



Pharmaceutical Benefit Management Under Medicare Part D Conference Report July 13, 2006

New innovations in pharmaceutical therapies have helped extend and improve the quality of life for millions of Americans, while often reducing utilization of other health care services. But as the U.S. begins to grapple with an aging population and pharmaceuticals continue to grow as an essential part of care management, prescription drugs will consume a larger portion of total health care spending. This represents a challenge for payers and plan sponsors, as other areas of health care expenditures continue to increase at rates significantly higher than general inflation. By 2014, total health care spending is projected to constitute 18.7 percent of gross domestic product, up from 15.3 percent in 2003,¹ total expenditures for prescription drugs in 2006 are projected to be \$292 billion, up from \$142 billion in 2000.² In recent years, fewer blockbuster drugs have been launched in the U.S. than in the 1990s, when trend increases were largely driven by utilization and new therapies. Today, cost trends (which are now lower) are largely driven by price increases,³ marketing strategies by manufacturers, rising utilization, and the rising costs of bring new therapies to market.⁴

The continued rise of overall health care expenditures has increased pressure on public and private sector resources, as well as on consumers. Payers have reservations about the effectiveness and appropriateness of some prescription drugs, and have concerns about drug pricing. Payers also believe that the systems currently in place do not generate the level of evidence that they seek for coverage decisions. Meanwhile, manufacturers frequently feel burdened by the high costs of generating the evidence that payers are demanding. In between the payers and manufacturers are Pharmacy Benefit Managers (PBMs), which administer drug benefit programs for employers and health insurance carriers (plan sponsors), and government-funded health care programs. Plan sponsors expect PBMs to help provide affordable and appropriate benefits, by efficiently administering pharmacy benefits, and determining the best value among pharmaceuticals. The challenge is to ensure that patients receive the right medications (without errors) based on evidence and value, while maintaining economic incentives for continued innovation in the development of new pharmaceutical therapies.

¹ Heffler, Health Affairs, Feb 2005

² Data from the Centers for Medicare & Medicaid Services, Office of the Actuary

³ Rosenthal, et al., "[Demand Effects of Recent Changes in Prescription Drug Promotion](#)," Kaiser Family Foundation, 2003.

⁴ Dickson M, Gagnon JP. Key factors in the rising cost of new drug discovery and development. *Nat Rev Drug Discov.* 2004 May;3(5):417-29.

The new Medicare Prescription Drug Benefit (known as the Part D program) expands access to pharmaceuticals for many Medicare enrollees. This important new benefit represents a substantial new federal fiscal commitment to health care and the Medicare program specifically. According to the Congressional Budget Office, Part D will account for 23 percent of total Medicare expenditures by 2016. The legislation establishing this program relies on private sector Prescription Drug Plans (PDPs) and Medicare Advantage (MA) plans to manage the program. In an effort to limit spending, the legislation's benefit design included a "doughnut hole" where beneficiaries would be responsible for 100 percent of drug costs between \$2,200 and \$5,800 of their annual drug spending. The program's structure has drawn increased public attention to issues of access to and cost of prescription drugs. In switching to the new plans, some beneficiaries have found their access to certain drugs limited by formulary restrictions and prior authorization requirements. Similarly, many beneficiaries, particularly those entering the "doughnut hole" have become much more aware of their prescription drug costs. This has also drawn increased attention to the business practices of pharmaceutical companies and PBMs and the inherent tensions between access, choice, and cost.

The Health Industry Forum met on July 13, 2006 to discuss new pharmacy benefit strategies under Medicare, but that are highly relevant outside of Medicare as well. The discussion centered on pharmacy benefit challenges facing manufacturers, payers, and beneficiaries, and steps that could be taken to address some of these challenges.

I. Tony Zook AstraZeneca

According to Tony Zook, President and CEO of Astra Zeneca (U.S.), drug discovery is being driven by a better molecular understanding of disease. The value of pharmaceutical innovation has been proven, while product differentiation is defined through real-world comparative effectiveness of drugs. The prescription drug market is being driven by evidence, and manufacturers never cease in their drug development efforts to create new innovations and enhance existing ones. However, the current model in U.S. healthcare is not sustainable. Therefore, no single segment of our healthcare system- no single industry, or specific company or agency can succeed alone. The industry must cooperate to improve the whole system.

