



Forum Session Meeting Announcement

Friday, October 19, 2007
11:45am–12:15pm — Lunch
12:15–2:00pm — Session

Medicare Drug Utilization Management: Balancing Cost, Convenience, and Access

A Discussion Featuring:

Daniel C. Lyons, MD

Senior Vice President, Government Programs
Independence Blue Cross

Holly King Morris

Pharmacist
Crittenden's Drug

Robert P. Smith, MD

Physician
Richland Medical Center

Suzanne H. Jackson

Director, Health Insurance Counseling Project
Associate Professor of Clinical Law
George Washington University Law School

THE GEORGE
WASHINGTON
UNIVERSITY
WASHINGTON DC

Medicare Drug Utilization Management: Balancing Cost, Convenience, and Access

OVERVIEW

Health plans, including Medicare prescription drug plans, use a variety of tools to manage prescription drug use and costs. The utilization management tools that plans use include quantity limits, refill limits, generic substitution, therapeutic substitution, prior authorization, step therapy, and restrictions on the use of off-label drugs. These tools are very effective in reducing drug costs, preventing clinical mistakes, and helping ensure that enrollees receive the most appropriate medication for their particular condition. They can also inconvenience beneficiaries—or worse, impair ready access to needed drugs. And the appeals processes designed to ensure the resolution of disputes between plans and beneficiaries are thought by many to be impractical or too difficult for typical beneficiaries to understand. This Forum session will explore whether or not Medicare Part D has achieved the right balance of cost containment, convenience, and access. Speakers will include a Medicare drug plan senior manager, a practicing physician, a community pharmacist, and a counselor who helps low-income beneficiaries navigate all of these issues.

SESSION

Hundreds of thousands of prescriptions are filled and paid for under the Medicare drug benefit, or Part D, every day. Virtually all of these prescriptions are subject to sophisticated utilization management tools. Medicare prescription drug plans (PDPs) and Medicare Advantage drug plans (MA-PDs) use these tools to reduce utilization and steer enrollees to preferred drugs, thereby keeping overall costs of the Medicare drug benefit as low as possible. The greater the number of utilization management tools used and the more aggressively they are applied, the more they have the potential to lower drug spending, plan premiums, and drug prices at the point of sale. However, they can also result in inconvenience to the beneficiary, pharmacist, or physician, higher costs to certain beneficiaries, or access problems. And, while coverage determination and appeals processes are designed to mediate such issues and ensure access to necessary medications, many argue that the processes are difficult for beneficiaries and their caregivers to understand and use. Has Part D achieved the right balance among cost containment, convenience, and access?

Cost Containment Under Medicare Part D

Medicare Part D is estimated to cost the federal government about \$50 billion in 2007 and is projected to grow at an average annual rate of 12.6 percent

National Health Policy Forum
Facilitating dialogue.
Fostering understanding.

2131 K Street NW, Suite 500
Washington DC 20037

202/872-1390
202/862-9837 [fax]
nhpf@gwu.edu [e-mail]
www.nhpf.org [web]

Judith Miller Jones
Director

Sally Coberly
Deputy Director

Monique Martineau
Publications Director

Forum Session Manager

Mary Ellen Stahlman
Principal Policy Analyst

between 2006 and 2016, according to the Medicare trustees.¹ Given the federal cost of the Part D benefit, strategies to contain overall program costs are an important part of the program. Part D relies heavily on a number of devices to keep overall costs (and premiums) as low as possible, including competition among plans, price discounts negotiated by the drug plan with manufacturers and pharmacies, and managing the use and mix of drugs (referred to here as drug utilization management).

Drug plans manage costs by controlling the number and type (brand versus generic, preferred versus nonpreferred) of drugs paid for by the plan. Formularies—lists of drugs covered by the plan under normal circumstances—are key to managing drug use. Plans commonly have four formulary “tiers.” The first tier is usually generic medications; the second, preferred brand; the third, other brand name drugs covered by the plan; and the fourth, specialty drugs (usually very high-cost drugs) covered by the plan. The beneficiary copays are usually lower on lower tiers, thus helping to steer patients toward drugs on those tiers. Steering enrollees to lower-tier and less expensive drugs when possible, even if it means working with the pharmacy and physician to change an enrollee’s prescription, is a goal of utilization management.

In order to direct enrollees to preferred formulary drugs, drug plans employ a number of utilization management techniques, including the following:

- **Drug utilization review** — refill edits, quantity limits, checks for adverse interactions with other medications, and checks for compliance with recommended dosing. These reviews are relatively inexpensive for the plan to perform. Plans also may perform utilization reviews on a retrospective basis. The Government Accountability Office (GAO) indicates that Federal Employees Health Benefits (FEHB) plans reported savings from drug utilization review of 6 percent to 9 percent, with most of the savings coming from utilization review done by the pharmacy as the prescription was being filled.² According to another study, virtually all of the 10 Medicare PDPs with the highest enrollment used quantity limits to manage utilization. The number of drugs subject to quantity limitations varies by plan, ranging from only 3 drugs on one plan in 2007 to 62 drugs in another.³
- **Generic substitution** — substitution of a generic medication for a prescribed brand name drug, when available. Generic drugs represented 63 percent of drugs prescribed in the United States in 2006. However, because they are less expensive than brand name medications, they accounted for about 25 percent of drug spending.⁴
- **Therapeutic substitution** — substitution of a preferred brand name drug (usually less expensive) for the drug prescribed, when available. The FEHB plans studied by GAO reported savings of 1 percent to 4.5 percent from therapeutic substitution.

