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Report to Congressional Requesters

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PRESCRIPTION DRUG BENEFITS

Implications for Beneficiaries of Medicare HMO Use of Formularies

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The Honorable Charles E. Grassley
Chairman
The Honorable John B. Breaux
Ranking Minority Member
Special Committee on Aging
United States Senate

The Honorable Ron Wyden
United States Senate

Prescription drug coverage may be the most important reason that over 6 million of the approximately 39 million Medicare beneficiaries have enrolled in health plans offered by health maintenance organizations (HMO) that participate in the Medicare+Choice program.[1] Although traditional Medicare does not cover outpatient prescription drugs, most HMOs in Medicare+Choice do provide this benefit, resulting in outpatient drug coverage for over 90 percent of the beneficiaries enrolled in Medicare+Choice plans.

Selecting a plan that meets a beneficiary's needs can be difficult. As we have reported, consistent comparative information on the benefits offered by Medicare+Choice plans is not readily available.[2] The lack of comparative information is particularly problematic in evaluating plans' drug benefits because so many different factors determine the true extent of coverage. Currently, Medicare beneficiaries can join or leave a plan on a monthly basis. However, in 2002, making informed choices among health plans will become more important, because under the Balanced Budget Act of 1997 (BBA) (P.L. 105-33) Medicare beneficiaries will not be able to change plans as frequently. If beneficiaries experience problems with a plan or decide that another plan's drug benefits better meet their needs, they will have a limited time each year to change plans.[3] Afterward, beneficiaries will be locked into their health plan decisions for the remainder of the year.

[1]A "plan" refers to a package of benefits, including out-of-pocket costs and terms of coverage.

[2]See Medicare+Choice: New Standards Could Improve Accuracy and Usefulness of Plan Literature (GAO/HEHS-99-92, Apr. 12, 1999).

[3]Beneficiaries will have 6 months in 2002 and 3 months in the years following to change their enrollment choices.

HMOs use various techniques to help control the cost of providing prescription drug benefits. One of the most common techniques is to use a formulary—a list of prescription drugs, grouped by therapeutic drug class, that an HMO prefers its physicians to prescribe.[4] HMOs may cover only formulary drugs or provide financial incentives, such as lower copayments, to use formulary rather than nonformulary drugs. In managing their formularies, HMOs perform several functions, including deciding which drugs to add to or delete from their formularies, notifying beneficiaries and physicians about formulary changes, and considering physician requests to cover deleted drugs and other nonformulary drugs for specific beneficiaries.

Increasing prescription drug prices and expensive new drugs have reportedly caused HMOs to more closely examine the drugs they include on their formularies. These decisions affect not only an HMO's drug expenditures, but also beneficiaries' care, particularly when their HMO deletes a drug they have been taking and requires them to obtain an exception to remain on the drug, switch to another drug, or pay more of the cost out-of-pocket.

Concerns have been raised that beneficiaries may not be aware of the implications of formulary management decisions before they enroll in Medicare HMOs—decisions that affect their coverage, whether and how they will be notified about formulary changes, and how their physicians may obtain exceptions from formulary changes that they believe are inappropriate. In response to these concerns, more than half of the states have enacted legislation related to HMOs and other managed care organizations' (MCO) formulary management, including laws that require MCOs to disclose their formularies and procedures by which plan enrollees may obtain coverage of specific nonformulary drugs.

Because of your interest in these issues, you requested that we study how Medicare HMOs manage drug formularies to control drug expenditures and what the implications are for beneficiaries of these formulary management activities.

To address these issues, we obtained information from 16 HMOs in the Medicare+Choice program in three markets: 6 in Los Angeles; 7 in Miami (Dade, Broward, and Palm Beach counties); and 3 in Philadelphia. These 16 represented more than 25 percent of all beneficiaries enrolled in Medicare HMOs. From each HMO, we obtained information on the policies

[4]A drug class is a group of drugs that are similar in chemistry, method of action, and purpose of use.

and procedures used to make formulary decisions, notify health care providers and beneficiaries about formulary changes, and consider physician requests for nonformulary drugs. We also obtained copies of formularies in effect for each HMO on November 1, 1997; November 1, 1998; and January 1, 1999.

We performed our work between October 1998 and July 1999 in accordance with generally accepted government auditing standards. Appendix I contains more information on our scope and methodology.

