source Brand Drug under patent protection that is sold under a brand name and is thus available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder). No generic version is available. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Spread Or spread pricing is a general term used to represent the difference between the cost billed to the plan sponsor (employer) for an item and the cost the PBM pays for the item. For example, the average wholesale price (AWP) spread is the difference between the drug ingredient cost billed to the employer by the PBM and the drug ingredient cost the PBM pays to the dispensing pharmacy for that line item." It is not a factor in any co-payment, dispensing fee, or transaction fee provision. When the difference is positive, it is a common source of revenue for PBM companies under a traditional pricing model. When the difference is negative, it is a loss absorbed by the PBM company. Since a spread can exist in almost every transaction with the PBM, it is important to define where the spread exists within the contract. (From Journal of the American Pharmacists Association, The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue Posted 03/26/2004 Robert I. Garis; Bartholomew E. Clark and notes.)

Therapeutic Maximum Allowable Cost (TMAC) Managed care intervention that establishes a defined benefit dollar amount per therapeutic procedure or indication, such as \$0.75 per day of drug therapy for heartburn based on the omeprazole over-the-counter (OTC) price or \$0.50 per day of therapy for allergic rhinitis based on the market price of loratadine OTC in 2007. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Tiered Co-payment Benefits A pharmacy benefit design that financially rewards patients for using generic and formulary drugs by requiring the patient to pay progressively higher co-payments for brand-name and nonformulary drugs. For example, in a three-tiered benefit structure, co-payments may be \$5.00 for a generic, \$10.00 for a formulary brand product, and \$25.00 for a non-formulary brand product. (Taken from Glossary, www.AMCP.org.)

Usual and Customary (U&C) charge/price The price for a given drug or service that a pharmacy would charge a cash-paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the pharmacy. (Taken from AMCP Guide to Pharmaceutical Payment Methods, www.AMCP.org.)

Usual, Customary, and Reasonable (UCR) Amount determined to be "reasonable" (acceptable) by comparing the U&C charges among providers in a given geographic region. UCR prices are commonly used by traditional health insurance companies as the basis for physician reimbursement.

Wholesale Acquisition Cost (WAC) Price reported by the manufacturer as the price paid by a wholesaler for a drug purchased from the wholesaler's supplier, typically the manufacturer of the drug. Publicly disclosed WAC amounts may not reflect all available discounts, such as prompt-pay (cash) discounts.

Appendix B: Summary of Purchasers Guide Questions

CHAPTER ONE: PBM PROCUREMENT 101

PRICING ARRANGEMENTS	
Spread pricing	Ask the PBM what their contract is with the network pharmacies and how those discounts compare with the contract they offer you.
	Ask to see sample financial reports that are provided to clients and data definitions used in developing the elements of the reports.
Pass-through pricing	Ask the PBM to show you different options for pricing arrangements they propose to use in a contract for services in relationship to your benefits, services, and financial goals.
CONTRACT ELEMENTS	
Benefit Design	Ask the PBM if it supports the type of benefits you wish to provide your employees.
Pricing and Payment	
Maximum Allowable Cost (MAC)	Ask the PBM to explain MAC pricing terms in the contractual agreement with its network pharmacies. Ask the PBM if MAC pricing applies to generics dispensed in all pharmacy types, retail, mail, long term care, and specialty.
	Ask what is not covered by MAC pricing (for example single source generic drugs, drugs available over the counter, or branded generics) and negotiate for a competitive discount as close to the MAC discount as possible on these items.
	Management Tip and Information: Have the PBMs you are considering take a current list of your claims (e.g., a representative distribution during a 6 month time period at a minimum) and apply their pricing to it. This will give you an idea how each PBMs pricing works in relationship to each other and your member/employee needs
Dispensing Fees	Ask the PBM to explain the contractual agreement on dispensing fees with its network pharmacies.
Administrative Fees (Point of sale, others)	Ask the PBM what services have associated administrative fees and the pricing schedule for those fees.
	Ask for specific information as to whether fees are charged on a per paid claim basis, across all claims (paid and rejected), per employee, per member, per service rendered, or per clinical intervention.
Discounts -- direct from manufacturer (also called discount off invoice, bulk, or purchase discounts)	Ask the PBM if it owns distribution channels like mail service, retail and specialty pharmacies.
	Ask if the purchase discounts are passed along to the purchaser or are kept as margin by the PBM.

