

NHPF Forum Session
Meeting Announcement

**NATIONAL
HEALTH
POLICY
FORUM**

**Implementing the Formulary
Requirements Under the New
Medicare Prescription Drug Benefit**

A DISCUSSION FEATURING:

Robert Donnelly, MPP
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Center for Beneficiary Choices
Centers for Medicare and
Medicaid Services

Anthony Barraeta, JD
Vice President
Government Relations
Kaiser Foundation Health Plan, Inc.
Oakland, CA

WITH COMMENTS FROM:

Charles Clapton, JD
Chief Health Policy Counsel
Committee on Energy and
Commerce, Republican Staff
U.S. House of Representatives

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*Chief Health and Entitlements
Counsel*
Committee on Finance,
Democratic Staff
U.S. Senate

**Wednesday,
December 1, 2004**

11:45 am — *Lunch*

12:15–2:00 pm — *Discussion*

**Reserve Officers Association
of the United States**

One Constitution Avenue, NE
Congressional Hall of Honor —
Fifth Floor
(Across from the Dirksen Senate
Office Building)

To register:

Please send your contact information to nhpfmeet@gwu.edu or call 202/872-1392 as soon as possible. Space is limited.

For additional information:

Download “The Basics: Prescription Drug Formularies” at www.nhpf.org.

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Implementing the Formulary Requirements Under the New Medicare Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new outpatient prescription drug benefit known as Part D. This benefit will be provided by private plans—both stand-alone drug plans and Medicare Advantage plans—that will share risk for the cost of the benefit with the federal government. To help plans manage this cost, the MMA allows plans to utilize cost-saving mechanisms. In particular, plans are permitted to use formularies, or lists of drugs that are approved for coverage by a plan (or other payer). It is anticipated that plans participating in the Part D benefit will utilize formularies, the design of which is left to the individual plans. Some may choose formularies that are “open,” allowing coverage for both listed and nonlisted drugs, and others may opt for “closed” formularies, providing coverage only for listed drugs. In addition to the formularies themselves, many plans are likely to include in their formulary policies other mechanisms that encourage the use of listed drugs, such as tiered copayments (for example, generic and preferred drugs require lower copayments than brand name and nonpreferred drugs), or step therapy, which would require the use of a preferred drug before a nonpreferred drug could be prescribed.

Though plans offering benefits under Part D are given the flexibility to design their own formulary policies, they are required to meet certain requirements.¹

SESSION OVERVIEW

This meeting will provide an overview of the requirements that will apply to plans (both stand-alone drug plans and Medicare Advantage plans) in the development and application of their drug formularies under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. It will review the draft model guidelines issued by the United States Pharmacopeia related to Part D drug categories and classes and will examine the implications of these guidelines on various stakeholders, including beneficiaries, providers, pharmaceutical manufacturers, and participating plans.

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MMA FORMULARY REQUIREMENTS

Under the MMA, plans are required to have their formularies developed by a pharmacy and therapeutic (P & T) committee. This committee must comprise a majority of practicing physicians and/or pharmacists. At least one of the practicing physicians and one of the practicing pharmacists must be independent from the sponsoring plan and have expertise in caring for the elderly or the disabled. Committee decisions must be based on scientific evidence and standards of practice. When determining whether to include a drug in the formulary, the committee must consider whether certain covered drugs offer therapeutic advantages in terms of safety and efficacy.

A key component of the MMA formulary provisions requires plans to include in their formularies drugs within each “therapeutic category and class” of covered Part D drugs. To assist plans in their formulary development and to give the Centers for Medicare and Medicaid Services (CMS) a benchmark against which to evaluate plan formularies, the MMA required the secretary of the Department of Health and Human Services (DHHS) to request the United States Pharmacopeia (USP), a nongovernmental, scientific, standards-setting organization, to develop a model classification system. Plans may use the USP system in the development of their own formularies, but they are not required to do so. (See below for more information on the USP system.) Regardless of the classification system a plan elects, it may only make changes to its formulary’s categories and classes at the beginning of each plan year.