Results in Brief

Evaluating the prescription drug benefits Medicare HMOs offer is an important but challenging undertaking for prospective enrollees. To determine which plan best meets their needs, beneficiaries need to assess how HMOs' use of formularies can affect their drug benefits. Comparing plans can be difficult because the types of formularies HMOs use and the ways in which formularies are managed differ considerably. The choices beneficiaries make can have a significant impact on the value of their drug benefits and out-of-pocket costs. Plans vary widely in the drugs they cover on their formularies, the copayments they require beneficiaries to make, and the annual limits on beneficiaries' coverage. Further, beneficiaries in some plans may not learn about formulary changes until the beneficiaries are at the pharmacy counter. Some plans also make it difficult for physicians to obtain an exception to allow patients to remain on their existing medication at no additional cost if it is dropped from the formulary.

The HMOs we studied vary considerably in the types of formularies they use and the methods they use to manage them. For example, 10 of the 16 HMOs use closed formularies that limit coverage to certain drugs, and another formulary is "partially closed," in that the HMO limits coverage of drugs within 20 classes but will cover all drugs outside those classes. The HMOs also use several types of formulary controls to manage drug expenditures. Twelve of the 16 HMOs require the use of generic drugs when they are available. Seven of the 16 use variable copayments, with a larger amount for brand-name drugs and a smaller amount for generics.

Twelve of the 16 HMOs we examined deleted drugs from their formularies in four therapeutic classes that are widely used to treat health conditions common to the elderly: hypertension, depression, ulcers, and high cholesterol. These deletions required beneficiaries to switch to alternative formulary drugs or increase their out-of-pocket expenses, in some cases to

the full price of the drug. However, 15 of the 16 also added drugs to their formularies in these classes. Considering all the deletions and additions, 12 of the 16 HMOs covered as many or more drugs in each class in January 1999 than they did in November 1997. With one exception, the HMOs continue to offer several alternatives for physicians to prescribe in each class.

The HMOs also use different methods to notify beneficiaries of formulary changes and to consider exceptions from formulary changes. While some HMOs do not notify beneficiaries of formulary changes, others send beneficiaries a copy of the formulary as well as a letter that informs them of specific changes that affect them and the reasons for the changes. Although some HMOs allow a physician to except a beneficiary from a change without providing the HMO justification for the decision, others require that the physician document, in some cases through several steps, that formulary alternatives are inappropriate for a beneficiary before the HMO will agree to cover a nonformulary drug. Some HMOs may also require that a beneficiary use a formulary drug for a trial period to see if there are any adverse effects before the HMO will cover the physician's original drug choice.

Background

Medicare beneficiaries may obtain health care through Medicare's traditional fee-for-service arrangement or enroll in a Medicare managed care plan if one is available in their county. The BBA established the Medicare+Choice program to replace Medicare's previous managed care program. Medicare+Choice expanded beneficiaries' health plan options by permitting new types of entities, such as preferred-provider organizations and provider-sponsored organizations, to participate in Medicare. As of March 1999, about 6.1 million beneficiaries were enrolled in 244 Medicare+Choice plans that offer prescription drug benefits. All of the plans offering these benefits were HMOs.

The BBA directed the Health Care Financing Administration (HCFA) to provide beneficiaries with general information about managed care plans. HCFA's goal is to make beneficiaries aware of their health plan options and to provide some summary information to help beneficiaries compare those options. For example, HCFA plans to provide each beneficiary a Medicare handbook that contains information about the benefits offered by available plans. Beneficiaries may also call HCFA's toll-free number (1-800-MEDICAR) or access an Internet site (www.medicare.gov) that also provides basic comparative information about plan options. However, for

detailed information about specific plans, HCFA directs beneficiaries to MCOs.

HCFA reviews and approves all written information that MCOs provide beneficiaries to ensure that the materials are not inaccurate, misleading, or unclear. Although HCFA does not require plans to notify beneficiaries of formulary changes, it reviews any materials or letters the plans send beneficiaries regarding drug formularies or formulary changes. However, HCFA does not review plans' formulary decisions. We previously reported that inconsistent review standards have contributed to inconsistent reviews.[5]

HCFA is also responsible for reviewing changes to plan benefits. HCFA's contracts with MCOs establish the minimum benefits a plan must offer and the maximum fees it may charge during a calendar year. The contracts stipulate that MCOs are not allowed to make benefit changes that reduce benefits or increase fees for any benefits until the next contract cycle. According to HCFA officials, however, the agency has not determined whether formulary deletions constitute a benefit reduction. The officials said that the agency has just begun to consider the issue.

