

Chapter 16 Pharmacy Benefit Management

Pharmacy Benefit Management

Craig S. Stern

Pharmacy Benefit Management --Craig S. Stern

This chapter focuses on prescription medications used in the ambulatory environment.* Nonprescription medications, which include herbals, nutraceuticals, and over-the-counter (OTC) medications, are traditionally not included in pharmacy benefits because they are considered to be discretionary and not medically necessary. However, because of the relatively high cost of prescription medications, OTC medications are being considered for inclusion by some benefit plans.

The Basics	16-2
Pharmacy Benefit Design	16-8
Cost Control	16-8
Coverage Disclosure Considerations	16-10
Cost Considerations	16-11
The Global Drug Market	16-17
Pharmacy Benefit Managers	16-19
Choosing a Pharmacy Benefit Manager	16-24
Ensuring Quality	16-28
Cost Management Concepts	16-33
Utilization Management Concepts	16-34
Formularies	16-35
Prior Authorization Programs	16-40
Disease State Management	16-42
Quality Management/Oversight	16-44
Pharmacy Issues in Workers' Compensation Insurance	16-48

The Basics

The Basics

Historically, ambulatory medications were packaged with vision and dental plans to complement medical benefits. Pharmacy benefits, including medications, were sold as “riders” to be added to the major medical package for an additional premium. Yet prescription drugs differ from vision and dental care in that the latter are frequently elective and predictable in nature, whereas prescription drugs may be predictable for many chronic conditions but are infrequently elective. As prescription drug price inflation rose, due in part to the introduction of new medications and increased outpatient drug therapy, the pharmacy benefit (or prescription drug benefit) was unbundled from the major medical benefit. Before the 1970s, drug prices lagged behind the consumer price index (CPI). In the 1980s, drug prices soared, outpacing the overall CPI and its medical component. As a result, prescription drug benefit programs have followed designs that are focused on decreasing overall drug price inflation relative to the medical CPI.

*Dr. Stern is president of Pro Pharma Pharmaceutical Consultants, Inc., located in Northridge, California.

(Taken from C. Stern, “The History, Philosophy, and Principles of Pharmacy Benefits,” *J. of Managed Care Pharmacy*, 1999; 5(6): 525–31.)

Q 16:1 *What is a prescription drug plan?*

Until the late 1980s, the term *prescription drug plan* was most often used to describe a prescription drug benefit within a health plan member’s major medical benefit or a separate benefit sold as a “rider” to the major medical benefit. Under the medical benefit program, plan members would submit receipts to the medical claims administrator or insurance company and the member employee would be reimbursed for prescription drugs in the same manner as medical claims. However, these programs did not offer the plan sponsor discounts nor control over the use of prescription drugs.

The newer prescription drug plans usually are “carved out” from the medical benefit and are typically administered by a pharmacy benefits manager (PBM) (see [Qs 16:49–16:59](#)) or third-party administrator (TPA). These plans offer payers discounts off normal pharmacy charges, electronic claims administration according to benefit requirements, and utilization reports. They also offer programs to reduce costs through mail service, the Internet, and rebates from manufacturers for volume purchasing. In an effort to differentiate their offerings, PBMs provide various value-added programs for drug and disease management.

Q 16:2 *What are the elements of a prescription drug plan?*

A variety of prescription drug plans are available, but all usually include the following elements:

- Member eligibility cards (see [Q 16:20](#));
- Online claim adjudication (see [Q 16:49](#));
- Tiered copays or deductibles and coinsurance (see [Q 16:36](#));
- Pharmacy networks providing discounts for branded medications (see [Q 16:49](#));
- Maximum allowable cost (MAC) pricing for generics (see [Q 16:13](#));
- Mail service (see [Q 16:68](#));
- Formularies and/or preferred drug lists (see [Qs 16:79–16:90](#));
- Prior authorizations for certain high-cost medications (see [Qs 16:91–16:93](#)); and
- Therapeutic interchange or switching (see [Q 16:78](#)).

Q 16:3 *What is a brand name medication?*

A *brand name medication*, also known as “pioneer” or “branded” medication, is made by one manufacturer under a patent issued by the United States Patent Office. The manufacturer of the branded medication has a 20-year exclusive patent during which no other manufacturer is allowed to produce the exact same product. Examples of brand name medications include Lipitor, Exubera, and Humira.

Q 16:4 *What is a generic medication?*

A *generic medication*, or *multisource medication*, is a medication produced by multiple manufacturers. Generic products are allowed to be marketed after the brand-name medication loses patent protection (see [Q 16:3](#)). Generic manufacturers vie to be the first one on the market, as they are given a six-month exclusivity period to regain development costs. After six months, any manufacturer may apply for a license to market a generic version of the pioneer product. Pricing discounts, which are typically 10 to 15 percent in the first six months, drop to 50 to 70 percent or more after the six-month exclusivity period.

“Multisource” simply means that multiple manufacturers produce the same medication. Some payers

refer to a multisource medication as the first generic on the market after the pioneering brand-name medication loses patent protection. Within the industry, the terms “generic medication” and “multisource medication” are used interchangeably.

Authorized generics are considered brand drugs under a generic label. Put simply, a brand drug manufacturer supplies its drug to a generic firm and allows the firm to market the product under a different label for royalties. Brand companies also can create their own companies or subsidiaries to manufacture these authorized generics. By taking either route, these authorized generics can compete with the first generic drug maker during their 180-day exclusivity period. The implications of such actions create a price war that reduces the price of both generics in the 180-day period, thereby reducing the market share and profitability for the generic manufacturer.

Q 16:5 Are generics as good as brand name medications?

Yes. The Food and Drug Administration (FDA) approves generics as safe and effective alternatives to the pioneering branded medication. Generics contain the exact same active ingredients as the branded product and must fulfill the same properties for dissolving and disintegrating in the body as the pioneer brand. The FDA approves generics as therapeutically equivalent to the pioneering branded product and publishes all approved generics in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, frequently called “the Orange Book.” Generic drugs are frequently made by the same companies that market the pioneer branded product and by public companies that are listed on the major stock exchanges. Claims that generics contain various binders and fillers that are not the same as the pioneering branded product may be true, but such claims are irrelevant. All companies that manufacture medication, both brand and generic, use the same fillers and binders. A generic may have a different size, shape, and color, but it cannot be marketed without FDA approval.

Q 16:6 What role do generic drugs play in a prescription drug plan?

Generic drugs are nonbranded medications. They contain components identical to those of their name-brand counterparts. Generics are produced by a variety of manufacturers and can typically save the buyer 20 percent to 50 percent or more of the cost of branded drugs.

Major pharmaceutical firms spend millions of dollars developing new (“innovator” or “pioneer”) drugs. Once created, drugs are patented and become the sole property of the firm. Drugs are typically patented for an average of 20 years, although patents may be extended if the product develops a new and unique “extender,” such as an “extra strength” or “sustained release” version. At the end of 2005, 14 significant drugs with almost \$15 billion in sales lost their patents. In 2006, six branded drugs lost patent protection with over \$2.5 billion in sales. These drugs are now available to other drug manufacturers to produce as nonbranded or generic drugs. Pharmacy benefit managers (PBMs) may use generics to help manage the cost of prescription drug plans, although plan sponsors must be diligent in moving preferred tier brand drugs to nonpreferred once these brand drugs have lost their patent status.

Q 16:7 What are *branded generics*?

Branded generics are brand-name drugs that contain the same active ingredient as the original branded drug but can act somewhat differently in the body because they contain slightly different compounds. Traditional generics do not have to pass the rigorous testing process of branded drugs, but branded generics do need to win FDA approval. Makers of branded generics do not infringe on patent protections. Traditional generics do not appear on the market until after patents expire. Branded generics appear on the market sooner and cost more than traditional generics, but less than the original brand name drug. PBMs usually treat branded generics as brand-name drugs, but branded generics are likely to win a spot on a formulary and push the original drug to non-formulary status. (See [Qs 16:79–16:90](#) for discussion of formularies and non-formularies.)

Q 16:8 What is the FDA's position on generic drugs?

In a statement released January 28, 1998, the FDA stated: "To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug." This statement was issued in response to concern expressed about drugs with so-called narrow therapeutic indices (NTI), that is, small differences between the therapeutic and toxic doses. This statement provides reassurance to plan sponsors that encourage generic drugs over brand drugs.

The FDA uses guidelines on pharmaceutical equivalence, bioequivalence, and therapeutic equivalence to ensure that generic drugs are interchangeable with brand drugs. Pharmaceutical equivalence means that the generic drug has the same active ingredient or ingredients, is in the same dosage form (tablet, liquid, etc.), and is identical in strength as the brand drug. Bioequivalence means the generic drug is absorbed into the bloodstream at the same rate and extent as the brand drug. Therapeutic equivalence is achieved when a generic drug is proven to be safe and effective and is both pharmaceutically equivalent and bioequivalent.

Much discussion has taken place among physicians that generics have a wider range of strength allowed per dosage unit than branded medications. The branded pharmaceutical industry has promoted this distinction in order to discourage generic usage. The FDA has published the allowable strength and measurement tolerance that must be confirmed by generic manufacturers in their FDA submissions. These tolerances are not different from the measurement error allowable among branded products for their published strengths. As a result, concerns about the lack of strength of a generic product are unwarranted.

Q 16:9 What is a biotechnology or specialty injectable medication?

Biotechnology medications are drugs that are manufactured by re-engineering proteins, manipulating genes, and other sophisticated techniques for generating new molecules. These medications may be self-injectable by patients or require injection by a health care professional. These medications were originally targeted to treat obscure diseases, but they are now being developed to treat common chronic diseases.

Q 16:10 How many biotechnology drugs are being developed?

As of June 2008, 619 biotechnology medications and vaccines are in drug trials. Of the medications in trials, 292 medications are targeted to treat cancer; 24 to autoimmune disease; 79 to treat HIV and related disorders; and 15 to treat cardiovascular diseases.

Q 16:11 How does the 2008 experience compare to earlier biotechnology drug development?

The 2008 experience indicates that the industry is heating up and more drugs are being developed for chronic care management. For example, as of August 2006, 418 biotechnology medications and vaccines were in drug trials. These medications were being tested for more than 100 different diseases. Of the medications in trials, 210 medications are targeted to treat cancer; 50 to treat infectious disease; 44 to treat autoimmune disease; 22 to treat HIV and related disorders; and 22 to treat cardiovascular diseases.

Q 16:12 What is the average wholesale price of a medication?

The average wholesale price (AWP) of a medication is the price assigned by the drug manufacturer.

This price is used as a reference price for all discounts paid to pharmacies and PBMs. PBM contracts usually refer to the price that will be paid to pharmacies as a discount off the average wholesale price for a branded medication. It is important to understand that the average wholesale price may have no direct reference to the actual cost of providing the medication. However, public and private contracts include the AWP as a reference for pricing guarantees. Separately, the Centers for Medicare & Medicaid Services (CMS) developed an “average sales price, or ASP” as a reference price based on purchase price rather than drug cost. The ASP price is used for Medicare reimbursements to providers.

Q 16:13 What is the maximum allowable cost of a generic medication?

The CMS publishes a federal upper limit (FUL) price for all generic medications paid in the Medicare and Medicaid programs. Unfortunately, all therapeutic categories of medications are not covered on the FUL, nor is it updated as frequently as manufacturers change prices. As a result, health plans, PBMs, and TPAs developed their own maximum allowable cost (MAC) lists to cover all generic medications. Since generics are made by many manufacturers, several options are used for pricing the MAC. It may be the average cost of all manufacturers' average wholesale prices, or the lowest average wholesale price, or a formula for arriving at an aggregate average wholesale price discount for the entire MAC list. Most plans offer payers a MAC list that will deliver a 50 percent or more discount off the average wholesale price. As a reference price for generics, the MAC is referred to in PBM contracts, but it may or may not apply to all generic claims. The MAC may be quoted as an “average” or as a range of discounts.

Q 16:14 What is the average manufacturer price (AMP)?

The *average manufacturer price (AMP)* is the “average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt payment discounts.” [Deficit Reduction Act of 2005 (DRA) [Section 6001](#) that amended Social Security Act [Section 1927\(k\)\(1\)](#)] The AMP was originally designed as a basis for rebates paid to the states. It is now being expanded as the basis for payments of drugs to pharmacies under the Medicare Part D program. It will eventually replace AWP as the basis for retail pharmacy payments.

Q 16:15 What is the function of codes established by the National Association of Boards of Pharmacy?

