

EXECUTIVE SUMMARY

As part of the Medicare Part D pharmacy benefit scheduled for implementation in 2006 by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), beneficiaries will have a choice of private plans administering the benefit. Although plans are required to provide access to needed drugs, the law does not require plans to provide equal coverage for all drugs. Instead, it is expected that plans will offer a variety of packages that cover different drugs at different levels of cost-sharing.

The Secretary may develop policies around drug classification systems, formularies, or cost tiers to enforce the statutory provision that allows him to disallow arrangements that discriminate against certain beneficiaries. This would be particularly important if there is evidence that plans use these design elements as ways to avoid enrolling high-risk beneficiaries or that beneficiaries cannot effectively shop in this market. In preparation for implementation of the pharmacy benefit, ASPE asked a team from NORC and Georgetown University to research current formularies and classification schemes, and to model how beneficiaries might react to formularies under the Part D benefit.

Health plans and other users of prescription drug data use a wide variety of schemes for organizing information about the thousands of drugs on the market. The MMA asked the US Pharmacopeia (USP) to develop a benchmark classification scheme that can be used as the basis of comparison for formularies submitted by prospective private drug plans (PDP). We found that the USP scheme has a level of detail that falls in the middle of a continuum, with some schemes having more classes and levels, and some having fewer. We also found that the USP scheme leaves out some commonly used drugs, most notably combination drugs.

Plans are required to establish their formularies with the assistance of Pharmacy and Therapeutics (P&T) Committees. In interviews with pharmacy directors, we found that some of the MMA requirements for the structure and operations of P&T Committees are already common practice, while others will require changes. In particular, most plans we spoke with will have to make the decisions of their P&T Committees more binding, and many will have to increase their committees' independence.

Under Part D, plans can establish their own formularies and classification systems, subject to CMS' verification that they are not discriminatory. Plans will have "safe harbor" if they follow several rules relating to the USP classification system, such as:

1. At least one drug in each USP key drug type must be covered.
2. At least two drugs in each USP class must be covered.
3. All or substantially all drugs in the antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics classes must be covered.
4. There should be appropriate access to drugs listed in widely accepted national treatment guidelines.
5. Drugs should only be on a higher tier only when therapeutically similar drugs are available on a lower tier.

In addition, CMS will check drug lists against risk adjustment categories to avoid drug selection and discrimination. Although these rules seem straightforward, there are many nuanced policy issues surrounding how drugs are counted, such as how to treat differing forms or strengths of the same drug.

To analyze how these CMS rules will affect plan choices about which drugs to cover, we ran two tests. First, we asked whether drugs commonly used by Medicare beneficiaries would be covered by a plan that tried to cover only two drugs per class and one drug per key type. In 28 of the 146 classes, a minimally acceptable formulary would not cover all drugs that had at least 500,000 prescriptions filled by Medicare beneficiaries in 2001.

Second, we compared four sample formularies to these rules. The plans failed the minimum requirement for about one third of all classes. They consistently failed to list all of the drugs in the list of classes in which all drugs must be covered. These results indicate plans will need to adjust current formularies to participate in Part D, or make arguments to CMS about why their existing formularies are adequate.

Finally, we constructed a model that simulates beneficiaries' responses to plan decisions about formulary placement and cost sharing. This model is based on a theoretical understanding of how beneficiaries are likely to respond to price incentives, as well as expert clinical opinion about the likelihood that beneficiaries will change drugs in response to price. We included six classes of drugs with a range of price levels and generic availability, accounting for nearly half of all prescriptions filled by Medicare beneficiaries.

Tests of the simulation model with prototype formularies show that coinsurance provides more behavioral incentives than copayments, and that tiered cost sharing can further strengthen those incentives. In addition, a closed formulary will cause some beneficiaries to change to an on-formulary drug, but others will continue taking the off-formulary drug and face higher out-of-pocket costs. When we compared real-world formularies in the model, we saw similar results. In addition, the model provides a tool for identifying the potential for risk selection: one plan in our study was relatively expensive for all classes except cholesterol drugs, leading to the possibility that it might attract beneficiaries who only take one of those drugs.