

Maintaining the Affordability of the Prescription Drug Benefit: How Managed Care Organizations Secure Price Concessions from Pharmaceutical Manufacturers

Introduction

The purpose of this paper is to explain how managed care organizations (MCOs) are able to secure lower drug prices from pharmaceutical manufacturers as part of an effort to control drug expenditures. This paper describes the methods MCOs use to concentrate their purchasing power to acquire the least expensive therapeutically safe and effective drugs that are appropriate for the majority of patients, while allowing use of alternatives for individual patients with special medical needs. The paper describes the discounting and contracting practices commonly used between managed care organizations and pharmaceutical manufacturers to achieve these ends.

MCOs include health plans, health maintenance organizations (HMOs), pharmacy benefit managers (PBMs), preferred provider organizations (PPOs), integrated care organizations (ICOs) and insurance plans. Health plans are specific types of MCOs that finance and either directly provide health care to enrolled members through their own facilities and staff, or indirectly through contracted providers of care.

An MCO is able to provide drug benefit coverage based on payments from two sources:

- Plan sponsors that pay a pre-determined amount per month as a premium for drug coverage insurance or reimburse for individual prescription costs, and
- Patients who pay a portion of the cost of the benefit through co-payments, co-insurance, and deductibles.

Plan sponsors include employers, unions, trust funds, associations and government agencies, and are also referred to as payors.

Successful efforts by managed care organizations to lower drug expenditures usually save money for both plan sponsors who pay the premiums and for patients, and ultimately should help to ensure the affordability and sustainability of the benefit coverage.

Pharmaceuticals play an increasingly important role in the prevention, cure and management of disease. At the same time, expenditures for drugs have been and are expected to continue to increase at rates higher than or comparable to expenditures for other health-related products and services. Prescription drug spending is projected to increase by 10.7 percent per year between 2004 and 2013.ⁱ Figure 1 demonstrates 10-year spending trends for hospitals, physician services and pharmaceuticals.

(Figure 1.6, Annual Percentage Change in National Spending for Selected Health Services, 1994-2004, from Trends and Indicators in the Changing Health Care Market Place: Section 1, accessed at www.kff.org/insurancel7031)

Increases in expenditures for prescription drugs are attributable to three broad categories: increased utilization, higher costs for new medications and escalating prices. Figure 2 illustrates the impact of each of these components on increased spending for pharmaceuticals.

(Figure 1.17, Relative contributions of Utilization, ..., 1997-2002 from Trends and Indicators in the Changing Health Care Market Place: Section 1, accessed at www.kff.org/insurance/7031)

With more than 200 million Americans currently receiving their health care through managed care organizations, the role of managed care pharmacy in maximizing the value of pharmaceuticals is significant. With the implementation of Medicare Part D, the number of lives affected by managed care pharmacy programs will increase dramatically as more Medicare beneficiaries access drug benefits.

The goal of managed care organizations' drug coverage programs is to provide appropriate, affordable and accessible prescription drug benefit coverage so that positive patient outcomes are achieved. The challenges in meeting this goal, however, are numerous and complex. Managed care drug benefit coverage programs routinely use a variety of tools and strategies, frequently in tandem, to achieve the goal of managing costs for consumers and plan sponsors, including:

- Establishing formularies or preferred drug lists so that purchasing resources can be concentrated on making appropriate drugs available to most MCO members, while allowing for medically necessary alternatives for selected patients.
- Negotiating volume discounts and implementing maximum allowable cost (MAC) pricing with retail and mail order pharmacies to provide MCO members with convenient access to pharmaceuticals
- Working with prescribers to ensure they are using drugs appropriately based on sound scientific evidence and principles
- Promoting the use of appropriate generic products. Such generics must be determined by the Food and Drug Administration (FDA) and/or the MCO to be as safe and effective as the original product and interchangeable with it. Most MCOs structure their prescription drug coverage to promote the use of generics because they usually offer greater value
- Implementing disease management and medication therapy management programs designed to improve the quality and efficiency of patient care
- Implementing medication evaluation policies and systems such as drug utilization review, prior authorization and quantity and dosage management to ensure high quality, medically safe and effective therapy and cost efficient use of prescription drugs
- Negotiating contracts with pharmaceutical manufacturers to obtain lower drug prices

While most of the managed care tools identified above can be used to reduce the cost of pharmaceuticals, the focus of this paper is on contract arrangements between manufacturers and MCOs that directly result in lower costs, as well as understanding concepts related to the purchase of pharmaceuticals. (For information on other managed care pharmacy tools see AMCP's [The Value of Pharmaceuticals and Managed Pharmaceutical Care](#)ⁱⁱ [Principles of a Sound Drug Formulary System](#)ⁱⁱⁱ

the Concepts in Managed Care Pharmacy series of Formulary Management^{iv}, Drug Use Evaluation^v, Prior Authorization and the Formulary Exception Process^{vi}.)

