

The Effect of Formularies and Other Cost Management Tools on Access to Medications: An Analysis of the MMA and Proposed Regulations

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Introduction

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides for an outpatient prescription drug benefit to be delivered through private prescription drug plans and Medicare Advantage plans. The law puts the plans at risk for the cost of the drug benefit (although it includes some provisions for the government to share that risk). Plans thus have a clear incentive to control the cost of the benefit, both to protect their own bottom line and to offer a favorable premium in marketing to potential enrollees.

In the private sector, employers and health plans offering drug benefits employ a variety of tools to manage costs. They typically contract with pharmacy benefit managers (PBMs) to design and implement these tools. Many of these tools are centered on the use of a drug formulary, defined as a list of drugs selected as those that are most useful in patient care, based on both clinical effectiveness and cost considerations. In some cases, formularies are closed, thus excluding coverage for some drugs. In other cases, the formulary is open and all drugs are covered. In either situation, drugs may be arrayed into tiers and incentives intended to encourage use of drugs in the preferred tiers. These incentives can take the form of differences in the cost sharing faced by plan enrollees or procedures such as prior authorization or step therapy that make the use of non-preferred drugs more difficult.

In general, the MMA presumes that most or all of the tools that are commonly employed in the private sector will be available to Medicare drug plans. The law and the recently released proposed regulations to implement the law address the need for certain constraints on the use of these tools, such as the law's provision that the use of formularies and other cost containment tools do not discriminate against certain types of beneficiaries and that the use of tiered cost sharing be actuarially equivalent to the basic benefit design in the law. The proposed regulations for implementing the law generally provide only limited amplification of these policies, leaving many key decisions open for comment or subject to other procedures for providing guidance.¹

This policy brief examines the provisions of the law and the proposed regulations with regard to the use of cost management tools. In particular, it considers implications of these provisions for beneficiaries' access to needed medications and for the ability of plans to manage overall costs. The first half of this brief reviews the major cost management tools and the statutory and regulatory provisions that might affect their use. The second half lays out several major issues, most of which affect more than one of the tools.

¹ Department of Health and Human Services, Centers for Medicare & Medicaid Services. "42 CFR Parts 403, 411, 417, and 423: Medicare Program: Medicare Prescription Drug Benefit," *Federal Register* 69(148): 46632-46863, August 3, 2004. Page citations in the text are from this reference.

The Use of Formularies

Formularies have become a nearly universal tool in the management of drug benefits. In the private sector, nearly 90 percent of health plans use a formulary of some sort.² It seems certain that Medicare drug plans will have some kind of formulary, but that they may employ these formularies in very different ways.

The MMA anticipates this use of formularies and includes just two basic requirements. First, Medicare will establish a therapeutic classification system that can serve as the basis for plan formularies. Such a system includes a listing of drug classes and categories to which all drugs can be assigned. The law calls for US Pharmacopeia (USP) to develop a model classification system, which will then be published by the Secretary. Plans are not required to use the model system, but there are certain incentives to do so.

Second, the Secretary has the authority to disapprove a drug plan whose design or benefits (explicitly including the formulary) substantially discourage enrollment of certain beneficiaries. This nondiscrimination rule, as discussed below, is potentially a key mechanism for protecting beneficiaries. Those plans that use the model classification system will be protected from further secretarial review for nondiscrimination, but they can still be reviewed for the selection of drugs within categories and classes.

In addition to these major requirements, the law also requires that a plan's formulary must be developed and revised by a pharmacy and therapeutic (P&T) committee, which must include at least two independent members, and that the plan must have a scientific basis for deciding what drugs are included on the formulary. The preamble to the proposed regulations suggests that the Secretary is considering strengthening the statutory requirement by asking for comment on an interpretation that the P&T committee's decisions regarding the formulary should be binding on the plan. It also seeks comment on the appropriateness of strengthening the law's requirement that at least one pharmacist and one physician on the committee be independent of the plan (p. 46659).