The American National Standards Institute (ANSI) establishes codes so that electronic data transmissions can be standardized and easily understood across many data platforms. The ANSI establishes codes for the National Association of Boards of Pharmacy (NABP), which assigns a unique code for every pharmacy in the United States. These NABP codes are based on the state in which the pharmacy is located (the first two digits of the NABP code) followed by the order in which the pharmacy has been approved by the state board of pharmacy in which the pharmacy is licensed.

The NABP's influence extends beyond the United States. The NABP is composed of association boards from the 50 states, the District of Columbia, three U.S. territories, nine Canadian provinces, and four Australian states. As such, the NABP has influence over international pharmacies that do business over the Internet.

Q 16:16 What are national drug codes?

In the United States, drugs are assigned codes that act as a virtual fingerprint for all packaging of prescription medications. The FDA assigns each drug a unique national drug code (NDC), which is a universal product identifier for human drugs. Every prescription medication is assigned a unique 11-digit code that is divided into three segments: the first segment represents the drug manufacturer, repackager, or distributor; the second segment represents the drug strength and formulation; the third segment represents

the package size. Claims are adjudicated using the NDC of the medication used by the pharmacy to fill the prescription. (See [Q 16:44](#) for more information about NDC codes.)

Q 16:17 What data is available for the trends in drug spending for ambulatory patients?

The Agency on Healthcare Research and Quality (AHRQ) published spending data for medications prescribed in outpatient settings from 1997 through 2004. AHRQ identified that drug spending increased from \$72 billion in 1997 to \$191 billion in 2004. The data, covering people who live in the community and not in institutions such as nursing homes, showed that the average annual expenditure for prescription drugs for people age 65 and older increased 130 percent, rising from \$819 in 1997 to \$1,914 in 2004. The average out-of-pocket cost more than doubled for this group, increasing from \$483 in 1997 to \$1,027 in 2004. The average annual amount spent on prescription drugs purchased by people under age 65 rose 140 percent over the eight-year period, climbing from \$347 in 1997 to \$838 in 2004. The average annual amount this group spent out-of-pocket on prescription drugs rose from \$143 to \$304. According to the report, from 1997 to 2004, total purchases on outpatient prescription drugs increased from approximately \$2 billion to nearly \$3 billion. [AMCP Weekly News, 5/25/07]

Pharmacy Benefit Design

Q 16:18 What options does an employer have for managing a pharmacy benefit plan?

Employers and other payers can (1) manage the benefit and adjudicate claims internally; (2) outsource the benefit management to a health plan, PBM, or TPA; or (3) contract directly with pharmacies and adjudicate claims internally. Although no hard and fast rule exists, payers covering fewer than 15,000 lives usually do not insure the management of the pharmacy benefit. Some large employers have chosen to insure the management of their benefits because they feel that they can negotiate better terms with pharmacies and pharmaceutical manufacturers than can PBMs.

Cost Control

Q 16:19 Who offers prescription medication plans?

Prescription medication plans originate through many sources both private and public, for profit and not for profit. Medical carriers such as Blue Cross Blue Shield organizations and for-profit insurance companies can offer prescription drug programs. Plan sponsors also may “go direct” to a PBM.

Q 16:20 What is a *prescription drug card program*?

A *prescription drug card program* provides participants in the program with prescription medications from a participating pharmacy at a prenegotiated discount rate. The employee presents his or her prescription to the participating pharmacy. The pharmacist uses an online computer network to enter answers to a number of questions, such as whether the individual is eligible for the medication, whether the drug is covered by the plan, and whether any limitations are associated with the medication, before filling the prescription. The employee typically pays a fixed copayment, and the payer is billed at a prenegotiated discount rate.

Although prescription drug card programs are convenient, they may encourage drug overuse because the member does not pay out of pocket for the prescription and wait for reimbursement. Sponsors of prescription drug card programs should conduct periodic audits to ensure that the PBM and their retail

network of pharmacies are processing only legitimate claims. Today, very few plans do not offer a prescription drug card program.

Q 16:21 Are all prescription drugs covered under health care plans?

No. Generally, health care plans cover only prescription drugs that treat an illness or injury, subject to applicable limits and copayments. Common plan exclusions are medications used for smoking cessation, hair loss, obesity, and cosmetic conditions (e.g., Retin-A for facial wrinkles).

Q 16:22 Do prescription drug plans cover biotechnology medications?

When these medications can be self-injected, they are frequently covered under the pharmacy benefit. When a health care professional must administer, they are usually covered under the medical benefit and billed under a JCode or other HCPCS code. Many plans are placing these drugs under the pharmacy benefit in order to apply managed care tools for control of utilization and cost. The pharmacy benefit allows for more discounted pricing, formulary management, edits, and physician profiling for managing the use of these medications.

Q 16:23 Do prescription drug plans cover contraceptive prescription drugs?

Yes. Most prescription drug plans cover prescribed contraceptives. Insured plans may have a rider that allows a plan sponsor to opt for coverage of contraceptives. Multiple court rulings have required plans to cover contraceptives, even plans for religious organizations, but this trend is starting to be reversed. In March 2007, the Court of Appeals for the Eighth Circuit ruled that Union Pacific Railroad was not in violation of the Pregnancy Discrimination Act because it did not cover any contraception, for women or for men. [*In re Union Pac. R.R. Empl. Practices Litig.*, 479 F.3d 936 (8th Cir. 2007)]

Q 16:24 What are lifestyle drugs?

The term *lifestyle drugs* is applied to prescription products that do not necessarily cure illness but can be used to improve daily life by boosting psychological attitudes, energy levels, sexual performance, and body image. Common examples are Viagra, testosterone supplements for women to improve sexual desire, and Rogaine to counter hair loss. Lifestyle drugs have occasioned a debate over what should be covered in health care insurance and over the essential nature of insurance. Conditions treated by so-called lifestyle drugs are not subject to actuarial risk analysis. As a result, such drugs are frequently excluded from pharmacy benefit plans.

Q 16:25 Do any plans cover over-the-counter medications?

Very few plans cover over-the-counter (OTC) medications. A few plans cover some OTC medications, such as insulin, needles and syringes, prenatal vitamins, and diabetic devices and test strips. Some plans have experimented with covering OTC medications that are lower in cost, but equally effective, for the treatment of allergies or female yeast infections. Very few plans have covered alternative medications (e.g., herbals, nutraceuticals, or vitamins) as part of their alternative options for health care maintenance and prevention services. As an overall trend however, OTC medications have not been generally adopted as plan benefits.

Coverage Disclosure Considerations

Q 16:26 What are the coverage disclosure limitations in managed pharmacy plans?

Insured managed pharmacy plans provide full disclosure of the medications they do or do not cover by publishing formulary listings. PBMs and insured programs may publish the medication categories that are not covered or are not preferred on a formulary. Plan sponsors should carefully review all elements of the plan to be certain that they are aware of any specific drugs that the PBM does not cover. Current member utilization should be compared with the drug coverage available in each plan or PBM considered.

Q 16:27 How can employers protect themselves from nondisclosure?

The plan design is driven by the employer's benefit. Employers should stipulate their plan design in detail, including all excluded categories, and review the plan design documents with the PBM. If the employer is purchasing a PBM's plan design, then the plan sponsor should also carefully review contract terms to ensure the availability of data, full audit rights by auditors of the employer's choice, and complete definitions of included drugs and drug categories.

Q 16:28 What role does capitation play in pharmacy benefit management?

Negligible to none. Capitation involves an agreement between a payer and a PBM to provide prescription benefits for a predetermined amount per covered life, regardless of the cost of the prescriptions actually dispensed. In the early 1990s, some plan sponsors and PBMs explored capitation as a method of ensuring that their incentives were aligned. Payers wanted the PBMs to “manage” the benefit cost beyond expense reduction. The major PBMs could not determine a cost-equitable capitation formula, and most capitation arrangements were never realized. The major concern was that PBMs could not control physician prescribing to an extent that would make the plan profitable. As a result, few of these arrangements were ever successful.

Some plans have found better success with a “risk sharing” arrangement in which the PBM and plan sponsor share accountability for the pharmacy benefit costs. Risk sharing better aligns goals and incentives and avoids many of the pitfalls seen in either pure capitation or fee-for-service arrangements. However, these agreements have been limited by the ability to measure actual expense reduction beyond that provided by claim administration, and to attribute any successes to the plan benefit or to PBM programs.

Cost Considerations

Q 16:29 Why are prescription benefits a growing concern for health insurance planners?

Prescription drug prices have increased consistently in the past decade. Today, they represent 10 to 25 percent of an employer's overall health care benefit costs. Therefore, prescription drug costs are a significant area to target for better outcomes and lower costs. Selecting a marginal PBM or not knowing how to optimize the services a PBM offers can cost a health plan sponsor considerable money. New therapeutic categories and complicated plan designs have increased the need for competent prescription drug benefit managers.

Q 16:30 Why is the cost of prescription drugs increasing?

The overwhelming majority of the increases in expenditures on prescription drugs is attributable to the increased volume, mix, and availability of pharmaceutical products, as well as cost increases passed on by the pharmaceutical industry. In some cases, prescription drugs are a substitute for other forms of health care. More appropriate utilization of prescription drugs can potentially lower total health care expenditures and improve the quality of care. For example, by taking the right medicine, an asthmatic patient might be able to avoid emergency room visits and hospitalizations. H2 antagonists, such as Tagamet and Zantac, have virtually eliminated painful and invasive ulcer surgery that was common a few years ago. However, many more patients take proton pump inhibitors (PPIs; e.g., Nexium and Prilosec), which were originally developed for severe gastric bleeding problems, but are now used for common heartburn. (Prilosec was the most frequently dispensed medication in America in 2000, according to IMS America, a data collection and reporting service.) Medication offers an effective and less invasive method of treatment; as a result, more patients are being treated and thus expanding the potential for inclusion in the therapeutic category in terms of sales of the medication.

Direct-to-consumer (DTC) advertising has increased the demand for many drugs. In 2000, DTC advertising by the drug manufacturing industry had grown to \$2.5 billion, more than double what was spent in 1997. In 2005, the pharmaceutical industry spent \$4.2 billion on advertising in all media, compared with the \$7.2 billion spent on physician detailing in 2005. The effect of increased advertising has yielded a tremendous boost to sales. For example, IMS America reports sales have increased:

- Sales for 2000 were \$145 billion in 2000, compared with \$126 billion in 1999 (a 14.9 percent increase); and 66 percent of the increased sales was based on volume, not increased prices.
- Sales for 2003 were \$216.4 billion, up from \$194 billion in the previous year (an 11.5 percent increase).
- Sales for 2005 were \$251.8 billion (a 5.4 percent increase).
- Sales for 2006 were \$274.9 billion (an 8.3 percent increase).
- Sales for 2007 were \$286.5 billion (a 4 percent increase).

A Harvard University study funded by the Kaiser Foundation found that for every \$1 spent on DTC advertising, manufacturers reap \$4.20 in sales. Recent evidence indicates that DTC advertising is less effective in current media, so it is being redirected to the Internet and other distribution channels in order to have a greater impact on the general public.

Demographics are driving up prescription medication costs as the population ages. However, more and more new drug therapies are targeting the “young old” population, individuals in the 40 to 60 age group, in an effort to prevent certain diseases, such as hyperlipidemia and hypertension, from progressing and increasing the chances of heart disease and stroke later in life.

Q 16:31 How much are prescription drug costs increasing?

Most of the industry sources provide similar trends. Based on the 2007 *TrendsRx Report* issued by Caremark, prescription drug spending increased 5.2 percent from 2006 to 2007. Separately, the Kaiser Family Foundation Prescription Drug Trends report of May 2007 indicated that retail prescription drug prices increased 7.5 percent versus 8.3 percent annually from 1994 through 2005. The Medco 2007 Drug Trend Report gave slightly different data, citing a 7.7 percent trend for 2006 and a projected 8.2 percent annual trend through 2010.

Q 16:32 What are the drivers of pharmacy benefit cost inflation?

Pharmacy benefit expense is driven by increases in raw drug costs, utilization (i.e., the number of

drugs used by each plan member), new entrants into the drug market, introduction of new biotechnology drugs, and the branded drug mix. The Caremark 2007 *TrendsRx Report* identified the relative impact of each driver in 2007; namely, drug cost rose 4.0 percent, and utilization increased 0.7 percent while product mix accounted for 0.5 percent. It is important to note that all these references base their trends on their specific books of business. Therefore, it is important to interpret these trends by comparing a specific company or industry against the sectors represented in these reports.

Q 16:33 What is the trend in biotechnology drug spending?