In many ways, managing the cost of pharmaceuticals is comparable to how costs are managed by each of us as individuals in every day business and family life when securing the lowest possible net cost is typically a primary objective. The following are among the most commonly encountered examples:

- Concentration, e.g. “frequent buyer” cards and purchase commitments
- Discounts, e.g., “specials” and “sale” items at the grocery store
- Bulk purchases, e.g., purchases at large warehouse-type retailers where the typical size of the product might be two or three times as large as at a more conventional retailer
- Rebates, e.g., when buying a car or electronics

Similar opportunities exist for MCOs and other purchasers of health care services and products, including pharmaceuticals. As is the case in any other business setting, MCOs routinely seek savings and lower pricing by utilizing contractual commitments that secure better prices through discounts, bulk purchasing and rebates for both goods and services. For example, health plans negotiate contracts with hospitals, physicians and clinics that provide services to their members, with pharmacies that fill members’ prescriptions, and with pharmaceutical companies that produce the drugs used to fill members’ prescription orders.

The Cost of Pharmaceuticals – Discounts and Bulk Buying

MCO members have access to prescriptions primarily through three distribution alternatives: staff model pharmacies, mail order pharmacies and network pharmacies. Mechanisms that can be used to achieve lower drug costs within each of these avenues are outlined below.

Distribution Alternatives

- **Staff Model Pharmacy Organization**

The least common distribution alternative is a pharmacy wholly-owned and operated by an organization for use by its employees or members. Examples include health plans such as Kaiser Permanente, Group Health Cooperative and Harvard Pilgrim, and government agency programs operated by the Department of Defense and the Department of Veterans Affairs, or a private entity. Typically a pharmaceutical manufacturer or wholesaler contracts directly with the staff model pharmacy organization. All products are shipped directly to the pharmacies or in bulk to the pharmacy organization’s own warehouse. By thus reducing the cost and risk to the supplier, the MCO may qualify for a price reduction. In some cases this reduction is known as a “discount off invoice” or a reduction from the full price shown on the invoice.

- **Mail order pharmacy**

Mail order service facilities account for 17 percent of expenditures on outpatient prescriptions.^{vii} Typically a pharmaceutical manufacturer or wholesaler negotiates and contracts directly with the mail order facility. All products are usually shipped directly to the facility for dispensing to patients who

have chosen to use this alternative. As described in the preceding paragraph, the pharmaceutical manufacturer may provide lower pricing to the purchaser of the drugs, in this case a mail order service facility, through a "discount off invoice" arrangement.

- Network Pharmacy

Managed care organizations such as health plans or PBMs provide drug products to covered members by entering into contracts with chain or independently owned pharmacies to create a network of pharmacies accessible to those members. These pharmacies are referred to as "network pharmacies." The majority of prescriptions in this country are delivered to patients through network pharmacies. The MCO does not receive shipments of drugs or take direct ownership of them from the manufacturer.

In the case of network pharmacies, the pharmaceutical manufacturer provides any negotiated discount to the MCO through a rebate to that MCO. Rebates are the mechanism used by MCOs to drive price concessions from manufacturers since the MCO does not actually take control of the product. Rebate agreements between MCOs and pharmaceutical manufacturers help drive down the costs of prescription drugs for consumers and payors.

Mechanisms that can be used to achieve lower drug costs

Just as there are several ways that MCOs purchase, deliver and pay for drugs for their members, there are several contract mechanisms that are available to MCOs to secure lower prices for drugs; they are related to the distribution alternatives described above.