- **Prior authorization** — requirement that the beneficiary receive permission from the plan before the pharmacy can dispense the drug. FEHB plans report savings ranging from 1 percent to 6 percent from prior authorization. Since prior authorization is expensive for the plan to conduct, it usually applies to only a small percentage of drugs.⁵
- **Step therapy** — requirement that the beneficiary try a plan’s preferred alternative(s) before approval will be given for the drug prescribed. Relatively few drugs are subject to step therapy. In one recent study of the most popular national Medicare drug plans, the maximum number of drugs subject to step therapy was eight.⁶
- **Off-label use restrictions** — drug plan limitations on the use of drugs prescribed for “off-label” uses, that is, uses for which the drug was not originally approved by the Food and Drug Administration or uses not supported by research in certain “authoritative compendia” noted in the Medicare statute.

The tools described above are used every day by Medicare plans to manage utilization and contain costs. The savings associated with each tool vary by drug plan and depend in part on how the tool is implemented. And not all plans track savings attributable to individual techniques. GAO indicates that, while the savings attributable to individual tools are difficult to quantify, savings for individual techniques in FEHB plans they studied ranged from 1 percent to 9 percent of the plan’s total drug spending. One plan reported savings from these techniques of 14 percent of total drug spending.⁷

The Congressional Budget Office (CBO), in estimating Part D costs, does not make an estimate for savings associated with individual utilization management tools. Combined with other important cost containment features of the Medicare drug benefit (including negotiating price discounts, controlling drug use, and changing the mix of drugs used), CBO assumed a “cost management factor” of 20 percent for 2006, and projected 25 percent for 2013.⁸ The cost management factor includes, but is not limited to, savings from utilization management. Similarly, the Medicare actuary combines price discounts and utilization management in assessing savings. For 2007, the Medicare actuary assumes savings attributable to drug utilization management and retail price discounts of 22 percent.⁹

Balancing Cost Containment with Convenience and Access

The cost containment measures used by Medicare drug plans are widely employed by health insurers seeking to manage drug costs. In that respect, Medicare beneficiaries are not subject to any more burdensome utilization management techniques than others insured for drug costs. Indeed, some have opined that Part D plans provide more protections for Medicare beneficiaries than plans designed for the non-Medicare population do for their enrollees. For example, CMS performs some review of drug plan formularies generally and utilization management tools in particular to

ensure that a broad range of drugs are available to beneficiaries and that the formulary and utilization management techniques do not discourage the enrollment of certain groups of beneficiaries (for example, beneficiaries with certain health conditions).

In addition to passing a CMS review process, drug plans must balance the potential savings of the tools with customer reaction or push back from the inconvenience they cause. In an environment where beneficiaries have dozens of drug plans to choose from, plans may put themselves at a competitive disadvantage if they are significantly more aggressive than their competitors in containing costs for average enrollees.

Disputes between plans and beneficiaries regarding utilization management or other issues may be appealed by the beneficiary. The appeals process has several components:

- **Coverage determinations** are the first decisions made by the drug plan about whether or not to pay for a drug or the amount of cost sharing owed by the beneficiary.
- **Exceptions** are a special type of coverage determination, whereby an enrollee can make requests about use of utilization management tools such as step therapy, prior authorization, dosing limits, or use of an off-formulary drug.
- **Appeals** permit an enrollee to challenge the plan's decision on a coverage determination. As many as five levels of appeals may be available to a beneficiary, including appealing to the drug plan, a Medicare independent review contractor, an administrative law judge, the Medicare Appeals Council, and ultimately federal district court. Furthermore, there is a "standard" process for non-urgent requests and an "expedited" process for issues needing resolution much quicker. According to CMS, roughly one-third of appeals involved drug utilization management tools in 2006, and 55 percent of those appeals were found in favor of the beneficiary.¹⁰

The procedures for resolving appeals have been articulated in detail by CMS. Some beneficiary advocates and physicians claim, however, that the first few stages of the procedures are unevenly applied at the plan level and that the latitude plans have to implement the procedures cause confusion for beneficiaries and hassles for pharmacists and physicians. This Forum session will explore whether or not the appeals process is working to resolve beneficiary issues surrounding plan use of utilization management tools.

KEY QUESTIONS

- Has Medicare Part D struck the right balance between managing utilization to keep costs as low as possible and ensuring reasonable access to necessary drugs for beneficiaries?