Trend varies depending on the agency reporting the numbers, but recent data from Express Scripts, a pharmacy benefit manager, reported that the biotechnology drug trend for 2007 was 14 percent versus a 21 percent trend for 2006. This increase is based on biotechnology trends purchased from community pharmacies and excludes spending for biotech drugs within the medical benefit, such as those administered in physician offices. Spending increased 25 percent in 2005. Released at the company's annual Outcomes Conference, the 2006 Drug Trend Report also estimated that overall biotech drug costs would reach \$99 billion by 2010, accounting for 26 percent of total drug spending.

Q 16:34 What is the typical cost of prescription drug coverage?

Prescription drugs typically account for approximately 8 to 11 percent of the total health care dollar. Many plans have set target pharmacy benefit limits to no more than 20 percent of major medical plan costs; but the pharmacy benefit trend was between 11 and 18 percent nationally for the last half of the 1990s. CMS predicts that pharmacy benefit trend will be about 9 percent in 2012 versus earlier estimates of 8.2 percent for the next few years. Current evidence bears this number out—the trend in pharmacy benefits slowed for the private sector to about 8.3 percent in 2006. However, while the trend for biotechnology-derived specialty injectables was about 35 percent per annum; for the past few years, it has slowed to 21 percent in 2006. By 2010, it is expected that new branded medications and new biotechnology drugs will drive the trend up once again into double-digit range. The only mitigating factor will be that several blockbuster drugs will lose patent protection at the same time, but that may not be enough to counter the impact of the rise in biotechnology products.

Q 16:35 What are average prescription drug copays?

For purposes of definition, copays are flat amounts paid by members for individual prescriptions. According to a 2007 Mercer survey, 72 percent of prescription drug card plans use three-tier copays. This is the same value quoted in 2006. The average copays for retail drugs are \$10 for generics, \$25 for formulary brand-name drugs, and \$42 for non-formulary brand-name drugs. Meanwhile, four- or five-tier structures are used by 5 percent of employers with at least 500 employees and 10 percent with at least 20,000 employees. According to the 2007 survey by United Benefit Advisors (UBA), 74.9 percent of all employers use a three-tier copay structure (cf. 75.1 percent in 2006), and the median retail copays are \$10 for generics, \$25 for formulary brand-name drugs, and \$50 for non-formulary brand-name drugs (vs. \$45 in 2006).

Copays have been increasing as is illustrated in the 2007 Kaiser Family Foundation report of Prescription Drug Trends based on 2006 data. This report indicated that for 2006:

- Generic average copay was \$11
- Preferred branded drugs average copay was \$24
- Non-preferred branded drugs average copay was \$38
- Seventy-four percent of all health care providers are on three- to four-tier plans

Q 16:36 What is a *three-tier copay*?

The major increase is in three-tier plans—that is, the lowest tier for generics, the next higher for preferred brands, and the highest tier for nonpreferred or nonformulary brands. The 2007 Mercer survey showed that 72 percent of the respondent plans used three-tier copays, up from 26 percent in 2000, but the same number was quoted in 2006. The average copays were \$42 for non-formulary brands, \$25 for formulary brands, and \$10 for generic drugs.

Q 16:37 What data is available for the trends in copays for ambulatory patients?

In 2007, the average copay decreased \$0.25 to \$13.20, while the average total prescription cost (including both brand and generic medications) increased \$0.92 to \$55.93. The decrease in copayments was attributed to an increase in the use of generic medications. The breakdown for trends in average copay changes for the period from 2002 through 2007 were:

- Preferred brand drugs increased \$4.52 to \$19.18.
- Non-preferred brand drugs increased \$11.28 to \$28.44.
- Generic drugs increased \$0.86 to \$7.57.

The above data should be used in the context of the Express Scripts, a PBM's, book of business and may not be applicable to all types of payers. [Express Scripts 2007 Drug Trend Report]

Q 16:38 Is a copayment more common than coinsurance for prescription drugs?

Yes. Coinsurance is the percentage of the cost paid by a plan member, as opposed to copay, which is a flat amount. The 2007 Mercer survey reported that over 20 percent of large employers and 55 percent of those with at least 20,000 employees require coinsurance for at least one medication class. On the other hand, according to the 2006 Mercer survey, only 14 percent of prescription drug plans required coinsurance and 9 percent had coinsurance for mail order. The 2007 UBA survey stated that about 67 percent of plans provide copayment only and 2.5 percent offer only coinsurance. This should be compared with the 2006 UBA survey, where less than 1 percent of all employers required coinsurance for all prescription drugs purchased at retail, but 9 percent had some combination of coinsurance and copays. The *Kaiser Family Foundation Employer Health Benefits Report of 2007* lists that on average, 84 percent of employees covered in a plan with three-tier cost sharing have copayments only, while 8 percent have coinsurance only. This is a decrease in coinsurance when compared to the *Kaiser Family Foundation Employer Health Benefits Report of 2006*, in which it reported that on average, 11 percent of employers use coinsurance and 82 percent use copayments.

Q 16:39 What are *quantity limits*?

Quantity limits help to improve compliance with medication therapy. Instead of taking lower strengths of a drug more frequently, quantity limits prompt patients to obtain higher doses less frequently. For example, instead of taking Zyprexa 5mg twice a day, the patient takes Zyprexa 10mg once a day. While improving compliance, these programs also lower costs.

Quantity limits also refer to limiting the number of tablets per what is considered a typically 30- or 90-day supply. Some drugs have both a prior authorization (PA) requirement and a quantity limitation. One of the most “famous” drugs in this category is Viagra. Most plans require a PA for Viagra and limit the coverage to six tablets per month.

Q 16:40 Why are medications more expensive in the United States?

Drug manufacturers in the United States state that the cost of medications includes research and development of new products, some of which never reach the market for lack of effectiveness or because of toxicity. The United States also does not have price controls on medications, as is common in Canada and in Europe. Finally, manufacturers say, the FDA ensures that less expensive products that are present in foreign markets are not available in the U.S. market.

Q 16:41 Can proper drug usage reduce other costs?

The evidence is equivocal. According to an article in the *American Journal of Industrial Medicine*, employees using sedating antihistamines purchased over the counter to treat allergic rhinitis have a significantly higher risk of injury than employees taking prescribed non-sedating antihistamines. In addition to adding to workers' compensation costs, the sedating antihistamines contributed to lower productivity.

Nonetheless, most plan sponsors have experienced increased costs in both medical and pharmacy programs. For this reason, it has been difficult to determine just how much proper drug usage has affected the medical health care trend. Many new "dot com" companies formed in the early 2000s to merge pharmacy and medical data, in an effort to answer questions concerning the effect of medical care spending as it applies to proper drug usage. A significant factor in not being able to tie drug use to medical spending is that diagnosis codes are not required for prescription drug claim adjudication. Because of this limitation, drug use must be inferred based on common uses rather than the specific disease that the drug is prescribed to treat.

Q 16:42 What is the motivation for an employer to have a separate prescription drug plan rather than combining medical and prescription drug coverage?

There are a number of reasons for having separate plans, but all of them have to do with cost management:

- Under the indemnity plan, there are typically no discounts for prescription drug coverage. Plan sponsors may pay as much as 10 percent above the average wholesale price rather than 15 percent below it.
- Medical claims processors often do not require detailed receipts for prescription drugs and therefore cannot review the prescriptions for coverage as effectively as the PBMs' online claims processing environment.
- Because detailed information is not entered into the medical claims processing systems, limited data are available in report format for reviewing drug trends.
- Rebates and other cost-savings programs, which are available in prescription benefit plans, are not available through medical claims processors.

Some employers may wish to avoid a free-standing drug plan in favor of covering medication under a major medical or comprehensive health plan so as to manage the entire medical benefit. However, carving the pharmacy benefit out of the major medical benefit may lead to micromanagement of the pharmacy portion, leading to losses for the medical portion. For example, excluding certain medications could lead to increased emergency medical visits or physician encounters. This problem is magnified when no alignment exists between the medical encounter and pharmacy claims databases that would allow for oversight of cost or utilization shifts.

The Global Drug Market

Q 16:43 Is there a global market for prescription medications?

Yes. The raw ingredients of medications are produced all over the world, and highly active and profitable markets are in the United States, Japan, Europe, Israel, India, China, Brazil, and South Africa. The raw ingredients are either used to manufacture prescription medications in the country of origin or shipped to the United States (and other locations) to be made into tablets, capsules, and so forth.

A major factor in the differential pricing of drugs internationally until recently has been the lack of information. With growing access to the Internet, consumers and public entities can comparison shop all over the world. The Internet has enabled the creation of a global marketplace for medications.

Q 16:44 What are NDC and NABP codes?

The American National Standards Institute (ANSI) establishes codes so that electronic data transmissions can be standardized and easily understood across many data platforms. ANSI establishes codes for pharmacies (National Association of Boards of Pharmacy—NABP) which assigns a unique code for every pharmacy in the United States. These codes are based on the state in which the pharmacy is located (the first two digits of the NABP code) followed by the order in which the pharmacy has been approved by the state board of pharmacy in which the pharmacy is licensed.

Similarly, drugs are assigned codes. A national drug code (NDC) is an 11-digit code assigned to each unique product. The first five digits represent the drug manufacturer, the next two represent the drug, the next two represent the strength of the drug, and the last two represent the package size.

Q 16:45 What is importation versus re-importation?

Importation is the process of importing foreign-manufactured drugs into the United States. The United States requires that imported products be manufactured in plants that are approved by the U.S. Food and Drug Administration (FDA) and meet the same requirements as U.S. manufacturers. This practice has been in existence for many years, and many of the high-volume prescription medications sold in the United States are actually manufactured overseas in countries such as Israel and India.

Re-importation is the process of importing into the United States products that were originally manufactured in the United States. The United States requires that re-imported medications have an audit trail showing that they have passed through only the hands of licensed entities (e.g., licensed drug wholesalers, distributors, pharmacies) when they were outside the United States. This practice has gained recognition through re-importation of medications from Canada and Mexico as well pharmacies on the Internet.

Q 16:46 Can drug benefit plans buy medications in bulk from Canadian pharmacies at prices lower than those in the United States?

No. Currently, the United States FDA prohibits drug wholesalers, distributors, pharmacies, hospitals, physicians, and others from reselling drugs manufactured in the United States and exported to other countries. However, the high cost of prescription medications in the United States has driven a significant movement within Congress to change these prohibitions. The major concerns are the need for the FDA to ensure that these medications have not been tampered with and are safe.

Q 16:47 Do health plans allow their members to purchase medications on the Internet?

Many health plans currently have an Internet pharmacy component. Members can order their prescriptions, check prices, and track the progress of their prescription delivery on the Internet. Many plans also offer special pricing for OTC medications or supplies ordered on the Internet.

The pharmacies on the Internet include sites that are not associated with any particular plan or pharmacy benefit manager. Some Internet sites are representative of licensed pharmacies in the United States or in other countries. However, many online pharmacies are unlicensed and unregulated by any governmental agency. The FDA and the NABP have discouraged consumers from buying drugs from those Internet sites.

Q 16:48 How can plans verify whether an Internet site is legitimate and provides approved medications?

In the interest of protecting the public's health, the FDA and the NABP encourage consumers to verify the licensing of Internet pharmacies. The NABP has established the Verified Internet Pharmacy Practice Sites (VIPPS) system to develop criteria for all internet pharmacies. To be VIPPS certified, an Internet pharmacy must meet the licensing and inspection requirements of the state in which it is domiciled and the states to which it ships medications. A VIPPS-certified pharmacy has a VIPPS hyperlink seal on its Web page. Consumers can verify whether a pharmacy is VIPPS certified and search for certified pharmacies that meet their needs by accessing the Web site <http://www.nabp.net>.

Pharmacy Benefit Managers

Q 16:49 What is a *pharmacy benefit manager*?

A *pharmacy benefit manager* (PBM) is an entity that administers managed pharmacy programs. It is defined as an application of programs, services, and techniques designed to control costs associated with the delivery of pharmaceutical care by:

1. Streamlining and improving the prescribing and dispensing process through online and real-time claims adjudication;
2. Maintaining a retail network of pharmacies and a mail order option that in turn offer discounts off the cost of prescription drugs and potentially monitor the performance of the network;
3. Offering limited drug utilization review (DUR) online at the point of sale/dispensing;
4. Providing data and reporting regarding drug use; and
5. Controlling the cost of prescriptions dispensed through clinical and financial programs, such as formulary development and rebate contracting with drug manufacturers.