Appendix B: Questions for Purchasers and Managers of PBM Services

	Ask if the PBM permits repackaged products in pricing algorithms with the pharmacy network.
Rebates	Ask, "What type of rebate agreement do you offer?"
	Ask, "What is your definition of rebates?"
	Ask, "How can the rebate agreement be audited?"
	Ask, "What other services are included in the rebate contract, for example fees, compensation, and discounts?"
Clinical Programs	Ask the PBM to clearly describe the clinical program offering and associated fees.
Saving Money by Changing the Drug Mix	Ask the PBM to see the formulary. Make sure the formulary and the data you consider are a good fit for your employee's demographics.
	Ask the PBM to show you their data on the effect of these programs and determine whether they are aligned with your benefit goals.
	Ask to see reports showing you information on patient adherence, generic dispensing, and controlled substance utilization.
	Ask the PBM how customizable these programs are and how much do they cost as designed and for custom tailoring to our needs.
	Ask, "What is the return on investment and how much will this disrupt my membership?"
Over-the-Counter Drug Support	Ask, "What kind of services can you offer for OTC medications?"
Pharmacy Distribution Channels	
Retail Network Pharmacy	Ask the PBM to inform you of state laws requiring that "any willing provider" be a part of a network and how the PBM handles such requirements at the network level.
	Ask the PBM to explain their pharmacy network options and offerings.
	Ask The PBM to illustrate their ability to offer a restricted network at a more aggressively contracted rate.
	Ask for a pharmacy access report which tells you how far your membership is from the pharmacies. You can set access standards. For example, if you are looking for a narrow range for your members/employees you could say, "I want 85% of my members to be within 5 miles."
Mail Service Pharmacy	Ask which pharmacy provides the mail services, whether the pharmacy accepts MAC pricing for generic drugs and the typical turn around to fill mail service prescription orders.
	Ask about the option to fill 90 day supplies within the retail network.
Specialty Pharmacy	Ask, "What specialty pharmacies do you expect to have available for your employees and for which conditions will these services apply?" You need to have a thorough understanding of what access options the PBM can provide and how this will fill the needs of your members/employees.
	Ask which pharmacy provides the specialty pharmacy services and how the first fill of specialty drugs is handled when members require immediate access

Appendix B: Questions for Purchasers and Managers of PBM Services

Prescription Claims Processing and Data	
Data Access	Ask the PBM how they plan to use your data and if they are compensated for data sharing. Include a paragraph in your contract to address whether your data is sold and how you would be notified of the sale.
E-Prescribing	Ask, "What are your capabilities for processing e-prescriptions?"
Customer Service and Call Center	Ask, "What are your performance standards for customer service and the call center?"
	Ask, "How are these performance standards measured and reported?" Make sure you specify your desires in your contract.
Account Management	Ask to meet with the account management team and the clinical pharmacy specialist and make certain that they are responsive to your needs for help and information.
Reports from the PBM	Ask, "What standard, customized, and ad hoc reports do you provide and how will these reports show me significant information?"
	Ask, "What is the typical turn-around-time for ad hoc report requests?"
	Ask, "What are your charges for standard and additional, customized reporting?"
	Ask, "Is there a reporting tool that clients can use to generate their own reports?"
Performance Standards	Ask the PBM to show you their quality metrics for your performance goals. These metrics may be in the areas of claims processing, customer service, financial guarantees, and accessibility standards.
CHAPTER TWO: URAC'S CORE STANDARDS	
Rigorous Information Management Required	Ask, "What is your application platform for data management; homegrown or outsourced? What plans are in place for your system stability, security, and disaster recovery?" Have someone who is technically qualified rate these data capabilities in detail.
	Ask, "What level of detail can I receive from the data?" Evaluate whether this level of detail will suit your needs for analysis of clinical programs and creation of ad hoc reports; especially regarding the interface with the claims history..
Communication Practices Monitored	Ask, "How do you inform consumers and clients of their rights and responsibilities, including obtaining services and submitting a complaint or appeal?"
	Ask someone to go through the process steps and show you the documentation.
	Ask for the complaint and appeal rate.
Consumer Safety Promoted	Ask, "How do you identify situations that could create potential harm to my members/ employees?"
	Ask, "How do you notify members/employees and or prescribers when you have an adverse event or a drug recall?"
Confidentiality Maintained	Ask, "How do you maintain the confidentiality of an individual's health information?"