Discounts direct from the manufacturer, often called "discount off invoice" or "bulk discounts"

As explained in the discussion of staff model pharmacies above, some MCOs own and operate their own pharmacies that dispense prescriptions to their plan members. In these situations, the MCO negotiates with the pharmaceutical manufacturer to purchase the drug. Typically the negotiated price is based on the market share that drug realizes within the MCO's covered population. The MCO is billed by the manufacturer for the drug it purchases, based on the negotiated price for the drug including any discount off invoice, and then the MCO pays the manufacturer directly for the product it receives. This is similar to any purchase from a manufacturer that a business may make whether it is for office supplies, laboratory equipment or drugs.

In some situations, pharmaceutical manufacturers may also offer "bulk discounts," an added discount given when MCOs purchase an extraordinarily large amount of product.

Rebate Agreements

A rebate is broadly defined as a discount that occurs following a purchase wherein the manufacturer of the product returns some of the money that was paid for the product to the purchaser. When drugs are purchased by an MCO, a rebate is determined based upon volume, market share and other parameters (*see description below*). Rebates are provided by a pharmaceutical manufacturer to MCOs, including health plans, PBMs or other type of MCOs.

Rebate discounts are the most common mechanism that pharmaceutical manufacturers use to provide lower pricing to MCOs, because most prescriptions are dispensed to plan members through network pharmacies.

The MCO/pharmacy network/pharmaceutical manufacturer relationship is comparable to what occurs when a parent buys a computer for a child and the computer manufacturer offers a rebate on the purchase. In this example, the parents are the purchasers, but the child gets the computer. The parents receive the rebate check from the computer manufacturer when they submit proof of purchase.

In the MCO/pharmacy network/pharmaceutical manufacturer arrangement, when a patient gets a prescription filled by a network pharmacy, a similar transaction occurs. The patient gets the prescription. The MCO, as the purchaser, sends the proof of purchase to the pharmaceutical manufacturer and earns the rebate for purchase of the drug.

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The following summarizes how the rebate process works when a health plan negotiates a rebate contract with a pharmaceutical manufacturer to provide savings to consumers and plan sponsors:

- *The health plan develops a network of chain and independent pharmacies that agree to fill prescriptions for the health plan members.*
- *The health plan negotiates a rebate with the manufacturer of a drug, based on potential volume, preferred positioning in the formulary, or some other basis that justifies a rebate.*
- *The network pharmacy purchases drugs either directly from the manufacturer or through a wholesaler, so it has a supply available when a patient presents a prescription.*
- *The manufacturer or wholesaler bills the pharmacy for the drugs that were shipped to the pharmacy, and the pharmacy pays the invoice for these shipments. These bills do not reflect any rebate arrangements that may have been negotiated between the manufacturer and health plan.*
- *A health plan member goes to the network pharmacy with a prescription for the drug for which the health plan has negotiated a rebate and has that prescription filled.*
- *The pharmacy fills the prescription and provides it to the patient. The pharmacy also bills the health plan for the prescription. This bill is based on the price the pharmacy paid for the drug, not the discounted price the manufacturer has negotiated with the health plan.*
- *The health plan reimburses the pharmacy.*
- *The health plan also sends a report to the manufacturer saying that it provided the drug for a member and that it now needs the rebate that was negotiated for the drug. This request is basically an invoice to the manufacturer for the difference between the price reimbursed to the pharmacy and the discounted price negotiated with the manufacturer.*
- *The manufacturer pays the health plan the rebate amount.*

There are several types of rebate agreements that are used by pharmaceutical manufacturers and MCOs. Manufacturers offer rebates for specific medications based upon plan and formulary design. A formulary or preferred drug list is a quality assurance and cost management tool that lists medications that are preferred by the plan. MCOs develop formularies that are continually updated by pharmacy and therapeutics (P&T) committees to stay up-to-date with new medications and new medical information. P&T committees consist of knowledgeable pharmacists, physicians and other health care professionals who evaluate medications based on safety, efficacy and clinical merit of the drug. A P&T committee meets on a regular basis to determine which medications should be placed on the formulary. The most important information that a P&T committee will consider is the safety and efficacy of medications. Once a P&T committee determines the clinical value of adding a drug to the formulary, the MCO will negotiate the most advantageous arrangements, including rebates. (For additional information on formulary development, see AMCP's *Concepts in Managed Care Pharmacy – Formulary Management*.^{viii} The reader should also refer to AMCP's *Principles of a Sound Drug Formulary System*^{ix}.)