Estimates of the current number of enrollees in some type of pharmacy program—whether managed or simply a claim processing or prescription card service—is at least 130 million and now higher due to the addition of Medicare Part D patients. Some analysts believe these numbers are inflated. One point is clear: within the past decade, the number of people enrolled in PBMs has increased significantly.

Q 16:50 Can plans or PBMs buy drugs in bulk from Canadian pharmacies where prices are lower?

No. The U.S. Food and Drug Administration prohibits businesses from reselling drugs manufactured in

the U.S. and exported to other countries.

Q 16:51 Which are the largest PBMs?

According to *Business Insurance*, the largest PBMs, ranked by 2007 revenues from unbundled PBM services, are the following:

1. Medco Health Solutions
2. CVS/Caremark
3. Express Scripts, Inc.
4. RESTAT
5. National Pharmaceutical Services

Q 16:52 What options do PBM prescription drug plans offer?

PBMs offer a standard portfolio of services and a variety of value-added options to differentiate themselves in the marketplace. A standard portfolio of services is common to all PBMs and includes:

- Claim processing;
- Account management and support for plan design alternatives, trend analysis, and general advice regarding prescription drugs;
- A retail network of pharmacies for the purchase of medication at discounts;
- Dispensing mail order prescriptions;
- Communication to patients regarding program use;
- Formulary development and rebate administration;
- Some drug utilization management, including prospective, concurrent, and retrospective review programs;
- Reporting of drug utilization and industry trends; and
- Some educational components for patients and physicians.

Q 16:53 How much do PBMs charge for their services?

PBM prices can vary dramatically by region, age of enrollees, type of industry the plan covers, overall health of beneficiaries, the size of the group that is being covered, and, most specifically, by the elements the plan sponsor wants to include. PBM administrative and prescription costs combined can range from \$25 to \$35 per member per month to \$60 to \$70 per member per month for a plan with few controls, older members, and low copayments. PBM administrative fees are typically 3 or 4 percent of total prescription plan costs.

PBMs charge claims processing fees to the plan for such services as account management, standard report delivery, and claims processing. These charges range from 15 cents to 75 cents per claim. The largest (also known as “jumbo”) clients pay nothing for the administrative claims processing fee, while the smallest clients usually pay 45 cents or more per claim. A pricing scheme composed of a combination of discounts off the average wholesale price and a dispensing fee are paid to retail pharmacies or the mail order firm for the actual medication. These discounts range as follows:

Retail network brand drugs	12% to 15% off average wholesale
----------------------------	----------------------------------

	price plus a \$1 to \$3 dispensing fee
Retail network generic drugs	MAC plus a \$0 to \$3 dispensing fee
Mail order brand drugs	20% to 25% off average wholesale price plus a \$0 to \$1 dispensing fee
Mail order generic drugs	50% to 65% off average wholesale price or MAC plus a \$0 to \$1 dispensing fee

In some cases, PBMs take the difference between what is charged to the client and what is reimbursed to the pharmacy. Therefore, the above rates are typically what are charged to clients. Actual reimbursement rates to pharmacies may differ by 1 to 2 percentage points. The margin made by chain drug stores can range from 5 percent and up for brand drugs to 25 percent for generic drugs, since chain pharmacies purchase prescription drugs in bulk and often obtain discounts from wholesalers.

Q 16:54 How are PBMs compensated?

PBMs may generate profits in many ways. The typical revenue streams are through claim administration fees, mail, and rebates. The following is a more extensive list of potential PBM revenue streams:

- Charging payers an administrative fee per transaction based on the number of prescriptions or employees;
- Retaining rebate administrative fees negotiated with manufacturers;
- Filling mail service prescriptions from their wholly owned mail order pharmacies;
- Disease management, education, and value-added programs negotiated with pharmaceutical manufacturers;
- Securing discounts through a contracted network of pharmacies or through direct purchasing when the PBM owns its mail service pharmacy;
- Retaining the pharmacy spread, the difference between the amount collected from the payer and the amount paid to the network pharmacies;
- Retaining the spread in MAC list payments for generics that is greater than what is paid to the network pharmacies; and
- Reducing payments to pharmacies based on certain package sizes, regardless of the package size dispensed.

Q 16:55 What is *pharmacy spread*?

The difference between the amount the PBM collects from the payer and the amount the PBM pays the pharmacy is called the *pharmacy spread*. Pharmacy spreads are a revenue source for PBMs and are frequently not stipulated in the payer contract. Payers should ask a PBM they are considering whether a spread exists, and how that will influence the performance of the PBM's network. Payers may choose between PBMs based on those retaining a spread and those that do not.

Q 16:56 What is *zero balance billing*?

Some PBMs allow pharmacies to collect the entire copay even when the cost of the drug is less than the copay. This is called *zero balance billing*. PBMs have used zero balance billing to extract greater discounts from pharmacies for their clients. When the pharmacy keeps the entire copay, the payer does not lose, but the plan member will pay more. Payers should question PBMs whether zero balance billing occurs, and whether that is consistent with their benefit philosophy.

Q 16:57 **What are rebates?**

A *rebate* is an agreement between a PBM and a drug manufacturer to secure significant reductions in the cost of prescription drugs. Some of the savings are passed along to employers. Over the past 10 years, rebates have grown from 1 to 2 percent of a payer's total drug expenses to 6 to 9 percent of the total. The growth in rebates paid to payers has paralleled the rise of pharmacy benefit inflation and the advent of multi-tiered copay designs.

The theoretical threshold is the rebates paid to the state Medicaid programs. This maximum rebate threshold for branded products (also innovator drugs) is 15.1 percent of AMP or the difference between AMP and the best price, whichever is greater. For generic products (or non-innovator products) the threshold is 11 percent of AMP. How can this be related to various retail contracts that use AWP? While no official relationship exists between AWP and AMP, many industry experts use AWP equal to 250 percent of AMP as a rule of thumb.

In some cases for specific drugs, rebates can account for up to 50 percent off the cost of the prescription medication. In the past, manufacturers would discount solely based on utilization; however, today manufacturers require an increase in market share before giving discounts.

With rebates, drug manufacturers reward PBMs that are able to encourage a significant percentage of enrollees to switch to the company's key products. At the end of a predetermined period, typically on a quarterly basis, the PBM and the manufacturer review utilization. If the goals agreed upon were met, the PBM receives a rebate that varies from 5 percent to 50 percent and can be as high as about 50 percent of the cost of the drug. In some cases, the savings are passed on to the PBM's client. Rebates are becoming increasingly more controversial because many plan sponsors are led to believe that they are receiving almost all of the rebate payments, when in reality, some plan sponsors only receive a small portion. Further, critics argue that rebates bias drug selection while the plan sponsor still pays more than they would for a generic or a lower cost therapeutic alternative.

Components of rebate contracts include administrative fees, access rebates, and market share rebates. Administrative fees are almost always retained by the PBM and average 2 to 4 percent of the average wholesale price cost of the drug under contract. Access rebates are minimum amounts paid by the manufacturer for placement on the formulary. Access rebates are about 5 percent of the "average wholesale price" cost of the drug. Additional rebates, or market share rebates are paid to the PBM if the market share of one drug within the therapeutic category reaches or exceeds the contract threshold. Market share rebates are usually based on the formulary driven claims payments to pharmacies and belong to plan sponsors.

Many PBMs do not allow disclosure of these rebate arrangements because they fear that if plan sponsors understand these arrangements, plan sponsors will demand more of the rebate monies and therefore reduce the profitability of the PBM.

Q 16:58 **What is the role of rebates in lowering drug costs?**

Rebates are payments to health plans, PBMs, TPAs, and payers for volume purchasing of medications within therapeutic categories that reach target market share. Rebates, which are paid to clients from PBMs, are based on drug manufacturer payments to the PBM. Rebates typically range from \$1 per prescription for open formularies, \$2 per prescription for preferred formularies, and \$3 per prescription for closed formularies; however, a wide variation occurs depending on contracts and class of trade. Rebates have been a controversial issue in the industry since PBMs have been reluctant to discuss the details of these arrangements with their clients or provide any information as to the accuracy of the billing and collection process. PBMs have been frequently criticized in the media for secretive deals with drug manufacturers where they retain, in some cases, as much as 50 percent of the total dollars paid by drug manufacturers rather than pass these savings on to clients.

Q 16:59 What kinds of educational programs do PBMs offer to enrollees?

Almost all PBMs offer new members enrollment materials that detail how to obtain retail and mail order prescriptions, how to obtain an ID card, and other basic information such as the difference between brand drugs and generic drugs. These materials may be included in the base claims processing fee or can be purchased for an additional per piece fee.

Many PBMs distribute monthly newsletters to enrollees offering information on specific health problems such as asthma or diabetes. The plan should review these communications to make sure they meet the plan's standards. A number of PBMs now allow members to order prescriptions on their Web sites, which are linked to medical information sites.

Few PBMs, however, offer true educational information regarding drug therapies for either physicians or members. Most PBMs defer to the patient's physician.

Choosing a Pharmacy Benefit Manager

Q 16:60 What questions should a plan sponsor ask a PBM?

The primary question a plan sponsor should ask a PBM is “How can you make my prescription drug benefit better meet the needs of my enrollees in a cost-effective manner?” Cost is a major factor; however, claims administration that is consistent with the plan benefit designs, service delivery, administrative oversight, and transparency of pricing are also critical. Other specific questions that should be asked are:

1. What are the options and pricing of the network of providers that the PBM offers? What support does the PBM provide for customizing the network (adding and deleting pharmacies that are important to the plan)? Does the PBM reimburse pharmacies at a rate different from what it charges to the plan?
2. Does the PBM own the mail order program? If not, how does the sub-contractual relationship work between the two organizations? How are mail order claims monitored for accuracy and timeliness?
3. Are price guarantees backed by unrestricted audits by the plan sponsor?
4. Are service and performance offerings backed by guarantees and significant financial penalties?
5. What kind of reports does the PBM offer?
6. What types of DUR edits are performed routinely? Can these edits be customized? Are the DUR edits limited to too-soon refills, prior authorization, quantity limits, and duplicate claims, or are pharmacists notified of DUR alerts (drug-to-drug interactions) (Such edits are conducted during the dispensing process so that the prescription may be changed if needed.)
7. Are DUR edits based on criteria that are measurable in the claims detail supporting the invoices? Is the edit performance backed by a return-on-investment (ROI) that can be independently verified in the claims?
8. How does the PBM work with physicians to educate and modify prescribing patterns?
9. What types of educational programs are offered to patients?
10. If the PBM offers disease management programs, how are the programs designed? Do they emphasize more than prescription drugs? How are the programs funded?
11. What types of ancillary services are provided? Are claims processed in house?
12. What drugs are preferred by the PBM? Can a client make changes to the preferred list? Are there therapeutic switching programs in mail order or retail edits to flag preferred drugs? Who are the representatives on the PBM's pharmaceutical and therapeutics (P&T) committee? What are their

affiliations? Do these members accept grant money from drug manufacturers?

13. What are the results of these programs? Does the PBM track savings and the return on investment of programs offered?

Q 16:61 What questions should a plan sponsor ask a PBM's current clients?

A plan sponsor that is considering purchasing the services of a PBM should ask the PBM's current clients the following questions:

- Are the PBM's reports delivered in a timely manner? Are reports available online and in real time using both standard and ad hoc query systems?
- Do the reports provide the type of information needed to improve management of the prescription benefit?
- What type of customer service does the PBM offer? Are enrollees treated courteously, and are their questions answered promptly?
- Do enrollees experience difficulty in getting prescriptions filled because of technical problems, such as computer system downtime?
- What is the PBM's reputation with physicians and pharmacies?
- What kind of therapeutic interchange protocol program does the PBM use?
- What kind of cost savings has the PBM produced for its clients?
- How has the PBM enhanced its clients' prescription benefit programs?
- How did the implementation process proceed?

Q 16:62 What is the most important element to look for when considering a PBM?

The most important element in selecting a PBM is the ability of the PBM to meet the unique needs of the plan sponsor. For example, if a plan sponsor wants a PBM to handle all administrative responsibility for the plan, it needs a plan that is simple, easy-to-understand, and does not require the sponsor to review formularies and drug trends, and provides excellent member service that will not give rise to “complaints” from members. A more sophisticated plan sponsor may want extensive reporting, full disclosure of rebate contract terms (so that a customized formulary can be developed), and carved-out traditional PBM services such as retail network management that it can take in house.

Every plan sponsor must develop its own list of objectives before soliciting proposals from PBMs. Through a short interview process, the plan sponsor may first determine which type and level of services it considers most important. Then, the plan sponsor may solicit formal proposals from only those PBMs that meet its list of needs.