Appendix B: Questions for Purchasers and Managers of PBM Services

	Ask, "Do you address the oral, written, or electronic communication and records that are transmitted or stored?"
	Ask, "Do all your employees understand their responsibility to preserve confidentiality?"
	Ask, "Show how the PBM ensures an individual's health information is used only for purposes necessary for conducting the business of the organization, including evaluation activities?"
	Ask, "Do you have credit protection in place for those times in which personal health information is accidentally or inappropriately disclosed?"
Consumer Satisfaction Promoted	Ask, "Show me an example of how you assess consumer satisfaction and some recent findings."
Consumer and Client Services Accessible	Ask, "What are your standards for access to your services? Show me your performance metrics."
Rigorous Complaints and Appeals Process Defined	Ask, "What is your process to handle complaints and appeals in your organization?" Ask, "How do you handle appeals that are categorized as urgent by the member or prescriber?"
	Ask, "Are your statistics on appeals and grievances reviewed by a quality committee?"
Quality Management Program Defined and Quality Improvement Projects Implemented	Ask, "How do you define a process error? When do you start measuring a process error, when do you stop measuring the process? " This tells you how the error reporting really works and allows you to make comparisons between PBMs.
	Ask, "How do you track and trend data so that you know when you have a problem related to consumer and client services?"
	Ask, "How do you communicate quality goals to your staff as a whole?"
	Ask, "Show me the outcome of a recent quality improvement project. How was this value added back into your processes/business?"
	Management Tips and Information Ask, "What is the stability of the management team?" This shows the level of quality beyond accreditation. Management does not have to come exclusively from the PBM industry; it could come from health care in general. You want to know that you have a stable, experienced team leading the way."
CHAPTER THREE: CUSTOMER SERVICE, COMMUNICATIONS, AND DISCLOSURE	
Consumer Information Disclosed	Ask, "Show me your communication materials and the update schedule on each of them." Check to make sure that everything on the list above is covered
Business Information Disclosed	Ask, "Can you provide me references of other clients with similar business needs whom you have served?" This will give strong insights to the disclosure experiences the PBM's clients have had and whether they were memorialized in the contract
Client Audit Rights Maintained	Ask, "Who may conduct audits?"
	Ask, "How often are audits performed and what is the depth and breadth of information available to the audit team?"
	Ask, "Who pays for audits?"

Appendix B: Questions for Purchasers and Managers of PBM Services

	Ask, "How many audits are allowed?"
	Ask, "What are the restrictions placed on the audit team selected by the client?"
Call Center Operations Defined	Ask, "Is your customer service outsourced?" Make sure you specify your desires in your contract.
	Ask, "How do you measure call performance?"
	Ask, "How do you handle calls after the normal business hours?"
	Management Tip and information
	Ask, "What is the PBM's ability to answer a consumer's question accurately on the first point of contact? How does the PBM measure this activity?" This is a key differentiator for good customer service.
Multiple Communication Formats Required	Ask, "Show me examples of your formats and materials for communicating with my members/employees."
Health Literacy and Cultural Sensitivity Encouraged	Ask, "How can you meet the specific needs of my consumers for reading level, multiple languages, and other performance measures? Do you have multi-lingual communication printed material options and at the customer service call center?"
CHAPTER FOUR: PHARMACY DISTRIBUTION CHANNELS	
Scope of Distribution Channels Defined	Ask, "What are the number and types of pharmacies necessary to meet the needs of eligible persons within the network? How should these pharmacies be distributed in the service area?"
	Ask, "Is a mail service pharmacy available? Are their multiple mail service distribution centers established regionally?"
	Ask, "How many retail pharmacies are in-network?"
	Ask, "Can you show me on a geographic access report indicating how close my members are to your network of pharmacies?"
	Ask, "Do you have adequate network coverage for my rural members?"
Quality and Safety Criteria Articulated	Ask, "Show me your definitions of errors, what is the process for finding errors." This will allow you to compare error rates.
	Management Tips and Information Look for a PBM that encourages networks to go through an audit, or uses some other type of incentive to increase pharmacy quality.
	Ask, "How do you audit network pharmacies? How do you resolve audit issues and recoupment of funds from an audit?"
	Ask, "How do you address issues of fraud?"
	Ask, "How many pharmacies have you audited annually in the area where my members reside?"
Network Access and Availability Articulated and Out of Network Criteria Articulated	Ask, "Do you have any policies and procedures for making sure my members have access to prescriptions when your pharmacies don't have them, or when they are traveling?"