Prior to 1996, few states had laws regulating the use of drug formularies by MCOs. However, according to the National Conference of State Legislatures, by April 1999 at least 26 states had enacted laws concerning the disclosure to plan enrollees of formularies, procedures to obtain nonformulary drugs, or both.[6] For example, 13 of the 26 states enacted legislation that required MCOs to disclose both their formularies and the procedures they require to obtain coverage of nonformulary drugs.[7]

Two of the three states we visited have passed laws related to MCOs' formulary management. Pennsylvania law requires that, upon request, MCOs provide information on whether specific drugs are covered and a description of the process by which a physician can prescribe nonformulary drugs when the formulary drug has been ineffective or

[5]GAO/HEHS-99-92, Apr. 12, 1999.

[6]Jacob Herstek, Managed Care Drug Formularies (Washington, D.C.: National Conference of State Legislatures, Apr. 1, 1999).

[7]The administration has directed federal health plans, including Medicare MCOs, to comply with recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry concerning the information consumers should receive from plan sponsors about formularies, the drugs they include, and exceptions to formulary drugs.

causes an adverse reaction.[8] California law requires that MCOs provide copies of formularies, upon request, establish expedited processes to consider physician requests for nonformulary drugs, and continue coverage for any drugs deleted from their formularies that a physician continues to prescribe for individual plan enrollees.[9] The California Department of Corporations has reviewed the formularies of HMOs suspected of deleting drugs inappropriately from their formularies before the July 1, 1999, effective date of the law requiring continued coverage.[10]

The HMOs we studied rely extensively on the deliberations of pharmacy and therapeutics (P&T) committees within their companies to determine which drugs to add to or delete from their formularies. Typically, a company would use a P&T committee that included medical and pharmacy representatives from each of its HMOs. P&T committees consider several factors when they assess whether a drug should be added to or deleted from a formulary, including the drug's clinical effectiveness and safety, and whether the drug is therapeutically equivalent to drugs already on the formulary. Most of the P&T committees for the HMOs in our study also consider a drug's cost in their deliberations. Appendix II contains more information on the HMOs' P&T processes.

HMOs Use Different Approaches to Manage Formularies

HMOs use formularies to control their drug expenditures by limiting the number of drugs a plan will cover, using financial incentives to encourage the use of formulary drugs, and employing compliance programs that encourage or require physicians to prescribe formulary drugs. To accomplish these goals, HMOs develop and manage formularies in conjunction with decisions they make concerning the design of their drug benefit. Typically, the design includes such features as (1) the extent to which the plan will pay for nonformulary drugs, if at all; (2) the copayments the plan requires from beneficiaries for formulary or nonformulary prescriptions; and (3) limits or caps on the total dollar amount the plan will pay for outpatient drugs.

Formularies are often described as open, incentive-based, or closed. Open formularies are often referred to as "voluntary" because beneficiaries are not penalized financially if their physicians prescribe nonformulary drugs. HMOs that use open formularies may do so in conjunction with compliance

[8]Pa. Stat. Ann. tit. 40, section 991.2136 (West 1999).

[9]Cal. Health & Safety Code sections 1363.01, 1367.20, 1367.22, 1367.24 (West 1999).

[10]The Department has used a panel of consultants to review the deletions and develop an approach and criteria for their decisions. According to a Department official, the Department has decided to keep both the identities of panel members and the criteria they used to evaluate formulary changes confidential.

programs that encourage physicians to prescribe formulary drugs, even though the HMOs will still cover both formulary and nonformulary drugs. An incentive-based formulary provides beneficiaries financial incentives for their physicians to prescribe formulary drugs. Under this arrangement, the plan still covers nonformulary drugs, but it requires a copayment for them that is not required for formulary drugs or a higher copayment than that required for formulary drugs. A closed formulary takes these financial incentives one step further by limiting coverage to only formulary drugs. Therefore, if a beneficiary's physician prescribes a nonformulary drug, the beneficiary will have to pay the full cost of that prescription unless the HMO grants an exception. According to one report, the percentage of HMOs using closed formularies is expected to increase from about 25 percent in 1996 to about 37 percent in 1999.[11]

Ten of the 16 HMOs in our study use closed formularies, and another is "partially closed" in that the HMO limits coverage to drugs in 20 classes but will cover all drugs outside of those classes.[12] Two of the HMOs examined have open formularies in which beneficiaries pay the same copayment for formulary and nonformulary drugs, and the remaining three HMOs use incentive-based formularies that require a higher copayment for nonformulary drugs than for formulary drugs.