The Use of Closed Formularies

In a closed formulary, plans limit the set of drugs on the formulary and offer coverage only for those drugs. This approach has become quite rare in the private sector, used by only 2 percent of private plans.³ It has remained, however, more common in Medicare Advantage (previously Medicare+Choice) where about one-third of plans use closed formularies.⁴

The MMA requires that a drug plan's formulary include drugs in each therapeutic category and class, a standard that is clarified in the proposed regulations to require at least two drugs (as long

² *The Prescription Drug Benefit Cost and Plan Design Survey Report*, 2003 edition. Pharmacy Benefit Management Institute, Inc., 2003.

³ *The Prescription Drug Benefit Cost and Plan Design Survey Report*, 2003 edition. Pharmacy Benefit Management Institute, Inc., 2003.

⁴ Achman, Lori, and Marsha Gold, *Trends in Medicare+Choice Benefits and Premiums, 1999-2002*, The Commonwealth Fund, November 2002, and personal communication.

as there are two drugs in the class) (p. 46660). For beneficiaries, the significance of this requirement is twofold. They will have to pay the full cost out of pocket for any drugs not on the formulary, and the costs incurred for these drugs will not count toward the true out-of-pocket (TrOOP) amount that triggers the catastrophic benefit.

The impact of the two drugs per class requirement depends heavily on the therapeutic classification system in place. As noted above, the Secretary will publish a model system developed by US Pharmacopeia, but plans will not be required to use this system. Plans will face several strategic decisions, including whether to use the model classification system, whether to close their formulary in general or in particular classes, and what range of drugs to include on formulary in classes they choose to close.

Although the law did not provide specifically for an exceptions process for beneficiaries who want access to a drug that is excluded from the formulary, the proposed regulation would apply it to this situation. The preamble indicates that, since such requests are subject to external appeal, it makes sense also to require a process for requesting exceptions (p. 46720).

The Use of Formularies with Tiered Cost Sharing

Plans may apply different levels of cost sharing for drugs in different tiers of their formulary, regardless of whether a particular drug class is closed (i.e., only some drugs are covered) or open (all drugs are covered). A plan could even choose to cover all drugs in all classes (thus, in effect not have a formulary), while applying tiered cost sharing or prior authorization to encourage use of preferred drugs in some or all of the classes.

In the private sector, tiered cost sharing has become a dominant approach to cost management. In 2004, 65 percent of covered workers in the private sector faced three-tier copayments, where generics are placed on the lowest-cost tier with an average copayment of \$10 or a coinsurance of 20 percent. The second tier typically includes preferred brand-name drugs with an average copayment of \$21 or a 26 percent coinsurance. The third tier includes non-preferred brand-name drugs for \$33 or 31 percent. Another 20 percent of workers saw two-tier systems, with generics only or generics and preferred brand-name drugs on the first tier. A few plans have experimented with four-tier systems, where the fourth tier (\$48 copayment or 31 percent coinsurance) is typically reserved for very high-cost drugs or drugs that treat symptoms for conditions that are unlikely to have life-threatening consequences (e.g., allergies or sexual dysfunction). Most plans use flat copayments, although there has been some increase in the use of percentage coinsurance.⁵

Under the MMA, tiered formularies must meet the actuarial equivalence test set forth in the statute, in addition to being subject to the nondiscrimination rule. The statute includes several criteria that must be met to preserve some elements of the deductible, coverage gap, and catastrophic coverage established for the Part D benefit. The key is that plans may modify the flat 25-percent coinsurance that otherwise would apply between the deductible and initial coverage limit in establishing tiered cost sharing. There is no restriction on the absolute level of

⁵ *Employer Health Benefits, 2004 Annual Survey*, Kaiser Family Foundation and Health Research and Educational Trust, 2004.

cost sharing for a given drug or against substituting flat copayments for coinsurance as long as the actuarial equivalence test is met. The law also makes it clear that beneficiaries incurring higher cost sharing under a tiered system may apply these additional payments to meeting the TrOOP test.

The MMA provides that plans have a process for requesting exceptions to the tiered formulary for beneficiaries wishing to get access to a higher-tier drug at a lower cost. The proposed regulations specify some of the procedures that a plan must follow, for example that a request be based on a physician's determination that the preferred drug is less effective or would have adverse effects on the beneficiary (while noting that other stricter standards might be permitted). But the proposed regulations do not specify what kind of standard a plan may apply in judging whether an exception is granted (e.g., medical necessity) or what the remedy should be if one is granted (e.g., whether the drug should be available at the lowest cost sharing level). The preamble does note a preference for not being overly prescriptive on the plans in order to preserve flexibility and the ability of plans to enforce cost containment (p. 46719-20).