Q 16:63 Should the ownership of the PBM be a concern for employers?

Yes. Many PBMs used to be owned by pharmaceutical manufacturers. Medco Health Solutions was owned by Merck, and PCS was owned by Eli Lilly. Since Medco still has agreements with Merck to favor Merck medications on its formulary, and Merck products often cost more than competing products, choosing Medco as the PBM may increase members' costs. The plan sponsor should analyze members' current drug utilization to ascertain the impact of Merck medications and the potential for switching to

Merck products.

Many drug chains also own PBMs. In early 2007, CVS, which owns PharmaCare and Eckerd Corp., merged with Caremark, one of the largest PBMs.

Currently, American Drug Stores, Inc., owns RxAmerica; and Walgreen Corp. owns Walgreens Health Initiatives. Some health plans own their own PBMs; for example, Anthem/Wellpoint owns Wellpoint Pharmacy Services, and United Health/PacifiCare owns Prescription Solutions. In addition, smaller PBMs may be owned by chains or independent pharmacy consortiums. The ownership of PBMs should be scrutinized to ensure that the best discounts and oversight of owned pharmacies are available to the payer. In some cases, a plan funds claims for retail pharmacies from the PBM. In this situation, it is advisable to have controls in place, such as an external audit firm, to ensure that proper controls are in place for funding transfers.

Other relationships between PBMs and pharmaceutical firms can be of concern to plan sponsors as well. Many PBMs have contractual relationships with drug manufacturers for rebates.

Based on these relationships, a PBM's advice concerning medications must be taken with caution. Other PBMs are owned by managed care organizations, and the controls implemented with health maintenance organizations (HMOs) could be too severe for some employers or Taft-Hartley Funds.

Employers should carefully review the PBMs that they are considering before making their final selection. Biases regarding preferential treatment of certain products or of certain pharmacies can cost plans more than the potential savings through volume discounts.

Q 16:64 What kinds of reporting should a purchaser seek from a PBM?

Perhaps the single most important report a PBM can provide is a review of utilization. The information in a utilization review can be broken down in whatever manner the sponsor prefers—by region, sex, age, and so forth; however, some PBMs provide utilization in one report, claims data in another, and reports from different regions covered by the plan sponsor in yet another. For a complete analysis of the PBM's activity, it is preferable to have one integrated report that provides an overview of all elements of the pharmacy program; the reports should be available semimonthly, quarterly, and annually. Reports can be used to identify and manage trends, as well as to answer specific questions. Additionally, they are of critical importance in the day-to-day management of a successful PBM program. Many PBMs now offer the plan sponsor the ability to query data in a variety of ways, using the PBM's ad hoc reporting tool. These report query systems allow each plan sponsor to develop their own customized reports.

Q 16:65 What information is necessary to validate rebates?

Components of rebate contracts include administrative fees, access rebates, and market share rebates. Administrative fees are almost always retained by the PBM and average 2 percent to 4 percent of the AWP cost of the drug under contract. Access rebates are minimum amounts paid by the manufacturer for placement on the formulary. Access rebates are about 5 percent of the AWP cost of the drug. Additional rebates, or market share rebates are paid to the PBM if the market share of one drug within the therapeutic category reaches an agreed-to amount.

Many PBMs do not allow disclosure of these rebate arrangements because they fear that if plan sponsors understand these arrangements, plan sponsors will demand more of the rebate monies and therefore reduce the profitability of the PBM. However, the emphasis on transparency in client/PBM contracts is driving PBMs to disclose more about rebate payments, allowing clients to determine if they are receiving the contracted rebate payment. Rebate contracts are now written to pay a percentage of the rebated amount from the manufacturer or a guaranteed rebate per branded claim.

An example rebate payment is illustrated in Table 16-1. All of the drugs A–D are in the same therapeutic category. Rebates are paid on the number of units (e.g., tablets, capsules) paid. The rebate is the

total of some access amount per unit plus the additional incentive rebate for achieving a market share above the national market share. The rebate payment of \$25,258 is 6 percent of the total ingredient cost paid for the example category of medications.

Note

Table 16-1 shows that the difference in cost between the lowest (Drug D) and highest cost (Drug C) drugs in the category is about 70 percent. The rebate covered only 6 percent of the total difference. These types of rebate arrangements require that lowest net cost strategies (in this case \$70 per Rx) be compared to rebate offsets of drug costs. In this example, the rebate strategy is far more costly than designing the formulary around a lowest net cost strategy. If the PBM contract allows for a payment of 80 percent of the manufacturers' rebates to the client, then the rebate payment to the client would be 80 percent of \$25,258 or \$20,206. The PBM would receive the remaining 20 percent plus the administrative fee of 2–4 percent plus any formulary management, educational, or disease management fees paid by manufacturers.

Q 16:66 Is it important to have a PBM that has nationwide service?

Yes. Employees who are members of a PBM are required to have their prescriptions filled by a network pharmacy (except in emergencies) in order to receive benefits. If the plan sponsor and its enrollees are located in one area, a nationwide network may not be necessary. On the other hand, nationwide service can be beneficial for large employers with employees in multiple locations, employees (and retirees) who travel frequently, or employees who are frequently transferred.

Pharmacies join networks and provide services at reduced rates in exchange for volume business. A tight network of pharmacy providers allows a PBM to better control costs and quality. A PBM should design a network that meets the needs of enrollees and offers convenience, although obviously not every pharmacy can be in a network. The strategy of developing tightly controlled networks of pharmacies is somewhat limited by legislative action in many states. More than 20 states have adopted “any willing provider” (AWP) laws, which require PBMs and plan sponsors to allow any pharmacy that meets the PBM's maximum reimbursement rate to participate in its network. In essence, these requirements make it easier for PBMs and plan sponsors to eliminate pharmacies or pharmacy chains that are unwilling to participate at a desired targeted discount rate.

Ensuring Quality

Q 16:67 What factors influence the cost of the prescription benefit?

The cost of a prescription benefit depends on a variety of factors. First, the demographics (age and gender) of the population drive the disease mix that is being treated. Second, benefits, copays, and formulary design drive what is covered in the plan. Third, drug cost and the mix of branded products covered by the benefit drive the cost of drugs. Drug mix is a factor of the preferred drug list, or the restrictiveness of the formulary. Rebates may mitigate some branded drug cost, particularly if 100 percent of the rebates are being returned to the plan. Preferred drugs may actually cost more on a monthly basis in terms of the cost of the discounted ingredient costs. But, after rebates, the “net” costs of the preferred drugs should always be less than the nonpreferred drugs within a therapeutic category unless the agent (a particular drug) is clinically superior. Fourth, the utilization of prescriptions, that is, the number of prescriptions, used by the members is the multiplier of drug cost. Fifth, the costs charged by the PBM and the PBM's ability to gain profit from retail and mail order discounts, rebates, and other programs should provide offsetting discounts to the cost of the program. PBMs can increase costs, however, if all earned fees and discounts are not returned to the plan sponsor. Sixth, other factors influencing the cost of a prescription drug plan are fraud (by pharmacies, patients, or physicians) and prescription misuse. Seventh,

the ability of the plan to manage costs has a definite impact on the cost of the benefit. Tightly managed plans always yield lower costs on a patient-by-patient basis than those of nonmanaged plans. As a result, union plans, which may be restricted by labor agreements, may have higher costs than nonbargained plans.

Table 16-1. Example of Rebate Payment

<i>Brand Name</i>	<i>Rx in quarter</i>	<i>Total Units (30 units/Rx)</i>	<i>Market Share</i>	<i>National Market Share</i>	<i>Ingredient Cost/Rx</i>	<i>Rebate</i>
Drug A	116	3,480	3%	15%	\$91.00	
Drug B	1,951	58,530	50%	40%	\$109.00	
Drug C	1841	55,230	47%	35%	\$119.00	
Drug D	2	60	0%	10%	\$70.00	
Totals	3,910	117,300			\$442,434	

Q 16:68 What role do prescriptions by mail play in the prescription drug plan?

A mail service component in a prescription drug plan allows patients to obtain prescription drugs by mail. Mail service prescriptions are typically used for chronic conditions that require maintenance medications for long periods of time, like high blood pressure, asthma, or diabetes. Typically, 70 percent of all prescriptions fall under the category of maintenance medications. This service may save patients time and money and is a popular addition to the benefit design. Mail service pharmacies (MSPs) are staffed by a full complement of pharmacists and technicians, who ensure quality control and a high level of service. Mail service can typically save as much as 10 percent of the cost of traditionally delivered prescription drugs. In addition, most PBMs offer a toll-free customer service line (some with up to 24-hour coverage) to answer enrollees' questions about their prescription drugs. Prescriptions by mail also typically include newsletters or brochures about the specific diseases or conditions for which the medications were prescribed.

A mail service pharmacy is a revenue producer for a PBM, but it may not save money for the payer if copays are not structured appropriately. Studies have shown that the ratio of copays for mail to retail prescriptions must be at least 2.7:1 for the mail service to save money for the payer. Payers should analyze their costs to ensure that benefit designs do not inhibit the cost savings available from mail service.

Q 16:69 How do MSP programs compare to retail pharmacies filling maintenance prescriptions?

A constant battle rages between retail and MSPs over maintenance prescription business. Since the inception of mail service, retail pharmacies have fought to have mail regulated by each state, similar to retail outlet stores. MSPs have fought state regulation as being onerous because they do business in all states. According to a 2005 report from AHRQ, the percentage of mail-service users rose from 8.8 percent to 13.2 percent between 2000 and 2005. Yet the battle has heated up over mandatory mail service in PBM contracts. Several of the largest pharmacy chains, which also have mail service subsidiaries, announced that

they will not sign new PBM contracts that stipulate mandatory mail service from captive MSPs owned by the PBMs. These retail chains have promised discounts equal to those offered by the MSPs so that patients can receive their 60- or 90-day maintenance medications from their local pharmacies.

MSPs offer a lower cost of dispensing and quality control through automation that is uncommon in retail pharmacy. Many of the larger chain pharmacies, the Veterans Administration, and some multi-clinic pharmacies are using mail service to provide maintenance medications to their retail outlets with 24-hour turnaround times. This fulfillment practice has helped to mitigate some of the problems of pharmacist shortages and to reduce costs for retail pharmacies.

Q 16:70 Are prescriptions by mail safe?

Error rates in MSPs are at least equal to or, in most instances, below those of most retail pharmacies. A handful of leading PBMs offer state-of-the-art technology designed to improve efficiency and ensure safety. Among the techniques used to ensure safety are radio-controlled totes, a conveyor system that routes prescriptions to various stations, and intensive quality-control programs that ensure that prescriptions are filled efficiently and accurately. Another key to the quality and safety measures in MSPs is an imaging application that shows pharmacists on the computer screen the NDC number and the “image” of what the prescribed drug must look like. By carefully comparing the ready-to-ship product with the image on the screen, the pharmacist can confirm the content and thus ensure accuracy during filling operations.

The 2007 Mercer survey found that the median copayment for mail-order plans with three-tier copays is \$19 for generic drugs, \$48 for formulary brand drugs, and \$79 for nonformulary brand drugs.

Q 16:71 Why are MSP programs underused?

Typically, MSPs are underused because enrollees are not familiar with a plan's mail service benefit or are not sure how to access the service. Some patients with chronic conditions (e.g., asthma) are fearful of not receiving their medications in time. However, studies indicate that once enrollees are introduced to the convenience, simplicity, and safety of an MSP program, most express a high level of satisfaction with the plan. Industry analysts and the managed care pharmacy industry expect the mail service industry to experience tremendous growth in the next few years. They believe that, as millions of aging baby boomers begin to need more prescriptions, they will want to take advantage of the convenience offered by mail service. Yet, competition exists. Of particular note is the rise of 90-day point-of-service (POS) plans offered by retail pharmacy networks that provide competition to the mail service as they offer convenience, access, and comparable costs.

Q 16:72 Have any studies been done on the effectiveness of MSPs?

In the mid-1980s and early 1990s, the savings from MSPs were greater than they are at present. The Pharmaceutical Care Management Association (PCMA), which represents the PBM industry, cites numerous studies that conclude that managed care MSPs reduce overall prescription costs while maintaining and even improving quality. A Mercer study concluded that MSPs reduce a plan sponsor's total gross costs, despite minor increases in the use of their prescription drug program. The Boston Consulting Group obtained similar results. It found that “at the unit-cost level, [mail service pharmacy] plans offered savings of 30 to 35 percent on maintenance drugs over card and [major medical] plans.” A study by FIND/SVP observed a 26 percent difference in cost between a mail order prescription and a prescription reimbursed through a standard major medical plan.