Appendix B: Questions for Purchasers and Managers of PBM Services

Robust Pharmacy Relations Maintained	Ask, "Show me a copy of your provider manual."
	Ask, "How often does your provider relations committee meet?"
	Management Tips and Information Look for a PBM that has a positive, quality relationship with a pharmacy network that will be willing to assist the consumers with their needs at the pharmacy counter.
	Ask, "How do you encourage a positive relationship with your pharmacy network?"
CHAPTER FIVE: DRUG UTILIZATION MANAGEMENT	
Coverage Decisions Clinically-Based	Ask, "How do you influence prescribing behavior and what are the outcomes?"
	Management Tips and Information You have to figure out how much you expect to manage prescribing practices, in other words, and ask yourself whether or not you want a tightly managed pharmacy program. Generally, managed programs focus on the use of appropriate drugs and reducing drug costs while improving program quality but have more limitations and exclusions of particular drugs, which may lead to dissatisfaction in your membership. Then you must ask how do you put this type of clinical program in place, and how do you assess its effectiveness.
Clinical Review Criteria Defined	Ask, "What is the foundation on which you build your utilization management programs including prior authorization?"
	Ask, "What's the timing for authorization requirements? How do you communicate the findings? How do you manage this process?"
Non-Formulary Exceptions Communicated	Ask, "How do you inform consumers of how to request coverage of a non-covered prescription drug? How does your exceptions process work?"
Decision Notice Required	Ask, "How do you inform consumers of the reasons for clinical decisions? Show me examples of written notification."
Consumer-Friendly Appeals Process Defined	Ask, "Do you have the capability to perform appeals? Do you delegate the appeals function? Show me your documentation for the appeals process and some recent cases as well as any appeals delegation agreements."
	Management Tips and Information If the PBM is engaged in Medicare Part D, and they use the same process, then they more than likely have a structured approach to the appeals and appeals management process.
CHAPTER SIX: P&T /FORMULARY DEVELOPMENT	
Effective Formulary Development Required	Ask, "What is your process for promoting clinically appropriate, safe, and cost-effective drug therapy? Describe your Pharmacy and Therapeutics Committee process."
Formulary Decisions Therapeutically-Based	Ask, "How are formulary products selected? What place does price have in the placement of drugs on the formulary?"
	Ask, "What does the PBM do to promote optimal drug mix considering my members'/ employees' needs?"
Formulary Stakeholders Informed	Ask, "What is your process for informing physicians, pharmacists, other health care professionals, consumers, and payers about the factors that affect formulary system decisions."

Appendix B: Questions for Purchasers and Managers of PBM Services

	Ask, "Is the formulary readily available on the Internet for both prescribers and members? Can the prescriber and member easily identify utilization restrictions, or formulary alternatives for non-formulary or high-cost products?"
P&T Committee Membership Defined	Ask, "Show me a list of the P&T member qualifications (i.e. credentials and affiliations). Describe the various disciplines represented and how long each member has been serving on the committee. Are any of the voting members employees of the PBM?"
	Ask, "How often do you validate potential conflicts of interest and review the committee for its independence and areas of specialization?"
Formulary Kept Current	Ask, "What is your policy and procedure for review and recommending pharmacy updates?"
	<p>Management Tips and Information</p> <p>It is important for the purchaser of PBM services to understand the formulary development and maintenance process. It is also important to understand how the clinical decisions are supported by the organization and how business decisions are integrated without jeopardizing the clinical decision making process. A purchaser should develop a level of comfort by spending time understanding the workings of the PBM in determining drug selection and choice for its members.</p>
	Ask, "What is the default standard for member cost-sharing requirements for a newly released drug that has not yet been reviewed by the P&T Committee?"
	Ask, "How do you communicate formulary decisions to the prescriber network and plan membership?"
	Ask for a copy of minutes of quarterly meetings.
	Ask to sit in on a P&T meeting or conference call.

Appendix C: URAC Accredited PBM Organizations

PBM Accredited

Perform RX

Aetna, Inc.

Medco Health Solutions, Inc.

Caremark, Inc.

Prescription Solutions

Envision Pharmaceutical Services/
Rx Options

Express Scripts

Humana, Inc.

Prime Therapeutics

Navitus Health Solutions

MedImpact Healthcare Systems,
Inc.

US Script, Inc.

Catalyst Rx

Maxor National Pharmacy
Services Corp.

FutureScripts/FutureScripts
Secure

PBM In-Process

Memberhealth, LLC

United Healthcare Services,
Inc. D/B/A Unitedhealth
Pharmaceutical Solutions

MC-21 Corporation

RxAmerica

InformedRx, Inc

DTM Accredited

Aetna, Inc.

Prescription Solutions

Catalyst Rx

Medco Health Solutions, Inc.

Caremark, Inc.

Envision Pharmaceutical Services/
Rx Options

MedImpact Healthcare Systems,
Inc.

Prime Therapeutics

DTM In-Process

Diplomat Pharmacy, Inc.

