
NHPF Forum Session
Meeting Announcement

**Evidence- and Value-Based
Approaches to Drug Formularies:
What Role Will They Play in the
Medicare Prescription Drug Benefit?**

A DISCUSSION FEATURING:

Peter J. Neumann, ScD
*Associate Professor of Policy and
Decision Sciences*
Harvard School of Public
Health

Mark Gibson
Deputy Director
Center for Evidence-Based
Policy
Oregon Health and Science
University

WITH COMMENTS FROM:

David Clark
*Vice President, Pharmacy Benefits
Management*
The Regence Group/
RegenceRx

Gail Shearer
Director, Health Policy Analysis
Washington Office
Consumers Union

Jean Paul Gagnon, PhD
Director, Public Policy
Aventis Pharmaceuticals Inc.

**Friday,
February 6, 2004**

11:45 am — *Lunch*

12:15 – 2:15 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 call Tiombe Diggs at
202/872-1392 as soon as
possible. Space is limited.

**For additional information
on this topic:**

See "Evidence-Based and
Value-Based Formulary Guide-
lines," by Peter J. Neumann,
Health Affairs, 23, no. 1
(January/February 2004).

Evidence- and Value-Based Approaches to Drug Formularies: What Role Will They Play in the Medicare Prescription Drug Benefit?

While drug formularies have long been used to control the cost and utilization of prescription drugs, a new approach is emerging that reflects a broader movement in health care toward evidence-based practice. Drug formularies, also known as preferred drug lists, are lists of drugs that have been approved by a state, health plan, or hospital that can be dispensed without prior authorization. Recently, many payers have begun to adopt standardized, evidence- and value-based guidelines for formulary decision-making. Unlike the informal and less scientific processes that have typically governed traditional formularies, formulary guidelines are intended to create a decision-making process based on more stringent clinical and economic evidence.¹

The recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which permits the use of formularies by participating plans,² will subject formulary processes to even greater scrutiny. The potential role of more evidence-based guidelines in the implementation of the Medicare prescription drug benefit is as yet unknown. If such guidelines are used, the level at which they are implemented—nationally, regionally, or plan by

SESSION OVERVIEW

This meeting will focus on the processes used by health plans and other payers to make decisions about which drugs to include on formularies. Building upon a recent *Health Affairs* article by Peter J. Neumann, it will examine the trend toward evidence- and value-based formulary guidelines and their implications for drug companies, health plans, state Medicaid programs, and consumers, particularly in light of the recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The session will highlight the state of Oregon's experience in its development of an evidence-based Medicaid formulary.

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plan—may determine how well they are received by Medicare beneficiaries. Opposition to the use of such guidelines may occur if they are viewed merely as a cost-saving mechanism, a notion often met with political opposition within the Medicare arena.³

If a national model is adopted, what might it look like? One possibility is an approach taken by the Academy of Managed Care Pharmacy (AMCP) that is based largely on the work of Regence BlueShield health plan in Seattle.⁴ In 1998, in response to increased costs, Regence BlueShield asked drug manufacturers to provide clinical and economic evidence in order to have their drugs considered for inclusion in the plan's formulary.⁵ Similarly, in 2000, AMCP established a set of guidelines that outlines the types of clinical and economic evidence that health plans should request from drug manufacturers before deciding to include a drug in their formularies.

The AMCP Format for Formulary Submission, as the guidelines are known, encourages health plans to seek a standardized set of materials from pharmaceutical companies. Much of this information is designed to meet the specific needs of a given health plan.⁶ For example, data may attempt to demonstrate the value of a particular drug to a plan based on a plan's member population and utilization history. Entities covering more than 100 million lives have adopted the AMCP format.⁷

State Medicaid programs, faced with shrinking budgets and double-digit increases in spending, have also started to explore new processes for formulary development. Oregon adopted a particularly innovative approach in 2001, when its legislature, despite significant political opposition, successfully established an evidence-based process for the development of its Medicaid formulary. Under the Oregon law, the state was charged with evaluating the clinical efficacy and price of drugs in each of 25 classes.⁸ The Oregon Health Resources Commission has, since 2001, pursued evidence-based information about specific drug classes, evaluating their overall cost to Oregon Medicaid as well as their comparative effectiveness.

To date, the Evidence-Based Practice Center at Oregon Health and Science University (OHSU) has completed its evaluation of 12 of the 25 classes of drugs.⁹ OHSU is currently working with ten other states in a multistate collaborative. The work of the center is being made available to other public and private organizations and eventually will be made available to consumers.