In 2004, a 90-day POS competitive option was offered by many managed health care plans and some PBMs. The 90-day POS option offered retail network discounts of 16 to 18 percent off average wholesale price (AWP) with dispensing fees of \$0 or \$1. Pricing guarantees also contain the “lower of” U&C (usual and customary) language and MAC pricing. MAC and U&C pricing then make the overall effective rate close to average wholesale price less 18 percent with no dispensing fee. Mail service discounts have not

kept up with these changes in discounts in retail, therefore making the MSP not as financially beneficial as in the past. The increase in utilization is heightened when combined with therapeutic interchange programs (TIPs), which may switch maintenance medications that patients have been used to receiving in the retail program. A recent court decision against Medco Health Services has provided new rules preventing PBMs from switching medications without the patient's and their physician's consent, as well as the disclosure of any financial relationships that the PBM has with pharmaceutical manufacturers. Each plan should review their specific discounts and copay arrangements to determine if mail order is truly a cost-effective arrangement.

Q 16:73 How does a health care purchaser know if an MSP is right for its population?

MSPs are developed for any health care purchaser whose population uses maintenance medications. MSPs offer convenience for beneficiaries and may offer cost savings to plan sponsors. Good MSPs should also offer programs that add value for the sponsor and patient. The programs may include toll-free counseling with pharmacists, drug information mailed with every prescription, and health and wellness information as part of disease management programs.

Q 16:74 Do plans offer incentives to use a mail order program?

Yes. Some health plans have lower copays for mail order drugs; other plans offer a larger supply of the medication for the same copay; and still others offer larger supplies for lower copays. The backlash against managed care has had an effect on mail order programs. For example, a 1997 Missouri law bars HMOs from using benefit incentives to favor mail order drugs. Plan sponsors should structure copays to approximate the additional discounts obtained through the mail order program so that there is not a financial loss to the plan sponsor when members use the mail service program. Generally, copays should be at least 2.5 to 2.7 times the retail copays to obtain this balance.

Cost Management Concepts

Q 16:75 What can employers and health plans do to control pharmacy costs?

Many techniques are available to manage pharmacy costs. It is important to understand that although PBMs can offer programs and services to aid in managing prescription drugs, it is ultimately the responsibility of the plan sponsor to direct the PBM, design the plan coverage, and implement the programs that meet the plan's spending targets. The following is a list of techniques typically used by plan sponsors to control pharmacy costs:

1. Review the design of the pharmacy benefit and how it fits into the overall medical program. With flat dollar copayments that may not have increased in several years, many plans are subsidizing the cost of the pharmacy benefit by as much as 95 percent.
2. Analyze experience to identify areas needing better management. Typically, ulcer and depression therapy are the two most frequently dispensed medications. Ensure that a program is developed to help employees use those drugs properly.
3. Use the following pharmacy management tools and techniques:
 - a. Reduce the pharmacy network to the smallest size without compromising access; in addition, offer pharmacy incentive programs aimed at additional reimbursement for increases in generic substitution and formulary compliance to decrease cost trends.

- b. Offer mail service or 90-day retail POS prescriptions as a convenient option to members, rather than make mail service prescriptions a requirement, and make the copayments per day's supply equal in both retail pharmacies and mail order pharmacies.
 - c. Adopt a plan design that encourages generic drug substitution (where patients have to pay the difference between the cost of brand medication and the generic drug if the patient or the physician requires a brand).
 - d. Use a formulary that is designed to promote cost-effective and clinical therapeutic drugs coupled with a rebate program that passes 100 percent of the rebates to the plan sponsor.
 - e. Practice utilization management that targets high-cost users and intervenes with physicians and patients to ensure quality outcomes.
 - f. Offer physician profiling that highlights high-cost physicians with low-acuity patients coupled with an incentive program to dispense appropriate medications.
 - g. Health management programs designed to educate patients about alternatives to high-cost therapies.
4. Communicate cost trends to plan members to help them become better consumers.
 5. Anticipate the financial impact of new drugs and therapies and set policies and procedures for the new drugs before they are released.

Q 16:76 How is pharmaco-economic research being used to cut prescription drug costs?

Pharmaco-economic research can be used to determine the cost-effectiveness of pharmaceuticals, to design formularies, disease management programs, and pharmacy benefit programs. Such research can show plan sponsors which prescription drugs provide optimal therapeutic and cost values, with the goal of decreasing overall health care costs. For example, research may demonstrate that using a relatively expensive medication may be justified given its ability to decrease surgical treatment. Pharmaco-economic research may result in a decrease or an increase in actual prescription drug expenses, but it can contribute to a decrease in overall health care cost trends. Pharmaco-economic research can also use trends as a predictive tool to determine which patients are most likely to be high-cost patients in the future.

Utilization Management Concepts

Q 16:77 What is the role of utilization review in a managed prescription program?

DUR programs are designed to ensure that patients are taking medications that are appropriate for a particular condition and that will yield the optimum outcome.

Three types of DUR programs are available: concurrent, retrospective, and prospective. *Concurrent* DUR occurs at the point of service (i.e., the pharmacy) and flags potential overuse based on clinical monitoring criteria or “edits” that have been programmed into the PBM’s systems. These edits (referred to as “hard edits” because the claim will not be adjudicated until these edits are cleared) are for too-soon refills, duplicate claims, drugs requiring prior authorization, or quantity limits. These edits help eliminate overuse and abuse. Soft edits are also sent back to the pharmacist warning of drug/drug interactions. However, many pharmacists do not act on these edits because of the time needed to reach the patient and physician, and pharmacies are not routinely compensated for these cognitive services. In addition, in an effort to increase productivity, some retail chain pharmacy systems actually block these edits so that they are not viewable by pharmacists and technicians.

In *retrospective* DUR programs (pharmacy case management), pharmacists or nurses review patient

profiles to determine if patients are complying with their drug therapy or to suggest alternative therapies to their physicians that may be better or more cost effective. PBMs have been reluctant to offer these types of programs because PBMs are paid to fill rather than not fill prescriptions by plan sponsors (and drug manufacturers). Many PBMs refer to their therapeutic switching programs as retrospective DUR. However, therapeutic switching programs are aimed more at substituting one drug for another rather than determining if the therapy is appropriate.

Prospective DUR refers to educating physicians and patients about drugs or drug therapy. With the exception of a limited few, PBMs have not been successful at these programs or in cost justifying the return on investment. Many prospective DUR programs are funded by drug manufacturers.

Q 16:78 What are therapeutic interchange programs or therapeutic switching programs?

Typically a number of alternative prescription drug products are available to treat a particular health condition and are grouped together in a therapeutic class. For example, Tagamet, Zantac, Pepcid, and Axid are all drugs used to treat gastric ulcers or heartburn. Each of those products has a different chemical composition but has the same therapeutic effect in the body.

Therapeutic interchange programs (TIPs) are documented procedures for substituting one therapeutically equivalent product for another, with a goal of a more cost-effective medical outcome. The protocols are generally developed by a multidisciplinary group of physicians, pharmacists, and nurses. TIPs, when properly developed, executed, and communicated to physicians and patients, can be quite successful. Some PBMs have achieved close to a 90 percent success rate in moving patients to lower-cost therapies with TIPs.

Formularies

Q 16:79 What is a formulary?

In practice, a *formulary* is a list of drugs preferred by a health plan or PBM. A formulary is designed by a process of evaluation and analysis that is usually under the auspices of a pharmacy and therapeutics (P&T) committee. A P&T is composed of physicians, pharmacists, and nurses, who may be complemented by pharmacoeconomists, ethicists, the lay public, and plan administration. The P&T has the responsibility for evaluating all available evidence to choose medications to treat the conditions indigenous in the insured population. These deliberations consider all clinical and pharmacologic considerations first. Once the comparative effectiveness and safety of medications has been evaluated, economic considerations are reviewed to determine the most cost-effective medications of the clinically effective choices. The Academy of Managed Care Pharmacy (AMCP) has developed a standard format for drug dossiers to be submitted for P&T submission (see <http://www.amcp.org>). The development of a standard format is an evolutionary step in improving P&T deliberations, in ensuring that all available information is available for analysis, and that economic considerations are exhaustive and specific to the insured population.

If the P&T has determined that drugs within a therapeutic class are equally effective, a formulary selects drugs within the category that are most cost effective based on a combination of average wholesale price and rebates that manufacturers are willing to give to the PBM or plan. Although generic drugs may be listed on the formulary as preferred, formulary development typically centers on brand products. Some PBMs contract with generic manufacturers for rebates, although this practice is generally uncommon. It is critical for plan sponsors to ensure that they receive all earned rebates whether for brand or generic drugs.

When plan sponsors purchase formularies developed by health plans, PBMs, or TPAs, it is important for them to know who the representatives are on a PBM's formulary. Information should be available to the plan sponsor as to the composition of the P&T, their employers, and any relationships with pharmaceutical manufacturers in order to evaluate biases that these individuals may have toward any drug manufacturer.

Q 16:80 What is the difference between open, preferred, and closed formularies?

Open formularies allow plan enrollees any covered prescription drug prescribed for them. Open formularies traditionally have been quite popular with physicians and patients, who perceive that open formularies offer freedom of choice; however, since most physicians are familiar primarily with only the handful of prescription medications they use most often, formularies—which typically include hundreds of possible medications and several options per category—actually give physicians and patients the chance to make better-informed choices. In an open formulary environment, the list of preferred drugs is distributed to patients and physicians for informational purposes only.

Preferred formularies have become quite popular in the last several years. Preferred formularies encourage patients to use the preferred or formulary drugs in return for a reduced copayment. For example, generic drugs may require a \$5 copayment, preferred brands a \$10 copayment, and a \$25 copayment for nonpreferred drugs (referred to as three-tier copayments). Although not as popular with patients and physicians as an open formulary, most patients and their physicians can find effective drugs on the preferred listing.

Closed formularies often meet with resistance from plan enrollees. They simply mean that the plan will not cover the nonformulary drug. Employers typically do not use these types of formularies. Tightly managed HMO programs may use a closed formulary. Closed formularies are typically found in hospital settings.

Q 16:81 Where are open, preferred, and closed formularies most commonly found?

Open and preferred formularies are more prevalent in self-funded plans, while closed formularies are more frequently used in tightly managed HMOs. The use of formularies is growing because formularies, particularly preferred formularies, are very effective at moving patients to lower-cost drugs and maximizing rebate potentials.

Q 16:82 Are there any advantages to formularies?

The primary advantage to introducing formularies is to reduce costs and to encourage patients to use the most effective medication within a therapeutic class. Formularies also help educate patients and physicians about cost-effective alternatives to expensive brand medication.

Q 16:83 Are there any disadvantages to formularies?

One of the primary drawbacks to formularies is the constant communication to physicians and patients that is necessary regarding the current list of preferred products. Formularies differ depending on the health plan, PBM, or TPA that developed and maintain them. There may also be multiple formularies within each health plan, PBM, or TPA for different clients, such that not a single source exists that references “all preferred products.” Therefore, when a PBM changes its formulary and does not communicate those changes to members, members may become dissatisfied because their copayment may differ from what they had expected. Members and physicians may also resent having to limit selection within the therapeutic class in order to obtain the lowest copayment option.

Q 16:84 Do PBMs have influence over their formularies?

Yes. PBMs have a great deal of influence over the development and management of formularies. Plan sponsors frequently defer to the formularies developed by the PBM's P&T committee, the drug experts whose decisions are based on safety, efficacy, utilization, prescribing patterns, and cost. Plan sponsors need

to review the policies and decisions of the P&T to ensure that they meet the specifications of the plan's benefit.

Q 16:85 Which drugs are typically excluded from formularies?

It is important when answering this question not to confuse benefit coverage with formulary coverage. Typically, certain types of drugs are completely excluded from benefit coverage, including drugs used for cosmetic purposes (e.g., Rogaine for countering hair loss), OTC products (e.g., Tylenol), and drugs classified as experimental by the FDA. In addition, products such as vaccines and other injectables may be covered under a medical benefit rather than a separate prescription benefit.

Formularies may overlap benefit coverage, depending on the type of formulary being used. In a preferred formulary, drug products not listed on the formulary may still be considered a covered benefit, perhaps with a higher share of the cost borne by the beneficiary. In a closed formulary, drug products not listed are typically not part of the benefit coverage. If the physician prescribes a nonformulary product, the beneficiary would be responsible for the entire cost of the medication.