Other Cost Management Tools

In addition to tiered cost sharing, health plans may employ other tools to enforce their formulary or to manage the cost of drugs more generally. In the private sector, about three-fourths of plans use prior authorization, where the plan must grant permission before a particular prescription can be filled. About half of plans use therapeutic substitution, a program designed to switch a patient from one medication to another that is on a preferred drug list or formulary (either accomplished at the point of sale or after an initial prescription is filled with the drug originally prescribed). About one-fourth of plans use step therapy, where payment for a drug is restricted unless certain other drug therapies have been tried first (e.g., Cox-2 inhibitors for arthritis might be available only to patients who do not respond successfully to less costly non-steroidal anti-inflammatory drugs or NSAIDs).⁶ For any of these tools, the plan has the authority to deny payment for the drug, but a physician must authorize any change in the drug used by a particular patient. These tools may be used in conjunction with tiered cost sharing or as an alternative to that approach.

The MMA does not explicitly single out any of these techniques, but the preamble to the proposed regulations makes clear that their use by Medicare Part D plans is assumed. For example, the preamble states the expectation that P&T committees would be involved in decisions about their use and asks for comment on whether there are industry standards in this area. Their use would be subject to review under the nondiscrimination rule. In that context, the preamble raises questions about the impact of these tools on vulnerable populations such as those in long-term care facilities and notes the need to balance plans' flexibility in using prior authorization with beneficiary needs (p. 46659-61).

The law and the proposed regulations repeatedly make clear that high use of generic medications is a goal of the program; for example, the preamble explicitly suggests that formularies have a "wide range of generic drugs" (p. 46660). The law requires that information be provided to the beneficiary (at the point of sale for retail customers) on the savings available if he or she

⁶ *The Prescription Drug Benefit Cost and Plan Design Survey Report*, 2003 edition. Pharmacy Benefit Management Institute, Inc., 2003.

switched to the generic alternative. In addition to lower cost sharing for using generic drugs, private-sector plans sometimes pay higher dispensing fees to pharmacists when filling a prescription with a generic drug, especially effective in the roughly 40 states where state law allows pharmacists to fill a prescription with a generic drug unless the prescribing physician indicates on the prescription “no substitution” or that the brand-name drug is “medically necessary.”⁷ Other plans have engaged in education campaigns aimed at convincing either beneficiaries or physicians on the wisdom of substituting generic drugs where available. Some observers have suggested that seniors are often unwilling to challenge their doctor on what is prescribed and may not understand that generic drugs can generally be substituted without adverse consequences.

Another tool that is used by some private-sector plans is to encourage filling some prescriptions by mail order or even to require that prescriptions for certain maintenance medications be filled by mail. Where voluntary programs are encouraged, about 11 percent of prescriptions are filled by mail, and where some drugs must be filled by mail, the use of mail order rises to 34 percent.⁸ The MMA allows the use of mail order but insists that any prescription (even 90-day supplies) can be filled at retail. It does, however, allow plans to have lower cost sharing when a prescription is filled by mail, and the regulations make it clear that the cost sharing difference could be substantial. The use of cost sharing incentives to encourage filling prescriptions by mail is subject to the actuarial equivalence test, and the higher amounts paid by the beneficiary would count toward meeting the TrOOP test.

Finally, some plans – especially in certain Medicaid programs or Medicare Advantage plans – have controlled costs through quantity limits, for example, limiting some prescriptions to a certain number of pills or capping the number of prescriptions that may be filled in a month. The proposed regulations, however, do not prohibit the use of such limits.

Issue: The Nondiscrimination Criteria

The nondiscrimination rule could be one of the most significant tools for protecting beneficiaries from inappropriate use of cost management tools. It potentially gives the Secretary the authority to reject bids from plans whose proposed use of these tools is aimed at excluding beneficiaries, such as those with costly medical conditions. Should its application prove limited, beneficiaries who have serious chronic conditions may find few if any plans that provide them affordable access to the drugs they need. In addition, plans using tools that discourage enrollment of sicker beneficiaries will likely experience favorable selection and achieve an unfair advantage in market competition.