- What types of utilization management tools are commonly used by Medicare drug plans to control costs? How often are they used, and how effective are they? Are some tools more effective than others? How much more expensive would Medicare drug coverage be, without these tools?
- What is the experience of pharmacists with the cost containment tools employed by drug plans? How has Part D changed the way pharmacists practice? Are the communication and simplicity of procedures better or worse with Medicare drug plans than with other insurers?
- What is the effect of Part D on physician practices? Are physicians seeing patients more often to sort out formulary issues?
- What is the beneficiary experience with utilization and formulary management techniques? Are the appeals processes adequate to ensure access? Is the appeals process itself too difficult to access?

SPEAKERS

Daniel C. Lyons, MD, is senior vice president of government programs at Independence Blue Cross in Philadelphia. Dr. Lyons is responsible for government and social mission programs, including Medicare Advantage, Medigap, the Children's Health Insurance Program, the adultBasic insurance program, and the Caring Foundation social mission activities. Collectively, these programs provide comprehensive health benefits to more than 500,000 members. Dr. Lyons chairs the Centers for Medicare & Medicaid Services' Advisory Panel on Medicare Education, is a member of the Board of Visitors of Temple University School of Medicine, and serves on a variety of industry councils. His clinical experience is in geriatrics, and he has served as a physician reviewer for the Pennsylvania Quality Improvement Organization. He holds a master's degree in public health from the Medical College of Wisconsin, an MD degree from Temple University, and a BA degree from the University of Virginia.

Holly King Morris is a pharmacist at Crittenden's Drug in Crewe, Virginia. She is currently serving a second term as secretary/treasurer of the Virginia Pharmacists Association, and has been active in the association's board. She also serves as the pharmacist representative on Virginia's Prescription Monitoring Program's Advisory Panel. Ms. Morris is past president of the Old Belt Pharmacists' Association, and has been active in educating pharmacists, pharmacy technicians, and beneficiaries about Medicare Part D. She has a bachelor's degree in pharmacy from the Medical College of Virginia.

Robert P. Smith, MD, is a physician in private practice at Richland Medical Center in Richland Center, Wisconsin. From 1991 to 1999 and from 2003 to the present, he has served on the Board of Directors of Richland Hospital. Dr. Smith is also medical director of Pine Valley Healthcare and Rehabilitation in Richland Center. He is board certified in family practice and certified

in geriatrics, medical directorship, and bone densitometry. Dr. Smith received both his BS and MD degrees from Northwestern University, and he completed his residency in family practice at Broadlawns Medical Center in Des Moines, Iowa. Dr. Smith is a member of the Richland County Medical Society, the State Medical Society of Wisconsin, the American Academy of Family Practice, the American Geriatrics Society, the American Medical Directors Association, the Wisconsin Association of Medical Directors, and the International Society for Clinical Densitometry.

Suzanne H. Jackson directs the George Washington University Law School's Health Insurance Counseling Project, which provides information, assistance, and legal representation to Medicare beneficiaries with health insurance problems or high medical bills. As a professor of clinical law, she teaches the law school's Health Rights Law Clinic, where students learn advocacy skills while assisting project clients. She served as chair of the District of Columbia (DC) Department of Health's Medical Care Advisory Committee, which advises the director of the District's Medicaid program on policy, access, and quality of care issues. She is a graduate of Wellesley College and Harvard Law School and has received awards from the Superior Court of the District of Columbia, Ayuda, and the DC Coalition Against Domestic Violence for her work on behalf of low-income residents of the District of Columbia.

ENDNOTES

1. Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Medicare trustees), "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," pp. 22-23; available at www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf.
2. U.S. General Accounting Office (GAO), "Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies," GAO-03-196, January 2003, p. 13 available at www.gao.gov/new.items/d03196.pdf.
3. Jack Hoadley et al., "Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings," Henry J. Kaiser Family Foundation, November 2006, p. 29; available at www.kff.org/medicare/upload/7589.pdf.
4. Generic Pharmaceutical Association, "Statistics"; available at www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.
5. Prior authorization was used on 3 percent of 152 sampled drugs in 2007. Hoadley et al, "Benefit Design," p. 27.
6. Hoadley et al, "Benefit Design," p. 28. No PDPs included in the study required step therapy for more than eight drugs. Some of the top 10 PBMs did not use step therapy at all. Notably, Wellcare Signature decreased its use of step therapy from 23 drugs in 2006 to 3 drugs in 2007.
7. GAO, "Federal Employees' Health Benefits," p. 12.

Endnotes / continued ►

Endnotes / continued

8 Congressional Budget Office, "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit," July 2004, p. 14; available at www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf.

9 Medicare Trustees, "2007 Annual Report," p. 154.

10 Centers for Medicare & Medicaid Services, "Fact Sheet: Part D Reconsideration Appeals Data—2006"; available at www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/ReconAppealsData06.pdf.



The National Health Policy Forum is a nonpartisan research and public policy organization at The George Washington University. All of its publications since 1998 are available online at www.nhpf.org.