Q 16:86 How do PBMs get physicians to support a formulary?

Patients continue to look primarily to their personal physicians to recommend prescription drugs. With the plethora of formularies in the community, physicians frequently treat patients covered by 12 to 15 formularies or more on a daily basis. The task of remembering all these formularies is clearly beyond the ability of any health care professional. As a result, health plans, PBMs, and plan sponsors provide paper and electronic copies of their formularies for physician use. In actuality, physicians remember drug formulary coverage for the most frequently seen patient populations, and they expect pharmacies to contact them if they prescribe medications that are not on specific formularies. The advent of personal digital assistants (PDAs) has allowed formularies to be downloaded to these mobile products. Plan sponsors should evaluate the companies that perform these services to ensure that they are not unduly influenced by mass media marketing campaigns or pharmaceutical manufacturers.

The physician can help to enlighten a patient about a change in prescription drugs recommended by a PBM, or the physician can choose not to communicate appropriately and possibly instill fear and bewilderment in a patient when drugs are changed; therefore, it is imperative that health plans, PBMs, and TPAs place a great deal of emphasis on developing a cooperative relationship with physicians.

One of the most controversial tools to encourage physicians to support formularies is the therapeutic interchange program (TIP) or therapeutic switching program. Under a TIP, pharmacists contact prescribers to discuss more cost-effective therapeutic alternatives. Often, the TIP is combined with visits from pharmacists and educational seminars. In order for TIPs to have credibility, the programs must be based on evidence-based medicine, and there must be full disclosure of financial relationships affecting the choices of medications.

Some PBMs are particularly effective in communicating to physicians. The major publicly held PBMs have pharmacists across the United States whose primary responsibility is to meet with physicians to explain the formulary and review specific changes for specific patients that would result in increased use of preferred products.

Q 16:87 Are formularies usurping the role of physicians in prescribing medicine?

Physicians, pharmacists, and PBMs must work together to provide a prescription drug program to plan sponsors that yields optimal results. A well-managed formulary does not dictate what drugs a physician can

and cannot prescribe. Instead, the PBM works with the physician to help educate him or her about the myriad prescription drug options available and the cost associated with each. For example, the difference in cost between the lowest and highest cost branded medications in the same therapeutic category may be 50 percent or more. The question to be asked is whether a 50 percent clinical improvement exists between the lowest cost brand and the more expensive therapeutically equivalent drug. Often, physicians are unaware of this cost. Giving physicians all the facts about a particular prescription medication helps them make reasonable and appropriate prescription decisions for their patients. In addition, many formularies will encourage physicians to return to previous medications if desired results are not being achieved with a newly suggested drug.

Q 16:88 Are there ways to manage costs even without a closed formulary?

Formularies are only one tool in the management toolbox. At best, formularies may save about 15 percent in drug costs. Other cost-management methods, discussed in this chapter, include:

- Network management, better discounts with retail and mail order programs, and monitoring performance to avoid fraud and abuse;
- Designing plans that meet the objectives of the overall benefit program;
- Quantity limits and maximum dollar limits on all prescriptions;
- Step-therapy programs to ensure that prescribing complies with national guidelines for treatment of particular diseases;
- Prospective review of new drugs and early policy determination;
- Clinical management through a thorough pharmacy case management program;
- Other DUR programs, such as concurrent and prospective programs; and
- Quality data management that provides early intervention reporting.

Q 16:89 Why do formularies engender such controversy?

Formularies typically meet with resistance because plan sponsors, enrollees, and physicians mistakenly believe that they are being asked to sacrifice therapeutic efficacy in order for the plan sponsor to save money.

Recent consolidations in the PBM industry have also caused concern among consumer advocates, physicians, and the pharmaceutical industry in general. The Federal Trade Commission has voiced strong concern over alleged improprieties by drug manufacturers, which involve promoting the manufacturer's brands on the formularies of PBMs. Plan sponsors and formulary development panels should ensure that specific drugs included on formularies are balanced, keeping the needs of enrollees and the goals of the plan sponsor in mind.

Q 16:90 How do new drugs affect formularies?

In the first half of 2008, the FDA approved 24 new drugs and 6 biologic agents. These numbers are much lower than those in previous years. For example, in 2002, the FDA approved 78 new drugs and 7 biologic agents. Then in 2006, the FDA approved 53 new drugs and 5 biologic agents. Many of the new drugs treat illnesses that could require lengthy hospital stays or that were previously untreatable. Some of the newly released drugs are simply targeted to take market share away from a leader such as Nexium, which used to treat gastrointestinal diseases. Drugs considered breakthrough drugs should be included on a formulary to provide quality patient care and possibly control costs. Drugs added to formularies should clearly benefit the covered population. Formularies should be reviewed at least quarterly to ensure that new drugs are properly placed on or off the preferred list.

Prior Authorization Programs

Q 16:91 *What is a prior authorization program?*

A *prior authorization (PA) program* restricts coverage under the plan of certain drugs based on the patient's conditions and maximizes the outcome of the medication. Under this program, the physician must call into the entity that is administering the PA program (typically the PBM or health plan). The physician answers questions about the patient's condition and based on the information, the drug will either be covered under the plan or not. For example, some plans limit coverage of Celebrex (a COX-2 inhibitor), indicating that the patient needs to try another pain medication before using Celebrex as well as having the diagnosis of rheumatoid arthritis. Many drugs that are subject to PA programs have monthly costs that range from \$250 a month to \$2,000 a month. Some drugs also have quantity limits (see below) in addition to a PA requirement. Drugs that are typically subject to PAs are:

Actimmune

Actos

Alferon

Arava

Atacand

Atacand HCT

Avalide

Avandia

Avapro

Avita

Avonex

Axid

Betaseron

Calcitonin

Caverject

Copaxone

Cozaar

Demerol INJ

Differin

Diovan

Diovan HCT

Edex

Enbrel

Epogen

Evista

Genotropin
Growth Hormone
Humatrope
Hyzaar
Infergen
Intron A
Kytril
Lamisil
Leukine
Miacalcin
Micardis
Micardis HCT
Migranal
Muse
Neupogen
Norditropin
Nutropin
Procrit
Proscar
Protropin
Pulmozyme
Rebetron
Remicade
Renagel
Retin-A (and generic forms)
Revia
Roferon-A
Sandostatin
Serostim
Sporanox
Teveten
Tricor
Viagra
Zocor
Zofran

Q 16:92 Have studies been conducted that support the effectiveness of prior authorization programs?

Very few studies have been conducted to determine the overall effectiveness of PA programs. Yet health plans, PBMs, and TPAs claim that PA programs are very effective both at controlling costs and ensuring quality. A study of five Medicaid PA programs was commissioned by the Kaiser Foundation. This study found that the number of medications covered by PA programs varied from 20 to more than 3,000 drugs. Regulation and monitoring were minimal, and there was limited monitoring of the effects on beneficiaries or providers except in Oklahoma. The study concluded that PA programs were more effective and less controversial when developed with local provider input. Since most PA programs are developed by health plans or PBMs that are far removed from local input, it is necessary for plan sponsors to require evidence of the effectiveness and return on investment (ROI) of these programs.

Q 16:93 What are *quantity limits*?

Quantity limits (QLs) are predefined maximal quantities for specific medications. QLs restrict the number of dosage units (e.g., tablets, capsules) that can be dispensed for a 30-, 60-, or 90-day supply of a prescription. QLs were originally established to ensure that certain medications could not be abused or overused. At the same time, quantity limits help to improve compliance with medication therapy. Instead of taking lower strengths of a drug more frequently, quantity limits prompt patients to obtain higher doses less frequently. For example, instead of taking 5 mg. of Zyprexa twice a day, the patient takes 10 mg. of Zyprexa once a day. While these programs improve compliance, they also lower costs.

In addition, QLs refer to limiting the number of tablets to what is considered a typical 30-day or 90-day supply. Some drugs have both a PA requirement and a QL. One of the more “famous” drugs in this category is Viagra. Most plans require a PA for Viagra and limit the coverage to six tablets per month.

Disease State Management

Q 16:94 What are *disease state management programs*?

Disease state management programs (DSM programs) were developed to measure and manage all health care outcomes and costs associated with a particular disease (e.g., asthma) across the entire continuum of health care delivery. Costs associated with treating and managing many diseases include physician visits, emergency room visits, hospitalization, lab expenses, and pharmacy expenses. The goal of DSM is to decrease the total costs associated with treatment of the disease. This can be accomplished by managing the individual component costs, such as hospital or pharmacy services, that affect the total cost. DSM programs may indicate that, for example, increasing expenses for drug therapy helps to decrease emergency room visits, which results in an overall decrease in health care costs. According to the 2007 Mercer survey, 67 percent of employers with 500 or more employees already offer some form of DSM program. Programs for diabetes, heart disease/hypertension, and asthma are the most common. According to the 2008 UBA survey, 47.6 percent of all employers offer DSM programs.

Two types of DSM programs are offered: the medical model and the therapy directed model. The medical model consists of call centers staffed by nurses and their assistants to triage patients to appropriate levels of care. These centers follow up on patients with select diseases to ensure that the patients are scheduling physician appointments, receiving appropriate tests and procedures, and understand the importance of taking their medications. The therapy model is directed by PBMs, pharmaceutical manufacturers, health plans, and disease management companies. These entities foster improved compliance with medication therapy, patient education, and testing for outcomes of care. Critics argue that both models have no standardized methods to judge success, and ROI.

DSM programs have, in the last five years, come under careful review by some plan sponsors. Critics have argued that these programs are thinly veiled “advertisements” from the drug manufacturers (as in

information distributed to patients of mail order firms) rather than actively managed DSM programs. In addition, most PBM DSM programs have a financial interest in increasing consumption of low-cost prescription drugs that treat, for example, asthma and diabetes, rather than high-cost prescription drugs that treat depression, pain, or ulcers, for example.

Q 16:95 Can disease management offer real value to plan sponsors?

Disease management became one of the most popular health plan design options of the 1990s. Whether focusing on diabetes, cancer, maternity, or cardiology, a growing number of drug manufacturers work with PBMs to target enrollees with certain diseases. The strategy behind disease management is that, by concentrating on specific diseases with targeted medications, the PBM will be able to lower costs and improve outcomes. Although disease management holds promise, it is important to ensure that the program does more than simply target prescription drugs to treat the disease. To function optimally, disease management should focus on the full spectrum of treatment options available to treat the disease, not just prescription drugs.

According to the MEDSTAT Group, nine diseases (asthma, breast cancer, diabetes, heart failure, hypertension, ischemic heart disease, low back pain, otitis media, and peptic ulcer) make up about 20 percent of all health costs. Critics of DSM programs argue that these diseases are “low hanging fruit,” in that treatment for these diseases can be easily improved with compliance and education programs to properly use medications. They argue that the benefits of these programs are front loaded, in that the benefits are achieved with initial interventions, and further clinical improvements and cost reductions are marginal, or at best, incremental.

PCS Health Systems (now CVS/Caremark) reported that after introducing an information program aimed at physicians and patients, emergency room usage declined 58 percent for asthma and 27 percent for diabetes. Inpatient hospital costs for asthma also declined 38 percent, but costs for diabetes only declined 1 percent. Although this study holds promise, other PBMs have had more difficulty in proving the value of information-only programs.

Q 16:96 How are employers and health plans using disease management to cut prescription drug costs?

Employers and health plans are working with PBMs to introduce programs that will help manage health care costs related to a disease by optimizing the use of pharmaceuticals available. DSM programs offered through PBMs may increase, decrease, or have no effect on prescription benefit costs. The important measure of a DSM program is its effect on total costs related to the disease.

Medication compliance programs are an ideal way to help patients get the most benefit from the medication prescribed for them. It is estimated that \$100 billion in annual health care costs can be attributed to patients seeking care in emergency rooms, physicians' offices, and operating rooms as a result of not taking prescribed medication or of taking it improperly. In addition, working directly with physicians, PBMs can provide pharmacoeconomic information to physicians that can assist them in prescribing cost-effective medications.

Q 16:97 How can a purchaser evaluate DSM programs?

The May/June 1997 issue of *Journal of Managed Care Pharmacy* suggested the following evaluation tools:

1. Health care should be emphasized, not therapeutics.
2. Provider network support must be available.
3. Programs should include member education and motivation elements.