The statement in the law is broad, allowing disapproval of a plan bid if 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 beneficiaries under the plan.”⁹ In the proposed regulations, the regulatory text addressing this provision simply repeats the basic

⁷ NIHCM Foundation, *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace*, June 2002.

⁸ *The Prescription Drug Benefit Cost and Plan Design Survey Report*, 2003 edition. Pharmacy Benefit Management Institute, Inc., 2003.

⁹ Medicare Modernization Act, 1860D-11(e)(2)(D)(i).

requirement in the law. Preamble language, however, interprets discriminatory to mean discouraging enrollment “on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability.” The preamble goes on to say that the Secretary would review plans for features that would have “differential impacts on beneficiaries with particular medical conditions” (p. 46680).

Although this language addresses broadly the idea that the rule bars designs that discriminate based on medical conditions, it could be interpreted to leave open some discriminatory approaches. Suppose, for example, that a plan chose to exclude from its formulary or assign to a higher tier all drugs that cost more than a given amount (with exceptions only as needed to meet the statutory requirement of covering two drugs in each therapeutic class). The plan might argue that its formulary cannot be judged discriminatory since the criterion is strictly one of cost.¹⁰ Those arguing that this formulary design should be excluded would have the more difficult task of showing that it had the effect of excluding beneficiaries with conditions that could only be treated with expensive drugs.

This language might also make it difficult to exclude a formulary that was judged to discriminate against certain racial or ethnic groups. There is clinical evidence that beneficiaries of different races or ethnic groups respond differently to certain drugs, for example, those used to treat hypertension. If a formulary design excluded those drugs considered more effective for African American beneficiaries, it might be judged not to discourage enrollment on the basis of health status, again leaving it more difficult to deny participation to that plan or require that its formulary be modified.

Enforcement of the nondiscrimination standard may also be a significant challenge for the Secretary. On the one hand, it should be relatively easy to apply the rule (whatever its regulatory interpretation) in looking at the assignment of drugs to a formulary and to tiers on that formulary. Reviewers can look at which drugs are excluded or assigned to high cost-sharing tiers and make judgments about whether certain types of beneficiaries will need those drugs. Nevertheless, issues will arise. For example, a cost-sharing tier where the beneficiary pays 50 percent of the cost of the drug will have a different impact if the prescription costs \$10 or \$200, and that impact will vary according to the income of the beneficiary. Those with the lowest incomes are protected by the subsidies in the law, but those just above the threshold for subsidies (150 percent of the federal poverty level) will have a hard time paying half the cost of a \$200 drug each month. More generally, the absence of detailed regulatory language interpreting this standard may make it hard to enforce.

In addition, it will be even harder to apply the nondiscrimination rule to cost-management tools other than the formulary itself. Discriminatory use of a tool like prior authorization will require a judgment about how the process works. The preamble to the proposed regulations indicates an intention to review formal requirements, which might include both the list of drugs subject to prior authorization and the criteria for obtaining approval (e.g., whether the physician has to provide written documentation of the patient’s need or just place a request by phone). But it will

¹⁰ Jeanne M. Lambrew, “Highlights from the Medicare Prescription Drug Regulation: The Good, the Bad, and the Ugly,” Center for American Progress, August 12, 2004.

also be important to review how easily authorization is granted (e.g., whether most requests are authorized quickly or whether many are rejected or sent back for more documentation). Evidence of these variations may be unavailable until the system has been in place for several months.

Ultimately, the means of enforcement may be the key to the effectiveness of the nondiscrimination rule, yet the proposed regulations give little indication of the Secretary's intent or process for enforcing this provision. In a discussion paper released in conjunction with the publication of draft model guidelines for the therapeutic classification system, CMS notes that it "will review formularies for adequacy and nondiscrimination according to publicly reviewed principles that will make sure patients have reasonable access to important drugs."¹¹ In the paper, the agency also signals its intention not to allow plans to discourage enrollment by requiring higher cost sharing on drugs that disproportionately affect specific groups, such as by placing all antiretroviral drugs in the highest tier. The language in this paper appears to go somewhat beyond that in the preamble to the proposed regulations, although it would have to be incorporated in the final rule to have legal standing. Furthermore, the comments there do not broaden the standard to include discrimination on grounds other than health status.