The HMOs we studied also manage their prescription drug expenditures by using several types of formulary controls, such as generic substitution and variable copayments.[13] Generic substitution encourages or requires the use of generic drugs when they are available in place of more expensive brand-name drugs. Beneficiaries may also be required as part of the overall benefit design to make different copayments for brand-name, generic, and nonformulary drugs. While the use of generic substitutions has been common for over 90 percent of all HMOs since 1996, a dramatic increase appears to have occurred in the use of variable copayments, which were used by about 53 percent of HMOs in 1996 and are expected to be used by about 86 percent of HMOs in 1999.[14] Twelve of the 16 HMOs in our

[11]Novartis Pharmaceuticals Corporation, Pharmacy Benefit Report, Trends and Forecasts, 1998 Edition (East Hanover, N.J.: Novartis, 1998).

[12]Within the closed classes, this HMO encourages beneficiaries to use a subset of drugs that the HMO has informed beneficiaries and physicians are more economical. Formularies may cover as many as 100 drug classes. One of the four classes we reviewed, antidepressants, remains open for this HMO.

[13]Another type of control is prior authorization, which requires physicians to obtain prior approval from the HMO before prescribing certain drugs. This type of control was not common for the drugs we studied.

[14]See Novartis, Pharmacy Benefit Report.

study require the use of generic drugs when they are available.[15] At most of these HMOs, if beneficiaries do not choose the generic, they pay the cost difference between the generic and brand-name drug or the cost difference plus any copayment for the brand-name drug. Seven of the 16 HMOs also use variable copayments between brand-name and generic drugs, charging more for brand-name drugs than for generic drugs.

Between November 1997 and January 1999, all but one of the HMOs we examined made additions to or deletions from their formularies in at least one of four classes of drugs that are used to treat health conditions common to the elderly: hypertension, depression, ulcers, and high cholesterol.[16] Twelve of the 16 HMOs deleted a total of 62 drugs from their formularies, which required beneficiaries to switch to alternate formulary drugs.[17] These deletions were the result of the HMOs' clinical or cost assessments about the drugs, rather than the result of generic substitutions for brand-name drugs. Although deletions occurred in each class, most deletions occurred in the antihypertension class, in which 11 HMOs deleted a total of 39 drugs.[18] In addition, 1 of these 11 HMOs changed from using an open formulary for all drugs to a formulary in which many drug classes, including three we studied, were closed.[19]

While many plans deleted drugs from their formularies, 15 of the 16 HMOs added one or more drugs to their formulary in at least one of the classes we reviewed. Collectively, the HMOs made over 200 additions. Considering all formulary deletions and additions, 12 of the 16 HMOs covered as many or more drugs in each class in January 1999 than they did in November 1997. Moreover, with one exception, the HMOs continued to offer several alternatives for physicians to prescribe in each class.

Although most of the HMOs included a number of drugs for hypertension, depression, ulcers, and high cholesterol on their formularies, the number of drugs varied for each class. For example, in January 1999, the number of drugs for the four classes we reviewed ranged from 2 to 9 for antiulcer

[15]Exceptions may be authorized if medically appropriate.

[16]We reviewed the HMOs' formularies to understand the prevalence of changes beneficiaries might experience in Medicare HMOs and the extent to which the drugs on the resulting formularies might vary. We did not evaluate the clinical appropriateness of the formulary changes.

[17]The total includes some duplication of drugs that were deleted from different formularies.

[18]This general class or category, like others we reviewed, was divided into different classes of drugs.

[19]We could not determine the number of deletions this transition represented for these three classes from 1997 to 1998.

drugs, 3 to 10 for anticholesterol drugs, 12 to 22 for antidepression drugs, and 30 to 78 for antihypertension drugs.

Differences in Formulary Management Have Implications for Beneficiaries

Beneficiaries interested in determining the value of a plan's prescription drug benefits need to consider a number of factors. Differences in the types of formularies, the drugs they include, and formulary controls used by the HMOs can affect whether drugs are covered and how much they will cost. Beneficiaries may also be affected by differences in the methods the HMOs use to notify them about formulary changes and in how they consider physician requests for exceptions from formulary deletions. As a result, beneficiaries enrolled in some HMOs may be better informed about formulary changes than those enrolled in others, and it may be easier for some physicians to request and obtain coverage for nonformulary drugs.

Implications of Different Formulary Types and Controls

The type of formulary and formulary controls used by an HMO, combined with benefit design features, have implications for the extent and value of a beneficiary's coverage. Considering only copayments and annual limits on benefits to evaluate plans' drug benefits results in a superficial comparison of the coverage plans offer. For example, table 1 shows that HMOs using closed formularies differ considerably in the copayments they require and annual limits they set for prescription drugs. However, beneficiaries interested in comparing those plans should also determine whether the plans cover the drugs they currently use. Even closed formularies vary in the number of drugs included in a therapeutic class.