Regardless of the approach taken by state Medicaid programs, health plans, or entities participating in the new Medicare prescription drug benefit, the success of these efforts may hinge on their ability to achieve their goals while ensuring adequate access to prescription drugs by patients and their physicians. Evidence- and value-based formulary guidelines represent a more standardized

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system of evaluating drugs' safety, effectiveness, and economic value. Nevertheless, a considerable number of questions remain about the impact that these approaches may have on our overall health care system and, more narrowly, the role they may play in the implementation of the new Medicare prescription drug benefit.

KEY QUESTIONS

The Forum session will review the author's findings and will explore the future implications of more widespread use of evidence- and value-based formulary guidelines. Issues to be discussed include the following:

- What role, if any, will these evidence- and value-based guidelines play in the new Medicare prescription drug benefit?
- What impact will these guidelines have on consumer access to prescription drugs? What protections must be put in place to ensure adequate consumer protection?
- Is there a role for consumers to play in the development of these guidelines?
- Will these guidelines result in overall savings?
- Will the information provided by pharmaceutical companies be objective enough for evaluation?
- Do health plans, Medicaid programs, and other payers have the expertise necessary to appropriately evaluate the information provided to them by pharmaceutical companies?
- Will large plans and small plans (with less market share) alike be able to compel pharmaceutical companies to provide the requested information?
- Will formulary guidelines impose an undue burden on health plans and pharmaceutical companies?
- How will proprietary information provided by pharmaceutical companies be protected?

SPEAKERS

Peter Neumann, ScD, associate professor of policy and decision sciences in the Department of Health Policy and Management and deputy director of the Program on the Economic Evaluation of Medical Technology at the Harvard School of Public Health, will present an overview of his recent *Health Affairs* article, including a description of evidence- and value-based guidelines, work that is currently being done in this area, and critical issues raised by the use of these guidelines. Neumann's research focuses on economic evaluations of medical technologies, including evaluations of pharmacological treatments for Alzheimer's disease, asthma, and lung cancer. He

also directs a large-scale effort to develop a comprehensive database of cost-effectiveness analyses. Neumann is a contributing editor of *Health Affairs* and a member of the editorial boards of *Value in Health* and *Medical Decision Making*.

Mark Gibson, deputy director of the Center for Evidence-Based Policy at Oregon Health and Science University, will discuss Oregon's Medicaid formulary, including the history of its adoption and the work the state has done in analyzing the first 12 of 25 classes of drugs. The Center for Evidence-Based Policy is responsible for commissioning reports that will compare the effectiveness of prescription drugs within classes to better inform policymakers and consumers about better drug choices. Before joining the center, Gibson served as policy advisor for Health, Human Services, and Labor to Gov. John Kitzhaber of Oregon. In this role, he led a number of Oregon's health initiatives, including the creation of the Oregon Children's Health Insurance Program and reorganization and expansion of the Oregon Health Plan.

David Clark, vice president, pharmacy benefits management, for the Regence Group—which is headquartered in Portland, Oregon, and has health plans in Oregon, Washington, Utah, and Idaho—will provide a health plan perspective and share his experience in overseeing an evidence-based formulary process in four states. In his role at Regence, Clark is responsible for overseeing all pharmacy-related services, including formulary activities, pharmacy and therapeutics committees, product reviews, contracting, and benefit design. His pharmacy experience includes pharmacy benefit management as well as practice in hospital, managed care, clinical, and retail settings. He is an active member of the Academy of Managed Care Pharmacy.

Jean Paul Gagnon, PhD, director, public policy, at Aventis Pharmaceuticals Inc. will provide a pharmaceutical perspective on evidence- and value-based formulary guidelines. Gagnon has practiced pharmacy in various practice settings, taught pharmacy administration, and completed research studies and publications on prescription pricing, consumer attitudes toward pharmaceutical services, drug use, the effects of public policy decisions on drug distribution systems and pharmacy services, and the cost-effectiveness of drugs.

Gail Shearer, director, health policy analysis, Washington Office, Consumers Union, will discuss the impact of these guidelines on consumers. Shearer, who has been with Consumers Union for 17 years, has extensive experience in health-related issues such as health care reform, health care financing, Medicare prescription drugs, Medigap, long-term care insurance, and medical savings accounts.

ENDNOTES

1. Peter J. Neumann, "Evidence-Based and Value-Based Formulary Guidelines," *Health Affairs*, 23, no. 1 (January/February 2004): 124.
2. Certain beneficiary protections are built into the provisions related to formulary development. See the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1860D-5(b)(3).
3. Neumann, "Evidence-Based," 132.
4. Neumann, "Evidence-Based," 125.
5. Neumann, "Evidence-Based," 125.
6. Neumann, "Evidence-Based," 125.
7. Neumann, "Evidence-Based," 126.
8. "State Medicaid Formulary Continues Evidence-Based Analysis of Rx Drugs," *BNA's Health Care Policy Report*, 11, no. 2 (January 13, 2003): 45.
9. Mark Gibson, telephone conversation with author, December 9, 2003.