Another challenge will be fitting a review into a tight timetable. The schedule for submitting and approving plan bids will constrain this process in the best of circumstances, since plan bids are due in early June and must be approved well in advance of the November open season (enough in advance to know if fallback plans are needed and to allow plans to get marketing materials approved). Especially in the first few years, the Secretary will not be able to draw on past experience with drug plans on the effect of different formulary designs. Nor is there any indication of what resources might be devoted to enforcement of the nondiscrimination rule. Finally, there is no indication of whether or how the Secretary will review midyear changes to the formulary or other cost management tools without regard to any potential discriminatory effect.

Issue: The Therapeutic Classification System

Although the proposed regulation is mostly silent on the establishment of a model therapeutic classification system, US Pharmacopeia issued model guidelines for drug categories and classes on August 19 and held a public meeting to solicit comments on August 27.¹² The model guidelines lay out a classification system with 146 distinct drug classes – a number larger than that advocated by PBMs and other potential drug plan sponsors, but smaller than that preferred by pharmaceutical manufacturers. Subsequent to publication of the model guidelines, CMS issued a discussion paper that comments on some aspects of the classification system, although it is unclear whether the ideas discussed carry status equivalent to preamble comments in the proposed regulation.¹³

¹¹ "Role of USP Draft Model Guidelines for Formulary Classification in Determining Formulary Adequacy for the Medicare Drug Benefit," CMS Discussion Paper, August 2004.

¹² *Medicare Prescription Drug Benefit Draft Model Guidelines: Drug Categories and Classes in Part D*, United State Pharmacopeial Convention, August 2004.

¹³ "Role of USP Draft Model Guidelines for Formulary Classification in Determining Formulary Adequacy for the Medicare Drug Benefit," CMS Discussion Paper, August 2004.

Beneficiaries will have the greatest opportunity to obtain drugs they need if there are a larger number of distinct drug classes, since this would require more drugs to be included on the formulary. In this one respect, beneficiary interests tend to be aligned with those of drug manufacturers. These aligned interests might break down, however, if beneficiaries gain access to more drugs but incur higher costs either because plans have less ability to bargain for lower prices or if they place the additional covered drugs in higher cost sharing tiers.

To illustrate the effects of formulary classes, anti-ulcer agents are one class of drugs in the model guidelines within the larger therapeutic category of gastrointestinal medicines. The anti-ulcer class contains both the older H2 blockers (e.g., Pepcid, Tagamet, and Zantac – all of which are available over the counter in low doses and by prescription for higher doses) and the newer proton pump inhibitors or PPIs (e.g., Prilosec, Prevacid, Protonix, and Nexium). Because a plan could meet the requirement of two drugs in the class by offering two H2 blockers on its formulary, a patient needing a PPI could be denied coverage. Yet if two separate classes of anti-ulcer drugs were created, the plan could still propose to cover the H2 blockers in a low cost sharing class and the PPIs at high cost sharing.

The potential for a finer or more granular set of classes is recognized by USP in listing a set of “recommended subdivisions” for some drug classes, which it offers to CMS as a comment for consideration. PPIs and H2 blockers would be separated under the recommended subdivisions. Should all the subdivisions be added to the classification system, the number of distinct drug classes would grow from 146 to about 235. Among the other drug classes where groupings in the model guidelines could affect large numbers of patients are anti-depressants, where older tricyclics are grouped with newer SSRI drugs; non-steroidal anti-inflammatory drugs, where Cox-2 inhibitors are grouped with older NSAIDs; and cardiovascular drugs, where ACE inhibitors are grouped with ARBs (although this group is distinct from beta-blockers, calcium channel blockers, and diuretics, all of which are also used to treat hypertension).

