HEALTH POLICY PERSPECTIVES

The New Medicare Drug Benefit: Formularies and Their Potential Effects on Access to Medications

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During congressional debate over the Medicare Part D prescription drug benefit, much attention was focused on nominal benefit design. Relatively little attention was paid to details about how plans would operate, such as the design of drug formularies. Yet, formularies will be important tools for controlling costs, and may be as important as nominal benefit design in determining enrollees' access to medications and out-of-pocket costs. We describe Part D plan incentives and how they may influence formulary design, and then provide recommendations for Part D formulary implementation. We encourage the Centers for Medicare & Medicaid Services (CMS) to develop standardized tools to provide physicians and patients with up-to-date and easily accessible information about covered drugs on each plan's formulary (perhaps via a central website) and a national set of easy-to-follow procedures for reconsideration and appeals. Such efforts should reduce administrative burden and better allow physicians to help patients obtain needed medications.

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The Medicare Prescription Drug, Improvement and Modernization Act represents the most significant expansion of the Medicare program in almost 40 years. The law created Medicare Part D, a voluntary prescription drug benefit to be implemented in 2006. A primary goal of Part D is to increase access to medications for seniors and Medicare enrollees with disabilities, particularly those with low incomes and/or catastrophic drug expenses.

During the congressional debate, much of the attention was focused on nominal benefits (e.g., the size of the out-of-pocket maximum). Relatively little attention was paid to details about how plans would operate, such as the design and implementation of drug formularies (lists of drugs available for coverage by the plan). Yet, formularies and associated utilization management programs will be important tools for controlling Part D costs, and may be as important as nominal benefit design in determining enrollees' access to medications and out-of-pocket costs.[1] The Centers for Medicare and Medicaid Services (CMS) has released regulations governing Part D implementation that address issues of formulary design.[2] The regulations will ultimately have important implications for Part D's ability to improve access to needed medications, and therefore require careful consideration.

After summarizing the benefit, we describe Part D plan incentives and how these incentives might influence formulary design, demonstrating how certain features might impact Mrs. R, a 75-year-old woman with several chronic illnesses (Fig. 1). We then provide recommendations for formulary implementation under Part D.

DRUG BENEFIT SUMMARY

The benefit will be administered by private Part D plans for Medicare fee-for-service enrollees and Medicare Advantage plans for managed care enrollees, under contract with the Department of Health and Human Services (DHHS). Under the standard benefit, enrollees pay a $250 annual deductible before the plan's coverage begins. After the deductible is met and up to an initial coverage limit of $2,250, the enrollee pays coinsurance (a percentage of the medication's cost) of 25%, on average, for each prescription. Patients then pay 100% of expenditures over $2,250 until they reach the out-of-pocket maximum of $3,600. Once out-of-pocket costs exceed $3,600 in a single year, the enrollee typically pays 5% coinsurance. Plans may vary the coverage as long as it is at least as generous as the standard benefit along some key dimensions. Certain medications may be excluded, such as those covered by Medicare Parts A or B and those that may be excluded under Medicaid (e.g., weight loss drugs). As shown in Figure 1, we estimate Mrs. R's annual out-of-pocket drug expenditures to be $2,960, not including her premiums, if each drug she takes is included on her plan's formulary.

PLAN INCENTIVES AND ADVERSE SELECTION

The legislation requires that a minimum of two plans compete in each region. In theory, competition between plans is likely to result in lower costs and possibly higher quality as Part D plans compete on these attributes to enroll beneficiaries.

Plans can minimize drug costs in several ways. First, plans can encourage patients and physicians to select lower-cost medications, such as generic medications. Second, plans can negotiate lower prices with pharmaceutical manufacturers in return for using certain drugs preferentially over similar drugs. Third, plans could discourage inappropriate medication use.