Table 1: Formulary Types and Controls Used by 16 Medicare HMOs for Selected 1999 Plans

HMO	Formulary type	Copayment for brand-name drugs	Copayment for generic drugs	Annual dollar limit on all drugs
1	Open	$15	$15	Unlimited, but $1,000 for brand-name drugs
2	Open	15	5	$1,600, with a semiannual limit of $800
3	Closed	10	5[a]	$1,750
4	Partially closed[b]	0	0[a]	Unlimited
5	Incentive-based[c]	0	0[a]	Unlimited
6	Closed	0	0[a]	Unlimited
7	Closed	0	0[a]	Unlimited
8	Incentive-based[c]	0	0[a]	Unlimited
9	Closed	0	0[a]	Unlimited
10	Closed	0	0[a]	Unlimited
11	Incentive-based[c]	12	3[a]	Unlimited, but $2,000 for brand-name drugs
12	Closed	15	5[a]	Unlimited
13	Closed	10	5[a]	Unlimited, but $4,500 for brand-name drugs
14	Closed	20	5[a]	$2,000
15	Closed	7	7	Unlimited
16	Closed	10	5	Unlimited

Note: Typically, copayments shown are for purchasing about a 1-month supply at a retail pharmacy.

[a]Generics required, if available.

[b]Formulary closed for specific drug classes but open for others.

[c]HMO requires a copayment for nonformulary drugs. HMO 5—$30, with a $1,000 limit for nonformulary drugs; HMO 8—$10; and HMO 11—$25.

Beneficiaries may also want to consider the trade-offs between certain factors in considering plans' coverage. As seen in table 1, some HMOs offer open or incentive-based formularies that cover any drugs beneficiaries may need but require copayments and limit the annual amount they will pay for drugs. In contrast, other HMOs use closed formularies that limit the drugs they cover but require small copayments and have higher annual limits. For example, one HMO that has an open formulary and variable

copayments for brand-name and generic drugs limits the total amount annually it will pay for all drugs. In comparison, another HMO in the same market has a closed formulary, a lower copayment for brand-name drugs, and a higher annual limit. In this example, a beneficiary would need to consider the trade-offs between having an open formulary with less generous copayment and annual limit amounts and having a closed formulary with more generous copayment and annual limit amounts. For some beneficiaries, having a closed formulary might not be a negative factor if the formulary included the drugs they used and was extensive in the drugs it included relative to other HMO formularies in the same market. The HMO's lower copayment for brand-name drugs could also be an attractive feature for beneficiaries who use a brand-name drug with no generic equivalent. For other beneficiaries, however, a lower copayment for brand-name drugs and a slightly higher annual limit would not outweigh the benefit of an open formulary that would include any drug they might need.

Implications of Formularies' Covering Different Drugs

While the number of formulary changes the HMOs made provides a sense of the magnitude of formulary change, what is perhaps more significant to beneficiaries is that the specific drugs the HMOs covered in each of the classes we reviewed varied considerably. Beneficiaries need to be aware of the differences in HMOs' formularies to ensure that they select a plan with a formulary that includes the drugs they use or that offers alternatives that are acceptable to them and their physicians. For example, the number of antiulcer drugs included on the formularies of the HMOs we studied varied between two and nine, with only one drug, Tagamet, included on all of the formularies. Some HMOs added other drugs that are used for more severe ulcer cases or when other antiulcer drugs are not effective. Beneficiaries who have medical conditions that warrant the use of several antiulcerants may want to determine which plans offer a greater selection of these drugs on their formularies. Because many beneficiaries take several different prescription drugs, it is also helpful for them to know the extent to which HMOs offer formulary options in different therapeutic classes for drugs commonly used by the elderly.

How HMOs Notify Beneficiaries Affects Impact of Formulary Changes

Notifying beneficiaries about formulary changes is an important means for ensuring that beneficiaries know about potential changes to their current drug treatment and its cost. It can also reduce those instances in which beneficiaries first learn of a formulary change at the pharmacy counter. For most of the HMOs we studied, formulary changes can occur and be

implemented at different times throughout the year. As a result, for these HMOs, notification of formulary changes is an ongoing process.

The HMOs vary in the methods they routinely use to notify beneficiaries and physicians about formulary changes. For example, while 9 of the 16 HMOs provide copies of formularies on request, the other 7 routinely mail copies of formularies to beneficiaries, usually on an annual basis, with information that explains the formulary's purpose and how the beneficiary can use it to review formulary drugs in different classes. Four of these seven HMOs also send letters to beneficiaries notifying them about specific formulary changes that affect them, as do five of the nine HMOs that send formularies only on request. (App. III provides an example of a notification letter.) In contrast, four of the nine HMOs do not notify beneficiaries about formulary changes. Officials for these HMOs told us they did not consider it necessary to notify beneficiaries of formulary deletions or additions because the HMOs continue to cover nonformulary drugs in some way. These officials were concerned that beneficiaries would find formularies too confusing to be helpful.