Beneficiaries do not benefit only from having a large number of classes. They will also benefit if plans can use the competition among drugs in a larger class to obtain lower prices, thus presumably lowering both beneficiary copayments and plan premiums. The anti-ulcer drugs illustrate this tension. Some experts suggest that PPIs are over-prescribed and that many who use them would be better treated with the less expensive H2 blockers. Yet for some patients, especially those with gastroesophageal reflux disease or GERD, the H2 blockers are not satisfactory treatments. While an effective exceptions process could guarantee that these patients gain access to PPIs at a reasonable price, it is unclear whether the number of patients in this situation would burden the exceptions process or whether plans would have any real incentive to grant exceptions allowing the purchase of drugs that are considerably more expensive. Nor is it clear from the proposed regulations that the exceptions process envisioned is adequate to suit the needs of these patients.¹⁴

In the discussion paper it released immediately after the USP guidelines were published, CMS seems to put forward a higher standard than the required two drugs per class. The paper states

¹⁴ More discussion of issues relating to grievance and appeals procedures in the proposed regulations is in a forthcoming policy brief by Sara Rosenbaum, to be published by the Kaiser Family Foundation.

that “available drug choices must represent a full range of drug therapies necessary to adequately support current medical practice.” It goes on to note that while this requirement could be met by offering two drugs in some classes, the “majority will need to include more drugs” and that the agency will “evaluate available formulary choices and conditions at the sub-class level.”¹⁵ This apparently stiffer requirement would have to be incorporated in the final regulations, but may speak to the agency’s intent for its enforcement role.

Issue: The Actuarial Equivalence Standard

Because tiered cost sharing is expected to be a major tool for Medicare Part D drug plans, the actuarial equivalence test will have considerable importance in setting boundaries on allowable cost sharing. A plan is allowed to lower the \$250 deductible, change the \$2,250 initial coverage limit, and apply different coinsurance (or flat copayments) up to the initial coverage limit, as long as its assessment of the actuarial value remains equal to that of the standard benefit. Included in this test is the requirement that not only the value of the total coverage be the same as for the standard benefit, but also the value of coverage below the initial coverage limit and the value of unsubsidized coverage be the same as those segments of standard coverage. The proposed regulations indicate that a qualified actuary (a member of the American Academy of Actuaries) must certify the plan’s actuarial valuation as part of the bid the plan submits to the Secretary (p. 46676).

Within the bounds of actuarial equivalence and the application of the nondiscrimination standard, neither the law nor the regulations restrict the tiered cost sharing design. Thus, there are no absolute limits on how tiers can be structured. For example, a plan could provide for higher coinsurance for spending between the \$250 deductible and \$1,000 in drug costs and lower coinsurance between \$1,000 and the \$2,250 initial coverage limit. Alternatively, based on its formulary, a plan could set the coinsurance for some nonpreferred drugs at 90 percent or even 100 percent, and it could set different tier structures in each class. The calculations necessary for the actuarial equivalence test will determine, for example, whether a 90-percent tier for some drugs must be offset by a 5-percent tier or a 15-percent tier for other drugs. But the regulations do not require this test to be met within each class of drugs. The test must take into account expected behavioral responses to different cost sharing structures, although there is little if any empirical evidence to estimate beneficiary response to designs that are not used in the private sector.

CMS has indicated that, in enforcing the nondiscrimination standard, it will review the design of tiered cost sharing. But a design that passes muster on this standard (especially if the standard is interpreted narrowly) and that meets the actuarial equivalence test may still pose difficulties for beneficiaries, especially if some categories and classes include no drugs in the lowest cost sharing tier.

Enforcement of the actuarial equivalence test also raises some issues. The proposed regulations rely on an actuary’s certification that the benefit design meets the test, and the preamble suggests that additional information will be provided in the form of interpretive guidance. The preamble

¹⁵ “Role of USP Draft Model Guidelines for Formulary Classification in Determining Formulary Adequacy for the Medicare Drug Benefit,” CMS Discussion Paper, August 2004.

also talks generally about specifying data elements to be submitted, so that the Secretary can “evaluate the analysis and assumptions for compliance and reasonableness” (p. 46675). As in the case of evaluating therapeutic classifications and the potential for benefit designs and formularies to discriminate against certain classes of beneficiaries, the actuarial equivalence test moves the program into relatively uncharted territory. Regardless of the regulatory requirements, the impact of this provision will be seen largely in how it is enforced.

Some concerns, such as whether tiers based on the level of drug spending or extremely high cost sharing for certain non-preferred drugs, may need to be addressed in more concrete terms than simply being left to a general review for actuarial equivalence and nondiscrimination. The Secretary could consider setting some overall limits to what is allowed. Alternatively, limits could be established in legislation.