Another important way in which plans can minimize costs is to enroll beneficiaries likely to have low drug expenditures, which can lead to something economists call "adverse selection." All things equal, individuals with high expected drug costs are more likely to choose generous benefit plans than individuals with more modest expected costs. Adverse selection

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Mrs. R is a 75-year-old woman with longstanding diabetes, hypertension, very-high cholesterol, depression, and arthritis, all of which are currently well-controlled. She takes atorvastatin (Lipitor®), atenolol, losartan (Cozaar®), glucophage, glipizide, venlafaxine (Effexor XR®), and celecoxib (Celebrex®). She has previously been treated with lisinopril, which caused a cough; sertraline (Zoloft®) and citalopram (Celexa®), selective serotonin reuptake inhibitors (SSRIs) that did not successfully treat her depression; and naproxen, which caused gastritis. The annual costs* of her drugs are listed below, as are her out-of-pocket expenses.

atorvastatin (Lipitor®)	80 mg a day	$1,000
atenolol	100 mg a day	100
losartan (Cozaar®)	100 mg a day	700
glucophage	1000 mg twice a day	300
glipizide	20 mg twice a day	180
venlafaxine (Effexor XR®)	150 mg a day	1,080
celecoxib (Celebrex®)	100 mg twice a day	1,100
	Total annual drug costs	**$4,460**

In addition to her monthly premium, Mrs. R's out-of-pocket expenses are:

$ 250	deductible
$ 500	25% coinsurance up to initial coverage limit of $2250
$2,210	100% of costs after initial coverage limit up to out-of-pocket maximum of $3600
$2,960	**Total out-of-pocket expenses**

Her Part D plan pays the remaining $1500 in drug expenditures.

FIGURE 1. Case study: a patient with several chronic conditions. *Drug prices were obtained from the www.medicare.gov website on May 17, 2004. The quoted prices apply to pharmacies within 3 miles of residents living in the zip code 02446.

occurs when one or more plans in a market (typically those with more generous coverage) disproportionately attract higher-cost patients but cannot charge them higher premiums.[3] Adverse selection can lead to instability in the insurance market because plans that disproportionately attract higher-cost enrollees over time may withdraw from the market, leaving only plans with less generous coverage.

Adverse selection is a particular problem for health care goods and services for which use is highly predictable from year to year, such as prescription drugs used to treat chronic conditions.[4–8] Because Part D plans face some financial risk for drug costs, they have an incentive to structure their benefit in a way that is appealing to low-cost individuals and unappealing to high-cost individuals, attempting to avoid adverse selection. Offering more limited coverage with a restrictive formulary or strict utilization management, particularly for the most expensive drugs, might discourage a patient like Mrs. R from enrolling. Alternatively, individuals with low drug costs might happily choose such a plan in order to pay a lower premium.

One way to temper incentives for adverse selection is to risk adjust payments so that plans are paid higher premiums for enrollees likely to have high expenditures. Under Part D, CMS will risk adjust payments to plans. Existing risk adjustment methods can explain a portion of variation in drug spending across individuals, particularly when they include information about previous drug use.[8,9] However, these methods are imperfect and may not adequately protect against adverse selection.

FORMULARIES

Formularies are lists of medications available to enrollees, and tiered formularies provide financial incentives for patients to select lower-cost drugs on the list. When used appropriately, formularies can help to manage drug costs without negatively impacting enrollees' health. However, there are two potential concerns about formulary design. First, certain designs could restrict access to needed medications for some beneficiaries. Although data suggest that implementation of a pharmacy management program similar to a formulary in Canada caused no adverse effects,[10,11] adoption of a three-tier formulary and/or increased cost sharing for prescription drugs has been associated with discontinuation of medications in the United States, both those taken daily for chronic conditions and those used intermittently to treat symptoms.[12,13] Second, certain designs may discourage beneficiaries with high drug expenditures from enrolling, leading to adverse selection. Four elements of formulary design have implications for access to medications: (1) definitions of therapeutic categories and classes; (2) formulary drug selection and tier assignment; (3) processes for formulary coverage reconsideration; and (4) utilization management.