Different types of rebates include:

Market share rebates

Market share rebates are often called “incentive formulary rebates.” They are used when a pharmaceutical manufacturer is interested in increasing the percentage of market share of its drug versus its competitors’ drugs within a particular MCO. The manufacturer will offer a rebate to the MCO if the MCO is able to increase the use of its drug versus its competitor’s. The MCO reduces costs by moving market share, capturing higher rebates and passing the savings through to consumers and employers. Such arrangements are put in place once the P&T committee has evaluated all competing drugs and has determined that the competing drugs in question are clinically equivalent and are appropriate for members. Market share rebate arrangements offer a variable percentage of rebate dollars based upon the market share level a drug captures compared with other similar drugs in the same class. This type of rebate is considered for use depending on the following factors:

- Number of drugs within a class of medications
- Utilization levels of a particular drug
- Ability to increase a drug’s market share in the class of medications beyond what direct-to-consumer advertising or the manufacturer’s sales force could potentially achieve.

Formulary-based rebates

There are two types of rebates related to formulary placement that can be used:

- *Formulary access rebate:* A manufacturer may offer a formulary access rebate to an MCO for placement of a drug on a formulary once the drug has been judged clinically appropriate by a P&T committee.
- *Rebates based on formulary type:* There are different types of formularies — for example, open, closed and tiered. An MCO with a closed formulary will cover a member’s medication only if it is on the formulary or otherwise authorized. Under a tiered formulary, more medications are usually eligible for coverage, but the amount

that a member pays is usually higher if that drug is non-preferred. With an open formulary, the member pays the same copay whether or not the drug is preferred. (See AMCP's *Concepts in Managed Care Pharmacy – Formulary Management*^x).

In general, a pharmaceutical manufacturer will negotiate a more generous rebate if competing drugs are either kept off the formulary or placed in a non-preferred status such as at a higher copayment tier or with utilization management restrictions (i.e., prior approval or step therapy).

A drug's position on a formulary can have a significant impact on the rebates that can be negotiated with manufacturers. For example, a P&T committee may review drug A, a higher-cost drug that is clinically superior to a lower-cost drug B (see Table 1.) Drug A is placed on formulary in a preferred position. Drug B is placed on formulary in a non-preferred position. An MCO can pass on money generated from rebates for Drug A through to members in the form of lower co-payments. Therefore, members may receive quality, clinically superior, higher-cost medications at a lower out-of-pocket co-payment amount. This will subsequently increase market share of Drug A and increase the amount of rebate earned. In addition to being able to offer lower co-payments for preferred drugs, the use of rebated and preferred drugs may help the MCO keep drug benefit premiums lower.

Table 1. Cost Analysis of Market Share Rebate of Drug A vs. Drug B

Drug	Cost of the Prescription	Percent Rebate	Drug Cost after Rebate
A	\$100	15%	\$85.00
B	\$90	5%	\$85.50

Conclusions

The cost for medications continues to rise year after year and is likely to escalate at levels greater than the Consumer Price Index.

To get the best price, purchasers of pharmaceuticals use mechanisms similar to and universally available to purchasers of any commodity.

Purchasing and contracting options of MCOs benefit plan sponsors and patients by lowering costs.

The goal of the various mechanisms used in pharmaceutical contracting is to drive down net costs while maintaining high quality, appropriate, affordable and accessible health care benefits.

Glossary

Access

A patient's ability to obtain medical care determined by the availability of medical services, their acceptability to the patient, the location of health care facilities, transportation, hours of operation and cost of care.

Brand Name Drug

The drug whose name is listed on the application to the FDA for approval of a new drug.

Closed Formulary

A type of formulary that limits the number of prescription drugs reimbursed by the plan.

Consumer Price Index (CPI)

A governmental program that produces monthly data on changes in the prices paid by urban consumers for a representative basket of goods and services.

Contract

An agreement between parties (individuals or corporate) who have the legal capacity to agree and who entered into the agreement voluntarily, in which the obligations set forth in the agreement are legally enforceable and the purpose of the agreement is not illegal or contrary to public policy.

Co-pay Amount

An amount insured members must pay each time they receive a prescription or medical care using their benefit. A fee charged to an insured member to offset costs of paperwork and administration for each office visit or pharmacy prescription filled. A cost-sharing arrangement in which a covered person pays a specified charge for a specific service, such as a fixed dollar amount for each prescription received; (e.g., \$5.00 per generic prescription, \$10.00 per preferred brand name prescription, and a higher charge such as \$25.00 for a non-formulary product).