A plan sponsor is required to provide information about its formulary to beneficiaries upon enrollment and annually thereafter, and it must have policies and procedures in place for educating providers and enrollees about the formulary. Plan sponsors must notify the secretary, affected enrollees, physicians, pharmacies, and pharmacists before removing a drug from a formulary or changing a drug’s preferred or tiered cost-sharing status. Finally, plan sponsors must have in place a process to enable enrollees to seek an exception to any tiered cost-sharing structure that may apply to its plan’s formulary. Such a process would allow an enrollee to purchase a nonpreferred drug at the preferred drug price if, for example, a physician determined that the preferred drug would be less effective or would have adverse effects on the beneficiary. It is important to note that the cost of nonformulary drugs is not factored in the calculation of a beneficiary’s out-of-pocket expenditures, an important consideration in determining a beneficiary’s level of coverage under this benefit.

USP Model Guidelines

At the center of significant debate are draft model guidelines that have been issued by USP. As requested by the secretary, the USP, in

consultation with pharmaceutical benefit managers and other interested parties, developed a list of categories and classes that may be used by plans in developing their formularies. Though plans are not required to adopt the USP formulary structure, another MMA provision, known as the “nondiscrimination rule,” provides an incentive for plans to do so. The secretary is directed, under MMA, to approve only those prescription drug plans whose design (including any formulary) does not “substantially discourage enrollment” by eligible beneficiaries, particularly those with higher expected drug costs, such as those with mental illness, AIDS, or other chronic conditions. A plan that designs its categories and classes in a manner consistent with those set forth by the USP is deemed by the secretary not to substantially discourage enrollment by beneficiaries. Despite this narrow “safe harbor,” CMS retains regulatory authority to review plan formularies to ensure adequate beneficiary access.

On August 19, 2004, USP published its draft model guidelines regarding these categories and classes, followed by a public comment period that ended on September 17. Final guidelines are expected to be submitted to CMS in December. In addition to receiving public comment, USP, in its effort to produce model guidelines, formed four Advisory Forums representing beneficiaries, providers, pharmaceutical manufacturers, and drug plans. It also relied on an environmental scan that reviewed the formulary classification systems of a number of entities, including Veterans Affairs, employers, hospitals, managed care organizations, and Medicaid.

The USP guidelines were ultimately based on an international disease classification system, ICD-9. After reorganizing and simplifying that system, USP developed a classification system that includes 43 therapeutic categories and 138 pharmacologic classes, resulting in 146 unique categories and classes.

(Drugs can be classified on the basis of a number of different factors, such as their therapeutic indications or chemical structure. One example is the classification of antidepressants, which could be categorized into four different therapeutic classes. Some formularies may keep them separate, whereas others may choose to combine the classes. Because different types of antidepressants may not be effective for all patients, some plans recognize the need to allow choice among a particular group of drugs.)²

Though the actual number of categories and classes are of great importance, a complete understanding of the complex USP system is not needed in order to grasp the essence of the debate: Whether the categories and classes are defined more broadly or narrowly has a direct impact on the number of drugs that will be required to be covered and the level of competition for each.

Categories that are broad create increased competition among drugs within a category, but may limit the number of drugs included in the formulary. Formularies that use more narrow categories introduce less competition among drugs and give plans reduced influence over which drugs are prescribed. Providers and disease advocacy groups who would like to see greater prescribing flexibility are likely to support a more narrow set of categories and classes. Payers and those responsible for managing the cost of drugs, on the other hand, would likely support broader classes of drugs to allow more flexibility in formulary development and increased competition within classes of drugs. Again, these model guidelines are only intended to serve as a starting point, leaving the specifics of formulary development to individual plans. Ultimately, though, CMS has regulatory oversight of all plan formularies.

As the process of finalizing the model guidelines continues, CMS will undoubtedly face pressure to balance the competing interests at stake in the debate surrounding formulary design, namely beneficiary access to needed drugs and the need of drug plan sponsors to manage the cost of this new and challenging benefit. The number of categories and classes of drugs in the model guidelines will certainly play an important role, but these cannot be viewed beyond the context of other important formulary policies and cost management tools. Together, they may well determine the full impact and effectiveness of the Part D benefit.

SPEAKERS

Robert Donnelly, MPP, is the director of the Medicare Drug Benefit Group in the Center for Beneficiary Choices at the Centers for Medicare and Medicaid Services (CMS). In this position, he has responsibility for the operational implementation of the Part D drug benefit. Prior to this position, Mr. Donnelly served as the director of CMS's Health Plan Policy Group for three years, overseeing policies related to the Medicare Prescription Drug Benefit and Medicare Advantage (MA), as well as enrollment, appeals, and consumer protections for Part D, MA, and fee-for-service Medicare. Before becoming the group director, he was the director of the Division of Program Policy, dealing with Medicare+Choice benefit and payment policy. Prior to coming to CMS, Mr. Donnelly spent five years as a program examiner at the Office of Management and Budget, working primarily on Medicare and health reform issues. He has a master's degree in public policy from the University of Michigan.