Category and Class Definition

Although the U.S. Pharmacopeia released a model system for classifying drugs into therapeutic categories and classes, plans may define categories and classes as they wish each year, subject to approval by DHHS, but are not permitted to change definitions within the year. Plans must cover at least two drugs in each class. If a plan defines a class broadly (e.g., drugs that influence the angiotensin–renin system) instead of narrowly (e.g., angiotensin receptor blockers [ARBs]), the formulary could cover fewer drugs for certain conditions. Thus, a plan could cover two angiotensin-converting-enzyme inhibitors (e.g., captopril and lisinopril) and no ARBs. This could limit access to certain antihypertensive medications and discourage beneficiaries who use these medications (particularly patients with diabetes or heart disease who may take other expensive drugs, such as Mrs. R) from enrolling. Although this example seems unlikely, it nevertheless meets the guidelines of the U.S. Pharmacopeia model classification system.

Similarly, the U.S. Pharmacopeia model defines "antidepressants" as a category and "reuptake inhibitors" as a class. By their definition, reuptake inhibitors include selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, sertraline, paroxetine, and citalopram; selective norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine; and tricyclic antidepressants (TCAs), an older class of antidepressants with more problematic side-effect profiles for many patients than SSRIs and SNRIs. With this definition, a plan could, in theory, cover only 2 TCAs and no SSRIs or SNRIs, or cover only a small subset of reuptake inhibitors. This could limit access to antidepressant medications and discourage beneficiaries who use these medications from enrolling. The way a plan defines categories and classes will affect the relative generosity of the coverage and the enrollees attracted to the plan.

Formulary Drug Selection and Tier Assignment

Plans may select the type of formulary they will use. For example, under a 3-tier formulary, the first tier typically includes generic drugs with the lowest cost sharing (e.g., 10% coinsurance), the second includes preferred brand-name drugs with higher cost sharing (e.g., 25%), and the third includes nonpreferred brand-name drugs with the highest cost

sharing (e.g., 40%). Plans also decide the tier assignment for each formulary drug.

When selecting a Part D plan, beneficiaries taking high-cost medications to treat chronic conditions may review formularies to see whether the drugs they take are on tiers 1 and 2 (with lower cost sharing) instead of tier 3, and this may influence their enrollment decisions. To take an extreme example, if a plan's formulary includes on tiers 1 and 2 only drugs with lower efficacy or more side effects than other drugs used to treat a condition, individuals with that condition would be less inclined to enroll. For instance, if a plan's cholesterol-lowering medications include only generic lovastatin in tier 1, pravastatin in tier 2, and atorvastatin in tier 3, patients with particularly high levels of low-density lipoprotein (LDL), such as Mrs. R, may be less likely to join because atorvastatin, which lowers very high LDL levels more effectively, carries the highest cost sharing.[14]

The legislation is silent about formulary changes a plan can make when a generic alternative becomes available within a calendar year. Consider a 3-tier formulary that listed sertraline and citalopram in tier 2 at the beginning of 2001. Once generic fluoxetine became available in August 2001, the plan could have listed fluoxetine as a tier 1 generic drug and listed all brand SSRIs in tier 3 with the highest copayment (i.e., have no tier 2 brand SSRIs on the formulary).

Formulary Coverage Reconsideration

The CMS regulations[2] suggest that plans must have formal procedures that allow enrollees or their physicians to request reconsideration of coverage decisions (i.e., which drugs are considered "nonformulary") and the application of tiered cost sharing. For example, a patient with osteoarthritis who cannot tolerate the formulary's nonsteroidal anti-inflammatory drugs (NSAIDs) can request coverage of a cyclooxygenase-2 (COX-2) inhibitor (e.g., celecoxib). The reconsideration process is particularly important because costs for nonformulary drugs do not count toward the beneficiary's out-of-pocket maximum. The rate at which reconsideration requests are granted, the timeliness of the process, and the burden placed on patients and providers will have important implications for access to needed medications as well as whether certain types of enrollees remain enrolled or switch plans.

Utilization Management

Plans are required to implement a utilization management program that provides incentives to use lower-cost medications when appropriate. Utilization management could require documentation of certain clinical characteristics before granting nonformulary drug coverage or require that a patient fail a generic drug before granting approval for a more expensive brand medication. Although utilization management may promote more appropriate prescribing in some cases, these programs could also encourage patients and their physicians to select drugs that may be less appropriate. For example, if Mrs. R's plan will not cover her current antidepressant, venlafaxine, unless she fails the antidepressant fluoxetine (despite already failing treatment with two other SSRIs), the control she has achieved for her depression could be disrupted. Strict utilization management could also encourage individuals taking drugs affected by the program to seek a different plan.