Issue: Role of P&T Committees

As noted above, the law requires a role for the plan’s pharmacy and therapeutics committee in developing and revising the formulary. The preamble to the proposed regulations asks for comments on several options: clarifying that the committee’s role is binding on the plan, expanding the law’s requirement for having independent members, and involving the committee in reviewing other cost management tools such as prior authorization (p. 46659). It does not specify, however, that a P&T committee must be formed by a plan that has no formulary and uses only tiered cost sharing or prior authorization.

The initial requirement of two independent members falls short of creating an independent committee, and the possible expansion of that requirement could change its complexion considerably. Because neither the law nor regulations speaks to the size of the committee, however, the number of independent members may need to be stated as a proportion of committee members rather than absolute numbers. Still, it seems unlikely that potential plan sponsors will readily agree to a committee that is fully independent and whose decisions are binding on the plan. Further attention is needed to establish a role for the P&T committee that will help ensure that beneficiaries’ interests are well represented.

The law also requires that the committee’s decisions should be based on “the strength of scientific evidence and standards of practice.”¹⁶ There is growing interest in basing formularies on unbiased scientific evidence, and the directive at least points in this direction. For example, the preamble cites Public Health Services guidelines for treatment of HIV disease as “helpful” to P&T committees (p. 46659). As noted above, beneficiaries might be better off when plans put equivalent drugs in competition to obtain lower prices, but evidence suggests that some private-sector plans place a drug on a preferred tier based on the size of a rebate rather than on an overall lower price. It may be important to consider whether greater reliance on evidence-based decision making (as well as transparency of pricing) will help align the plan’s interests with those of beneficiaries in terms of obtaining lower prices. Although it is unlikely that regulatory requirements can accomplish this alone, they might push plans to move in this direction.

¹⁶ Medicare Modernization Act, 1860D-4(b)(3)(B)(i).

Conclusion

The array of cost management tools will be a major factor in determining what the drug benefit really means to the beneficiary. Formularies, cost sharing, and the use of tools like prior authorization will be critical to whether beneficiaries can get the drugs they need. For beneficiaries with modest drug needs who do not fall into the coverage gap, these factors will probably be the most important aspect of their benefit, driving whether their drugs are covered and how much they cost. For those with more substantial drug costs, formularies and cost sharing tiers will help determine the burden imposed by the coverage gap and when catastrophic protection kicks in. The way these tools are used will also speak to the hassle factor faced by beneficiaries and their physicians, that is, how often needed drugs are unavailable and when exceptions must be requested.

As noted earlier, there is a potential tradeoff between what helps individual beneficiaries at any given time (e.g., being able to obtain the drugs their doctors prescribe) and what helps beneficiaries more broadly (e.g., lower prices and lower premiums). For medical conditions like depression, bipolar disorders, or hypertension, treatment decisions are relatively individualized, that is, the drug that works for one patient may not work for another. For beneficiaries with these conditions, less restrictive formularies or fewer drugs on a high-cost tier may be important to maximizing quality of care. For other medical conditions such as allergies, arthritis pain, or ulcers, the choice of drugs may be less critical. But there are still some patients, especially those with certain accompanying conditions, for whom the preferred drug may not work. The average beneficiary in these circumstances may see reduced premium costs if plans use their market leverage to bargain for the best price among a set of drugs where good evidence on comparative effectiveness concludes that the drugs are generally equivalent. For these drug classes, a good exceptions process may be the key to protecting beneficiaries with special circumstances.

The MMA and the proposed regulations to implement the new drug benefit provide some guidance to address these issues, but they are silent or merely ask for public comment on many of the key questions. Undoubtedly, the Secretary will receive many comments from the public on these important provisions. In preparing the final regulations for the drug benefit, it seems critical that careful consideration be given to making sure that key beneficiary protections are workable: that the nondiscrimination test is meaningful and can be enforced, that the therapeutic classification system provides appropriate access to drugs that beneficiaries need, that the actuarial equivalence standard prevents the use of cost sharing that is prohibitive to beneficiaries, that P&T committees can base decisions on scientific evidence, and that their role in advising plan sponsors is more than symbolic.



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