Anthony Barrueta, JD, is vice president of government relations for Kaiser Foundation Health Plan, Inc., in Oakland, CA, and he co-chairs America's Health Insurance Plans' Federal Government Relations Subcommittee on Private Market Regulation. At Kaiser,

he coordinates the development of the organization's national legislative and regulatory policy positions. He advises senior management on policy issues relating to pharmacy services and coverage of prescription drugs, and he speaks frequently on health policy topics relating to prescription drug pricing and third party drug coverage. Mr. Barrueta is a member of Kaiser Permanente's Health Policy and Interregional New Technologies Committees and the Academy of Managed Care Pharmacy's Legislative and Regulatory Action Committee. Before joining Kaiser Permanente in 1994, Mr. Barrueta was in private law practice in Washington, DC. He received his AB degree in history from Boston College and his law degree from the University of Texas at Austin.

Constantine Lyketsos, MD, MHS, is a professor and the director of the Division of Geriatric Psychiatry and Neuropsychiatry at Johns Hopkins School of Medicine, where he is also on the Bloomberg School of Public Health faculty. Dr. Lyketsos is the principal investigator of several NIH-funded studies. He has authored over 150 peer-reviewed publications, including *Practical Dementia Care* (with Peter Rabins and Cindy Steele), and has been cited in America's Top Doctors for four consecutive years. Dr. Lyketsos is a graduate of Washington University Medical School and the Johns Hopkins School of Public Health.

Jean Paul Gagnon, PhD, is director of public policy at Aventis Pharmaceuticals, Inc., in Bridgewater, NJ. For 16 years, Dr. Gagnon has worked for Aventis, where he is responsible for the company's involvement with health policy. He is currently serving as treasurer for the United States Pharmacopeia and chairman of the Health Science Council of the International Society of Pharmacoeconomics and Outcomes Research. He is a former professor and division head of pharmacy administration in the School of Pharmacy at the University of North Carolina. He received both his BS degree in pharmacy and MS degree in pharmacy administration from the University of Connecticut and a PhD degree in pharmacy administration from Ohio State University.

DISCUSSANTS

After the four lead presentations, two representatives from Capitol Hill will provide comments.

Charles Clapton, JD, is chief health policy counsel for the Republican staff of the House Energy and Commerce Committee, where he works on all health related issues within the committee's jurisdiction. His prior experience includes serving as a committee health counsel for then Chairman Billy Tauzin during the drafting and subsequent conference that led to the MMA of 2003.

Elizabeth J. Fowler, JD, PhD, is chief health and entitlements counsel for the Democratic staff of the Senate Finance Committee. In this role, she has responsibility for issues related to Medicare, Medicaid, State Children's Health Insurance Program, and welfare. Most recently, she played a key role in negotiating the MMA.

KEY QUESTIONS

- What implications will the model guidelines, as currently drafted, have for beneficiaries, providers, drug plans, pharmaceutical companies, and other stakeholders?
- Do the model guidelines provide an adequate balance between ensuring beneficiary access to needed drugs while allowing drug plans sufficient flexibility to develop their own formularies to manage costs?
- Will additional protections be needed to ensure adequate beneficiary access? To ensure appropriate levels of competition?
- What role might other cost management tools, such as tiered cost sharing and prior authorization, play in plans' overall management of drug costs?
- How effective will the nondiscrimination rule be in protecting beneficiaries from decreased access, particularly those with higher expected drug costs, such as those with AIDS, mental illness, or other chronic conditions?
- How will CMS review plan formularies and associated cost management tools to prevent discriminatory practices?
- Will plans have adequate access to the scientific evidence necessary to make appropriate formulary decisions, as required by the MMA?

ENDNOTES

1. P.L. 108-173, Title I, Sec. 1860D-4(b)(3).
2. Medicare Payment Advisory Commission, "Implementing the Medicare Drug Benefit: Formulary and Plan Transition Issues," chap. 1 of *Report to the Congress: New Approaches in Medicare*, June 2004, 8.