The HMOs also have different policies regarding those situations when beneficiaries first learn of formulary changes that affect them at their pharmacy counter. In such instances, the pharmacist has on-line access to the formulary used by the beneficiary's HMO and is able to inform the beneficiary of the formulary change. Normally, the pharmacist will then contact the beneficiary's physician and notify him or her about the change and seek the physician's approval for a new prescription of a formulary drug. When the pharmacist is unsuccessful in contacting the physician's office or the physician does not approve the change, the HMOs in our study handled the situation differently. If the beneficiary wanted to fill the prescription at that point, most of the HMOs would require that the beneficiary pay the amount their plan required for a nonformulary drug. However, 3 of the 16 HMOs specifically allowed both new and established members in those situations a "grace period" in which they could have one refill of the original drug, and the plan would cover it as a formulary drug. This grace period allowed beneficiaries the opportunity to contact their physicians to discuss their options before they needed the next prescription.

All of the HMOs we examined send physicians copies of formularies at least once a year, as well as periodic newsletters that include information on formulary changes and other health-related issues. Eight of the 16 also send physicians letters notifying them of specific beneficiaries affected by

formulary changes. Although the HMOs provide this information to physicians, officials for most of the HMOs acknowledged that physicians who are associated with several HMOs do not realistically have time to keep up with formulary changes for multiple plans. As a result, the burden of informing many physicians when drugs are deleted from formularies falls on the beneficiary.

Exceptions Policy Can Insulate Beneficiaries From Formulary Changes

Beneficiaries are most directly affected by a formulary decision when the drug they have been accustomed to using is deleted from their HMO's formulary and their plan covers only formulary drugs. The change has health care and financial implications for beneficiaries because it requires that they either switch to a new drug that is on the formulary or continue to use the original drug that has become nonformulary and pay for it themselves. Beneficiaries who change health plans may face the same situation if their new plan does not cover the drugs they have been using. For a beneficiary whose drug has become nonformulary, the physician must decide whether an alternate drug on the formulary is appropriate for the beneficiary's care and, if so, write a prescription for the drug and help the beneficiary adjust to the new medication. However, if the physician believes that it is inappropriate for the beneficiary to switch to a formulary drug, the physician must contact plan representatives to request an exception for the beneficiary so that the HMO will continue to cover the beneficiary's original drug.

The number of beneficiaries or prescriptions affected by a formulary deletion depends on the drug deleted and the size of an HMO's beneficiary population. For example, one HMO with about 100,000 beneficiaries deleted an antihypertension drug that, according to HMO data, affected 275 prescriptions. The HMO reported that it received and approved only one or two exception requests a month. In contrast, another HMO with about 40,000 beneficiaries deleted drugs from 20 drug classes, affecting over 14,000 prescriptions and over 9,000 beneficiaries during a 6-month period in 1998. Because of the extent of these deletions, the HMO developed an extensive information campaign to notify beneficiaries and physicians about the changes and implications for beneficiaries of deleting the drugs. During this period, the HMO received about 300 requests for nonformulary drugs and approved about 65 percent of them.

The HMOs in our study vary considerably in the processes they use to consider exceptions for nonformulary drugs. Beneficiaries enrolled with 2 of the 16 HMOs are not affected by formulary changes because the HMOs use

open formularies. Thus, physicians in these plans can prescribe nonformulary drugs without going through an exception process. At the other 14 HMOs, requests for nonformulary drugs are handled in different ways. Table 2 summarizes the exception processes for the 16 HMOs.

Table 2: Processes Used by Selected Medicare HMOs for Making Nonformulary Drug Exceptions

Exception process	Number of HMOs using process
Physician must provide documentation, such as medical chart notes, to show that no formulary drug is appropriate.	5
Physician must call HMO administrators to discuss the reasons for an exception.	5[a]
Physician must submit an exception request form, but the physician's justification for the request is automatically accepted.	2
No exception process exists because the HMO uses an open formulary.	2
No exception process exists because nonformulary drugs are covered with a copayment.	1
Physician must document that the patient tried the formulary drug but experienced an adverse reaction or drug failure.	1

[a]Depending on the reason, four HMOs may require documentation following this discussion.