4. The delivery system should be integrated.
5. There should be a clearly defined system for organization and management.
6. There should be well-defined contractual criteria, including performance criteria.
7. A program for information management should be included.
8. There should be a well-defined program for measuring outcomes.
9. The economic impact must be well defined.
10. Any risk sharing should be based upon an actual risk assessment.
11. There should be a clear understanding of whether the program is a strategic partnership or a service offering.
12. There should be a clear evaluation of the total quality management (TQM) impact as an expectation or added value.
13. There must be performance audits and service guarantees, if applicable.

Quality Management/Oversight

Q 16:98 *What is evidence-based medicine?*

Evidence-based medicine (EBM) is an approach to medical decision making that emphasizes scientific evidence and statistical methods for evaluating outcomes and risk of treatments. EBM is at the center of formulary development, DUR, and comparative evaluations of cost-effective therapies. EBM is the response to the enormous volume of information available for diagnosis and treatment of disease. It is also a response to arrive at objective decisions in the face of mass media advertising, direct-to-consumer advertising of drugs, and the promotions of pharmaceutical and device manufacturers. EBM requires standard data submissions and statistical evaluations to ensure that all medical decisions are supported by objective information.

Q 16:99 *How do PBMs identify duplicate prescriptions?*

Pharmacies submit prescription claims electronically at the time the prescription is filled. A PBM's data center, or central clearinghouse, compares the submitted prescription with the patient's prescription profile. If a duplicate prescription exists, the pharmacy is notified immediately before the prescription is dispensed. Duplicates are generally defined as a drug dispensed to the same patient on the same day in the same therapeutic drug category.

It is fairly easy to track duplicate claims since PBMs use some of the most advanced and sophisticated software programs available. Software programs are available that identify the same drug dispensed to the same member by the same pharmacy. Concerns come into play when a generic of the originally dispensed brand-name drug is dispensed by multiple pharmacies.

With the support of retail pharmacists, duplicate dispensing can be prevented, and prescription abusers can be stopped.

Q 16:100 *What error detection and reporting programs are available?*

As part of the DUR process conducted by health plans, PBMs, and TPAs on behalf of their clients, a variety of clinical monitoring criteria or "edits" are applied to each submitted claim. An example would be a drug-to-drug interaction edit. If a potential harmful drug-to-drug interaction exists, the pharmacy is notified online. Identifying these potential problems is very important: between 10 and 25 percent of all

hospitalizations are estimated to be due to drug therapy problems. Some PBMs may provide clients with reports documenting the number of edits that were executed on behalf of these clients. The reports are helpful in identifying physicians who might not be properly reviewing a patient's history before prescribing medications.

Q 16:101 How is electronic data interchange being used to review prescriptions?

In today's environment, approximately 99 percent of all prescriptions paid by plan sponsors are processed electronically. The pharmacy enters vital patient and prescription information into the computer and transmits the information to a data center typically operated by a PBM. The PBM applies a variety of criteria in evaluating the prescription submitted, including determination of whether the drug is covered, at what price the pharmacy will be reimbursed, and if there are any limits or edits for the prescription. Information is transmitted back to the pharmacy that allows the pharmacist to fill the prescription or that informs the pharmacist of a potential conflict.

Q 16:102 What is *point-of-dispensing*?

Point-of-dispensing allows doctors to dispense certain drugs from their offices. This is common in workers' compensation insurance programs. The drugs dispensed are the most frequently prescribed medications that can be conveniently stocked. They are also usually medications to treat acute symptomatology rather than chronic conditions.

Typically, a computer provides the physician access to a variety of information, allowing the doctor to check for allergies, duplicate therapies, and drug interactions, while verifying that the product is on the formulary. Very few physicians have this capability. Currently, there is debate in the industry as to who will pay for the physicians to adjudicate the claim electronically. Physicians want to be paid for these services, since retail pharmacies are paid a dispensing fee for this same service. Plan sponsors believe it is the duty of the physician to research a conflict before prescribing the medication. PBMs and drug manufacturers have so far been unwilling to fund this activity.

Q 16:103 Can PBM enrollees go anywhere to have their prescriptions filled?

It depends on how the plan is designed. Typically, to receive coverage, employees participating in a prescription drug program must have their prescriptions filled by a network pharmacy, except in emergencies. However, some plan sponsors will pay for prescriptions filled outside the network, but may reduce reimbursement up to what would have been paid had the member gone to a participating pharmacy. Pharmacies join networks and provide services at reduced rates in exchange for volume business. It is up to the PBM to design a network that meets the needs of enrollees and is convenient and acceptable. A tight network of pharmacy providers allows PBMs to control costs and quality effectively.

Q 16:104 Can any size company participate in a prescription drug program?

Almost any size company can participate in a prescription drug plan. Until recently, only large self-funded companies, HMOs, and trust funds had the number of members (typically more than 2,000 members) that PBMs were willing to contract for discounts and develop appropriate programs. However, with the growth of coalitions, companies with fewer than 2,000 employees can usually find a way to enjoy the benefits of a prescription drug program. Some smaller employers should be cautious when totally self-funding the risk of prescription drugs; one large catastrophic case could be too large an expenditure. Reinsurance is typically available through numerous stop-loss carriers.

Q 16:105 Besides lower costs, how can the quality of a prescription drug plan be measured?

In addition to cost savings, plan sponsors should work with their PBM to develop specific, attainable goals for prescription drug plans. One goal might be the reduction in the utilization of anti-inflammatory medications (such as Celebrex) and the increased use of therapeutically equivalent OTC medications that plan sponsors may want to consider covering in limited quantities. An increased focus on enrollee educational programs such as exercise and smoking cessation, which can help diminish dependence on prescription drugs, might be another goal. Employers and other health plan sponsors should become actively involved in all elements of the pharmacy benefit to ensure optimal results.

Q 16:106 Are prescription drug plan satisfaction rates a valid way to measure the quality of services offered by a PBM?

Surveys of satisfaction rates can be quite subjective. The results can depend on variables such as wording of questions, recent changes in benefits design, and how often prescription benefits are used. For example, a 1995 study conducted by Care Data Reports, Inc., a managed care information company, reported that 70 percent of 10,272 employees at 81 companies in 5 regions nationwide were “extremely” or “very satisfied” with their prescription drug benefits. A similar study, also published by Care Data Reports, reported, however, that seniors in Medicare risk programs had a much higher satisfaction rate. These seniors, who used their prescription benefit much more often than the consumer population, were “extremely” or “very satisfied” with their prescription benefit 85 percent of the time. This is not to say that plan sponsors should not expect their PBMs to provide customer satisfaction surveys as a measure of quality service; however, it may be best to develop customized questionnaires specifically tailored to the needs of the plan sponsor and to update them periodically as the plan matures. In most cases, satisfaction rates increase as enrollees become familiar with the parameters of their plan. If the satisfaction rates do not rise, benefit administrators should discuss ways to improve the level of satisfaction with the benefit with their PBMs.

The Pharmacy Benefit Management Institute (PBMI) publishes an annual survey of the satisfaction of plan sponsor regarding their PBMs. Typically, the largest PBMs are evaluated by their clients. Results of the surveys can be viewed on PBMI's Web site, <http://www.pbmi.com>. Overall satisfaction has declined in the industry according to the latest survey results. As PBMs and their plan sponsors mature, and as prescription drug costs increase, there has been more discontent in the industry.

Q 16:107 How has HIPAA affected prescription drug programs?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires plan sponsors to fully disclose entities that retain information regarding a covered member's prescription drug data. This requirement extends to the PBM and any subsidiaries or subcontractors of the plan or PBM. Patients must be better informed as to what entities may review their personal prescription drug information and be better informed as to how such data are being used.

Q 16:108 How does HIPAA change the interaction of pharmacies with their patients?

Pharmacies must provide private counseling areas to protect the privacy of their customers. In addition, pharmacies are requiring signature logs to ensure that customers are informed of their rights and consent to the services that the pharmacy provides. In some cases, message boards in pharmacies have changed to remove patient names and display only numbers for customer pick up of their prescriptions. When

pharmacists are unfamiliar with patients, they are also requiring patient approvals for family or friends to pick up their prescriptions. In some cases, physicians are refusing to refill prescriptions without seeing their patients first. There are also concerns among pharmacists and physicians that patient-specific data violates HIPAA guidelines, even when such data are used for payment, or organizational case management, disease management, and utilization review.

All of the above are sources for member complaints and customer service problems. Plan sponsors should ensure that health plans, PBMs, and TPAs are adequately communicating with their pharmacy networks to minimize HIPAA-related privacy concerns.

Pharmacy Issues in Workers' Compensation Insurance

Q 16:109 What makes the prescription adjudication of a workers' compensation (WC) prescription different from a group health prescription?

The existence of different rules of coverage and payment of claims within each of the states' jurisdictions adds a level of complexity to the administration of WC claims that is not common in group health.

To lower the cost of prescription drugs, pharmacy vendors (i.e., PBMs, TPAs) have traditionally offered a discounted network of pharmacies. The pharmacy vendor acts as a "middle man" to adjudicate prescriptions, ensure that the prescriptions are paid only for eligible injured workers, and that pharmacy prescriptions are within the scope of the injury. A constant concern has been, and continues to be, "first fills" for prescriptions before eligibility is verified, the adjudication of prescriptions dispensed by physicians, and prescriptions re-priced and aggregated for payment by third-party payers.

Traditional PBMs and pharmacy benefit administrators (PBAs) are expanding the service offering through enrollment cards, online claim administration, prospective DUR, formularies when applicable, screening for prescriptions within the scope of the injury, and enhanced reporting. The result is that WC is becoming a commodity offering that is a subspecialty of the mainstream vendors. The following discussion provides an inventory of offerings that should be used when choosing vendors and their experience with WC. [Craig S. Stern, Workers' compensation pharmacy vendor contracts, *Healthcare Savings Chronicle*, Vol. 5, Issue 4, April 2007]

Q 16:110 What is the difference between a PBM and a PBA?

PBMs offer prescription adjudication, knowledge of prescription administration in various jurisdictions, enrollment cards, quality oversight of prescriptions through DUR and clinical edits, and further cost control through cost-effective formularies. In addition, they offer the ability to screen all prescriptions against the applicable diagnoses of each injured worker. Rebates are offered as cost offsets. These services are common and generally undifferentiated across the industry.

In contrast, PBAs focus on prescription administration. Most offer a discounted a pharmacy network, formularies, DUR edits that can be applied at the time of prescription adjudication, enrollment cards, and screening of prescriptions to ensure that they are within the scope of the injured workers' diagnoses. They emphasize "transparency" in adjudicating prescriptions such that the payer knows the actual cost of the prescription from the pharmacy, and actual rebates earned and collected.

Aside from transparency issues, the payer will have to decide how much support they require—the PBM provides all services, while a PBA may require more of the payer's time and input. Both will require the payer to continue usual oversight functions, such as accounts payable review of invoices, quarterly (or more frequent) review of progress, and final judgments on prior authorizations. *The key question for the payer is whether the additional services offered by the PBM provide sufficient value to the organization to be worth the additional cost premium over the PBA expense.* [Craig S. Stern, Workers' compensation

pharmacy vendor contracts, *Healthcare Savings Chronicle*, Vol. 5, Issue 4, April 2007]

Q 16:111 What are the key questions that should be asked of a PBM or PBA when deciding on the right vendor to adjudicate WC prescriptions?

When reviewing request for proposals (RFPs), contracts, or even evaluating current services, the following issues should be considered as part of contract negotiations:

- *Knowledge of Workers' Compensation*
 - Experience with WC
 - Experience with adjudicating claims in various jurisdictions
 - Compliance with Sarbanes-Oxley disclosures.
- *Pricing Questions*
 - Pricing language regarding “lesser of,” and the impact of AWP discounts, MAC, state fee schedules, and usual and customary pricing
 - Management of third-party prescriptions
- *Claim Administration Questions*
 - Management of physician-dispensed prescriptions
 - Management of customized formularies when allowed
 - Management of prescriptions to ensure that they are within the scope of the injury
- *Service Portfolio, Delivery, and Guarantees*
 - Management of eligibility
 - Prescription administration policies and procedures that comply with claim management
 - Service and performance guarantees must be provided
 - Audit policies consistent with the WC carrier and Sarbanes-Oxley requirements

More than ever, WC now has the opportunity to look more closely at quality issues and has greater clinical edit oversight with the expansion of vendor offerings for WC in the prescription payment arena. With greater offerings come choice, vendor price competition, and expansion of offerings. It is crucial, however, that the pharmacy expense is viewed as one component within the context of the entire claim review. This can only help WC to improve over time. [Craig S. Stern, Workers' compensation pharmacy vendor contracts, *Healthcare Savings Chronicle*, Vol. 5, Issue 4, April 2007]