Memberhealth, LLC

United Healthcare Services,
Inc. D/B/A Unitedhealth
Pharmaceutical Solutions

Appendix D: Further Information and Acknowledgements

For more detailed information consult the following:

AMCP Guide to Pharmaceutical Payment Methods. www.AMCP.org

AMCP Concepts in Managed Care Pharmacy Series Document: Drug Use Evaluation. www.AMCP.org.

AMCP Concepts in Managed Care Pharmacy Series Document: Maintaining the Affordability of the Prescription Drug Benefit (www.AMCP.org).

Overview at www.cms.hhs.gov/eprescribing

The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue. Robert I. Garis; Bartholomew E. Clark Posted to Journal of the American Pharmacists Association, www.JAPA.org

www.eValue8.org

www.NBCH.org

www.PQM.URAC.org

www.URAC.org

Acknowledging

Mercer Human Resource Consulting, for contributing parts of Table 7, www.mercer.com

About NBCH

The National Business Coalition on Health (NBCH) is a national, non-profit, membership organization of employer-based health care coalitions. NBCH and its members are dedicated to value-based purchasing of health care services through the collective action of public and private purchasers. NBCH seeks to accelerate the nation's progress towards safe, efficient, high-quality health care and the improved health status of the American population.

NBCH has a membership of nearly 60 employer-led coalitions across the United States, representing over 10,000 employers and approximately 34 million employees and their dependents. These business coalitions are composed of mostly mid- and large-sized employers in both the private and public sectors in a particular city, county, or region. NBCH member coalitions are committed to Community Health Reform, including an improvement in the value of health care provided through employer-sponsored health plans and to the entire community.

NBCH provides expertise, resources, and a voice to its member coalitions across the country and represents each community coalition at the national level. As a "coalition of coalitions," the NBCH spreads the tenets and practical applications of Community Health Reform to areas where employers have yet to organize their purchasing power. For five years, NBCH has pursued national purchasing initiatives to offer turn-key health care products and services to community coalitions and their member employers. The NBCH is dedicated to making the coalition movement the vehicle for meaningful change in the health care system throughout the United States. See WWW.NBCH.ORG for information on value-based purchasing programs and coalitions.

About URAC

URAC is an independent, nonprofit organization whose mission is to promote continuous improvement in the quality and efficiency of health care management through the processes of accreditation, education, and measurement.

Incorporated in 1990, URAC pioneered utilization management accreditation by creating a nationally recognized set of standards to ensure accountability in managed care determinations of medical necessity. As the health care industry evolves, URAC continues to address emerging issues: we now offer over 20 accreditation and certification programs across the health care spectrum.

Many states have found URAC accreditation standards helpful in ensuring that managed care plans and other health care organizations are meeting quality benchmarks. Thirty-eight states and the District of Columbia currently reference one or more URAC accreditation programs in their statutes, regulations, agency publications or contracts, making URAC the most recognized national managed care accreditation body at the state level. At the federal level, four federal agencies recognize URAC accreditation: The Centers for Medicare and Medicaid Services; the Office of Personnel Management; TRICARE/Military Health System; and the Department of Veterans' Affairs.

In URAC's continuing effort to achieve its mission to promote continuous improvement in the quality and efficiency of health care, URAC created the Best Practices in Health Care Consumer Empowerment and Protection Awards, Conference and Exhibit Program.

Recipients of 2008 / 2009 Best Practices Awards included:

- CVS Caremark, "Drug Therapy Management"
- Express Scripts, "Express Scripts Generics Today"
- Medco Health Solutions, Inc., "Improving Patient Safety for Diabetic Patients"
- MemberHealth, LLC, "Improving ACE-I Utilization in Medicare Part D"
- Prescription Solutions, "Drug Interaction Alert Program"
- Prescription Solutions, "Geriatric RxMonitor Program"

Thru a Call for Entries process, organizations operating as pharmacy quality management, health information/decision support, health management, and workers' compensation companies as well as health plans and health networks are asked to submit a practice that: Measurably demonstrates its purpose, as well as its impact on the two topics of awards categories: (1) consumer decision-making and/or (2) consumer health improvement; and Exhibits a potential for wide-spread implementation.

Entries are evaluated by a distinguished 30-member panel of independent judges that include experts in program evaluation, care coordination, health information technology, employer and purchaser decision making and patient safety. After debate and deliberation, the judges select the Gold, Silver, Bronze and Honorable Mention award winners in each of the organization categories, and the Platinum award winners in the two topic categories.

For more information regarding URAC's products and services, please go to WWW.URAC.ORG.