Six of the 14 HMOs that use closed or incentive-based formularies require physicians to submit specific medical documentation to demonstrate why formulary alternatives will not be appropriate for a beneficiary. One of these six HMOs also requires the physician to document that the beneficiary used the formulary alternative during a trial period and that either the beneficiary experienced an adverse reaction to the drug or the drug failed as a treatment alternative.

Three of the 14 HMOs that use closed or incentive-based formularies except beneficiaries already enrolled in the HMOs from formulary changes—a policy referred to as "grandfathering." Grandfathering allows a physician to keep a beneficiary on the original drug if the physician believes that is the most appropriate care.[20] In these cases, the physician's prescribing a nonformulary drug is not an issue as long as the beneficiary remains enrolled in the plan. Although an HMO's use of grandfathering could enhance the value of a drug benefit for many beneficiaries, this policy was not described in plan materials the HMOs provided beneficiaries.

[20]Three other HMOs use grandfathering in a more limited way, applying it to only some drugs used by both current and incoming members.

Conclusions

To fully evaluate the prescription drug benefits offered by different plans, beneficiaries need some knowledge of how HMOs use drug formularies in ways that can affect the value of their benefits. This knowledge helps beneficiaries determine which plan best meets their needs by enabling beneficiaries to evaluate a combination of factors, including the type of formulary an HMO uses and whether it covers the drugs they use, whether a plan requires beneficiaries to share in the cost of prescriptions through copayments, and whether a plan limits the amount of the beneficiaries' drug benefit. This knowledge also helps beneficiaries determine how well an HMO informs them about formulary changes and how flexible the HMO is in allowing exceptions to formulary drugs when necessary. Naturally, a beneficiary's preferences and circumstances will affect the importance placed on any one of these factors in evaluating drug benefits.

To compare Medicare+Choice plans and make informed health care decisions, beneficiaries need clear and easily understood information that includes the drugs the formularies cover, formulary changes, and policies and procedures for requesting coverage for nonformulary drugs. Beneficiaries and MCOs also need a clear understanding of those circumstances in which formulary changes result in a reduction of drug benefits.

We are sending copies of this report to interested congressional committees and Members and agency officials and will make copies available to others on request.

If you or your staffs have any questions about this report, please call me at (202) 512-7114 or John Hansen, Assistant Director, at (202) 512-7105. Others who made major contributions to this report include Joel Hamilton and David Michaels.

William J. Scanlon
Director, Health Financing
and Public Health Issues

Contents

Abbreviations

BBA	Balanced Budget Act of 1997
HCFA	Health Care Financing Administration
HMO	health maintenance organization
MCO	managed care organization
P&T	pharmacy and therapeutics

Scope and Methodology

Our study included 16 health maintenance organizations (HMO) in three markets: 6 in Los Angeles, 7 in Miami, and 3 in Philadelphia. As of June 1999, the combined number of beneficiaries enrolled in plans offered by these HMOs represented more than one-quarter of all Medicare beneficiaries enrolled in Medicare HMOs. We selected these three markets on the basis of several factors, including the number of Medicare HMOs in the market, the number of beneficiaries enrolled in each HMO, the types of HMOs represented, and the experience each HMO had in managing prescription drug benefits for Medicare beneficiaries.

From each HMO, we obtained information on the policies and procedures used to make formulary decisions, notify health care providers and beneficiaries about formulary changes, and consider physician requests for nonformulary drugs. We also reviewed copies of formularies for each HMO made available to physicians and beneficiaries that were in effect on November 1, 1997; November 1, 1998; and January 1, 1999. Specifically, we compared formulary changes for drugs used to treat hypertension, depression, ulcers, and high cholesterol. In addition, we interviewed representatives of associations concerned with issues related to formulary management, such as state pharmacy and medical associations, consumer groups, and the American Medical Association. Further, we interviewed officials of the Health Care Financing Administration (HCFA) concerning the agency's role in monitoring Medicare managed care organizations' (MCO) drug benefits and changes to their formularies.

The 16 HMOs in our study enroll the largest number of beneficiaries in each market and range in size from about 11,000 to about 440,000 beneficiaries. The largest HMOs were in Los Angeles, ranging in size from about 27,000 to about 440,000 beneficiaries. By comparison, the HMOs in the Miami market ranged from about 24,000 to about 230,000; the HMOs in Philadelphia ranged from about 11,000 to about 118,000. Eleven of the HMOs are for-profit and five are not-for-profit.