Formulary

A specific list of drugs that are included with a given plan for a client. A continually updated list of medications, related products and information, representing the clinical judgment of physicians, pharmacists and other experts in the diagnosis and/or treatment of disease and promotion of health. Types include closed formulary, negative formulary and open formulary. Also referred to as a "Preferred Drug List."

Health Plan

An organization that finances and either directly provides health care to its enrolled members, through its own facilities and staff, or indirectly through contracted providers of care (physicians, hospitals, pharmacies, etc.).

HMO - Health Maintenance Organization

A form of health insurance in which members prepay a premium for the HMO's health services, which generally include inpatient and ambulatory care. For the patient, it means reduced out-of-

pocket costs (i.e., no deductible), no paperwork (i.e., insurance forms), and only a small co-payment for each office visit to cover the paperwork handled by the HMO. There are several different types of HMOs.

Integrated Care Organizations (ICOs)

A specific type of MCO where various types of providers, e.g. physicians, hospitals, pharmacies, etc., are part of one organization that either includes a health plan or that contract together with one or more health plans, i.e. the care is “integrated.”

MAC - Maximum Allowable Cost

A cost management program that sets upper limits on the payment for equivalent drugs available from multiple manufacturers. It is the highest unit price that will be paid for a drug and is designed to increase generic dispensing, to ensure the pharmacy dispenses economically, and to control future cost increases.

Mail-Service Drug Program (Mail Order Pharmacy)

A growing number of Health Maintenance Organizations (HMOs) and Pharmacy Benefit Management (PBM) companies affiliated with corporations or federal contracts use mail-service drug programs to ensure their members have timely access to discount rate drugs.

MCO - Managed Care Organization

A generic term applied to a managed care plan; also called Health Maintenance Organization (HMO), Preferred Provider Organization (PPO) or Exclusive Provider Organization (EPO), although the MCO may not conform exactly to any of these formats.

Member

A participant in a health plan who makes up the plan's enrollment.

Network

The group of physicians, hospitals and other medical care professionals with which a managed care organization has contracted to deliver medical services to its members.

Pharmacy and Therapeutics (P&T) Committee

An advisory committee responsible for developing, managing, updating and administering the drug formulary system. P&T Committees are comprised of primary care and specialty physicians, pharmacists and other health care professionals. Committees may also include nurses, legal experts and administrators.

Pharmacy Benefit Management Companies (PBMs)

Organizations that manage pharmaceutical benefits for managed care organizations, other medical providers or employers. PBMs contract with clients interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM activities may include some or all of the following: benefit plan design, creation/administration of retail and mail service networks, claims processing and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization and disease and health management.

Plan Sponsor/Payors

Plan sponsors include employers, unions, associations and government agencies, and are also referred to as payors.

Preferred Drug List

See “formulary.”

Rebate

A monetary amount returned to a payer from a prescription drug manufacturer based on use by a covered person or purchases by a provider.

ⁱ *Health Affairs*. “Health spending projections through 2013. Feb 11, 2004. at www.healthaffairs.org.

ⁱⁱ *The Value of Pharmaceuticals and Managed Pharmaceutical Care*, http://www.amcp.org/data/nav_content/index%5Fvalue%2Epdf, accessed March 6, 2006.

ⁱⁱⁱ *Principles of a Sound Drug Formulary System*, October 2000.

http://www.amcp.org/data/nav_content/drugformulary%2Epdf, accessed March 6, 2006.

^{iv} Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy – Formulary Management*. 1998.

^v Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy – Drug Use Evaluation*. 1999.

^{vi} Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy – Prior Authorization and the Formulary Exception Process*. 2005.

^{vii} The Lewin Group, Mail-Service Pharmacy Savings: A Ten-Year Outlook for Public and Private Purchasers, prepared for: Pharmaceutical Care Management Association, August 2, 2005. p. ES-2.

http://www.pcmnet.org/newsroom/pr_08/Lewin_Study.pdf, accessed March 6, 2006.

^{viii} Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy – Formulary Management*. 1998.

^{ix} *Principles of a Sound Drug Formulary System*, October 2000.

http://www.amcp.org/data/nav_content/drugformulary%2Epdf, accessed March 6, 2006.

^x Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy – Formulary Management*. 1998.