FORMULARIES AND PART D IMPLEMENTATION

Although physicians working in a single health care delivery system generally have good experiences with formularies,[15,16] many physicians have negative attitudes toward formularies, particularly physicians who contract with multiple plans and do not use computers for paperwork and prescriptions.[17] Because most markets are served by several health plans, physicians often deal with multiple formularies and coverage rules, which may change throughout the year. The implementation of Part D, with each plan having its own formulary and reconsideration process, will increase the complexity of prescribing further. Moreover, it poses the risk of substantial burden on physicians and patients when up-to-date information about each patient's formulary is not readily available or when reconsideration requests are necessary. These issues may be particularly problematic for physicians of Medicare beneficiaries who live in more than one area of the country during the year (e.g., "snowbirds") because they will also be faced with formulary rules and reconsideration processes from plans outside their region.

Physicians consider insufficient time the most important barrier to discussing out-of-pocket costs with their patients,[18] and additional administrative burdens may negatively impact the discussions they have with patients about Part D. Even when physicians do spend time addressing Part D with their patients, the limited experience that most Medicare patients have with formularies and appeals of coverage decisions may create additional challenges to their obtaining the drugs they need in a timely manner. Ultimately, complicated or restrictive formularies could prompt physicians to encourage their patients to join plans with less restrictive formularies.

RECOMMENDATIONS

As CMS prepares to implement Part D, details about formulary design, associated utilization management, and reconsideration and appeals processes require careful consideration to assure enrollees access to necessary medications and to prevent adverse selection among Part D plans. The legislation requires that the Secretary of DHHS not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to "substantially discourage enrollment" by certain Part D eligible individuals.[19] However, it does not specify what criteria the Secretary would use to make such determinations or the extent to which these criteria would be enforced. This concept will be challenging to measure over time, particularly given the possibility of annual changes in class definition and frequent changes in formulary content.

Nevertheless, we believe it is crucial that CMS monitor Part D formularies to ensure that the designs do not discourage enrollment and that patients do not go without needed drugs. Given the complexity and multifaceted nature of plan design, we expect that additional resources beyond those already allocated will be necessary to ensure proper monitoring. Such monitoring could have several features. First, a central pharmacy and therapeutics (P&T) committee could review all formularies to assure that their design is evidence based and is not likely to promote adverse selection. Second, CMS could routinely audit reconsideration decisions to assure that patients are not being denied necessary medications. Third, CMS could identify certain patient populations (e.g., HIV/AIDS patients) for whom strict formulary designs may not be

appropriate. Fourth, plans could be required to provide person-level data on drug utilization, and CMS could sponsor studies of medication use among enrollees within markets using these data to assure that Part D has not promoted adverse selection and assess the extent to which the risk adjustment methodology is influencing enrollment dynamics.

Although a single national formulary would greatly simplify the use of formularies for physicians and their patients, the Congress elected to allow each plan to design and manage its own formulary and formulary reconsideration process, hoping that flexibility in the use of private sector management tools like formularies would stimulate competition between plans and help to control costs. To assist physicians and patients with the challenges associated with multiple formularies serving each market, we encourage CMS to develop standardized tools to provide physicians and their patients with up-to-date and easily accessible information about the drugs included on each plan's formulary (perhaps via central websites or by promoting the use of "smart" handheld or electronic-prescribing tools that could be developed for each market). In addition, a national set of easy-to-follow procedures for reconsideration and appeals will help avoid overwhelming physicians with burdensome administrative processes. Such strategies will be necessary to assure that physicians can help patients obtain the drugs they need. Physician organizations, patient organizations, Part D plans, and Congress can play a role by insisting that CMS provide evidence about the performance of the Part D program, including avoidance of adverse selection, effectiveness of risk adjustment strategies across populations of patients, and summary data from routine audits to assure that patients are not being denied necessary medications.

Drug formularies will have an important role in controlling the costs of the new benefit. However, it is crucial that these formularies be implemented in such a way that they do not impede the legislation's goal of improving access to medications for seniors and disabled Medicare beneficiaries.

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