The HMOs in our study have been providing beneficiaries prescription drug benefits for 3 to more than 10 years. This range of experience was an important factor for our study, because officials of these HMOs were able to provide a historical perspective on managing a drug benefit for Medicare beneficiaries. In contrast, some markets have few, if any, Medicare HMOs that have a history of providing prescription drug benefits to beneficiaries for longer than 1 or 2 years.

All 16 HMOs operate in mature and competitive managed care markets for Medicare beneficiaries, as reflected by the number of years Medicare HMOs have operated in each market and the extent of the pharmacy benefits they offer. For example, most HMOs in our study provide unlimited drug benefits. The Miami market is especially competitive: all of the HMOs in our study in that market provide unlimited prescription drug benefits and require no copayments from beneficiaries. Officials for several of these HMOs emphasized their market's competitiveness by explaining that, although they would like to consider copayments as a means to help control drug expenditures, such a change would cause a significant number of beneficiaries to disenroll and join competitors' plans. These HMOs have relied instead on formulary management and drug utilization techniques to help control their prescription drug expenditures.

P&T Committees

The HMOs we studied rely extensively on the deliberations of pharmacy and therapeutics (P&T) committees within their companies to determine which drugs to add to or delete from their formularies. Typically, the P&T committees operate at a company's national level and include medical and pharmacy representatives from each HMO in the company. The P&T committees consider several factors when they assess whether a drug should be added to or deleted from a formulary, including the drug's clinical effectiveness and safety, and whether the drug is therapeutically equivalent to drugs already on the formulary. Most of the P&T committees for the HMOs in our study also consider a drug's cost in their deliberations. Fifteen of the 16 HMOs use similar formularies for their Medicare and commercial plans, and 10 of the 16 HMOs are either using, or in the process of developing, formularies at the national level.

In addition, all the HMOs obtain input from physicians and other health care providers when considering formulary changes. In general, P&T committees will add a drug to the formulary if the drug clearly offers therapeutic benefits that other formulary drugs do not offer and the drug is as safe as or safer than other formulary drugs. To make this determination, committee members review available literature, including any studies that may compare the drug being considered for formulary addition with other drugs that may already be on the formulary. Some HMOs also use pharmacy benefit managers to help make decisions about which drugs to include on a formulary.[21]

At most of the HMOs we studied, the P&T committees also consider a drug's cost in their formulary decisions, while at other HMOs drug cost considerations are handled by staff that are external to the P&T process. According to HMO officials, cost considerations most often concern drugs that the P&T committee deems therapeutically equivalent to other drugs on the formulary. The committee may see no reason to add a therapeutically equivalent drug to the formulary unless there is an economic benefit. In these cases, the drug's cost is normally the tiebreaking factor that determines whether the drug is added and, perhaps, a therapeutically equivalent and more expensive drug is deleted from the formulary. Both the drug's purchase cost and any rebate the HMO is able to negotiate with a drug manufacturer are key factors in cost considerations. However, HMO officials told us that they lacked reliable comparative data for most drugs for considering the long-term costs of using one drug over another to treat specific health conditions.

[21]For more information on pharmacy benefit managers, see Pharmacy Benefit Managers: Early Results on Ventures With Drug Manufacturers (GAO/HEHS-96-45, Nov. 9, 1995).

The decisions P&T committees make about the drugs to include on their formularies vary for several reasons, including different assessments by P&T committees about the clinical aspects of drugs, as well as different assessments by HMOs concerning the cost of adding drugs to their formularies. The prices HMOs are able to negotiate with drug manufacturers can also affect HMOs' assessments of which drugs to include on their formularies and the extent to which beneficiaries must share in a drug's cost.

Sample HMO Notification Letter

The following is a typical example of the information some of the HMOs we reviewed provide beneficiaries in notifying them about specific formulary changes:

To make sure you have access to prescription drugs that are both clinically effective and reasonably priced, we regularly review the list of medications that are covered by your benefit plan. We have a committee of experts that includes independent physicians and pharmacists who review the prescription drugs on that list, which is called a 'formulary.' On the basis of the experts' assessment of therapeutic value and cost-effectiveness, drugs may be deleted from the formulary.

This letter is to advise you that _____ is being removed from the formulary as a result of our latest review. We are making this change because other drugs on the formulary are equally clinically effective while offering greater cost-effectiveness.

Our records indicate that you are currently receiving _____ , a drug that is affected by this action. Effective ____, this drug will no longer be on the formulary. Beginning ____, you will be responsible for paying the full price for the medication unless you are granted an exception by the health plan. Your doctor has been informed of this change, and we have provided a list of other drugs covered under your plan that are equally effective. It is important for you to speak with your physician before _____ to discuss using one of the formulary alternatives, or to request an exception to continue to use ____.

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