The marketplace for pharmaceutical manufacturers has become more difficult, as the costs of bringing new therapies to market have increased significantly. The continued rise of health care costs has increased pressure on public and private sector resources, as well as consumers. Payers have demanded more thorough evidence than what is required by the FDA. While the questions posed by payers on evidence are reasonable, the studies required to answer these questions on drug treatments are hard to do. Large patient populations significantly increase logistical challenges, and are very expensive. Evidence based management questions never answer all inquiries, yet the demand for these additional studies is increasing. The new information necessary to help payers make decisions can add \$2 to \$3 billion to the cost of a drug. Additionally, the longer it takes for payer to begin paying for a new drug, the less exclusivity that drug has in the

marketplace, thus creating a shorter window for manufacturers to recoup their development costs. If this trend continues unchecked, the result will be higher prices, reduced innovation, or both.

Manufacturers do have a role to play in improving this system. Manufacturers need to do a better job demonstrating value in their new products, and the value equation that payers seek is going to have to be factored in earlier in the drug development process. But the current model is becoming untenable. The approval process for a new prescription drug takes eight or nine years, and then payers request post-approval studies to demonstrate effectiveness under “real-world conditions.” These requests from payers for more information about a new drug therapy are overwhelming.

Payers, manufacturers, and regulators need to work together to identify the needs of patient subpopulations and individuals and tailor the delivery of care appropriately so that financial incentives are not counter-productive (i.e. reduce research and innovation), while also ensuring that patients do not face barriers to appropriate care. A possible solution is to consider developing alternative standards of evidence sufficient to support coverage decisions. An example may be more effective use of simulation-based trial design. Additionally, perhaps producing effectiveness data could be exchanged for earlier conditional approvals. This could be a fair trade between payers and manufacturers. The overarching point is that we need to spend more time identifying the right questions about drugs and better align policy goals with the availability and certainty of evidence. We also need to stay mindful that different strategies are needed for maintenance drugs versus those aimed at helping people battling life-threatening diseases like cancer. One size does not fit all.

Rob Seidman, PharmD, MPH
Wellpoint

Mr. Robert Seidman, Vice President & Chief Pharmacy Officer of Wellpoint stated three goals that he believes unite all Forum attendees. The first goal is to protect the safety of patients; the second is to maintain the long-term affordability of Medicare; and the third goal is to ensure optimal medical outcomes. From Wellpoint’s perspective (as a large payer), it seeks to balance a range of escalating health care costs. And while drugs are just one component of its health care expenditures, the rate of price increases for prescription drugs is unsustainable. However, Mr. Seidman agrees that manufacturers bear too many costs in bringing a drug to market, which could negatively impact patients. The new Medicare Prescription Drug Benefit represents an enormous new insured population, but this new covered population is challenging as well. Per capita spending is four times higher in Medicare Part D than in Wellpoint’s commercial population.

The focus of prescription drug management is to address shared concerns about patient safety, affordability and optimal medical outcomes. Internally, Wellpoint employs a number of techniques to manage its prescription drug program. Wellpoint’s formulary is designed to offer the most commonly used drugs in the senior population, while also considering the unique health needs of older patients. For example, Wellpoint does not

include some drugs deemed unsafe for seniors, as determined by the Beers Criteria.⁵ Wellpoint also covers most generic drugs. When a new generic comes to market for an existing formulary brand drug, Wellpoint will add the generic drug and move the brand drug to the non-preferred tier as soon as reasonably possible, and when CMS permits.

Another tool employed by Wellpoint is its National Pharmacy & Therapeutics Committee (P & T), which is made up of two separate committees. The Clinical Review Committee (CRC) assigns *clinical designations* determined through review of current guidelines and treatment criteria (from sources such as major medical publications, professional journals, medical specialty associations, product package inserts, etc.). The Plan uses external physicians in its CRC, and gives the following grades for drugs: “Superior,” “Comparable,” and “Uncertain Value.” Wellpoint then convenes a Value Assessment Committee (VAC) to analyze the relative cost and benefits of different products. The VACs meet *after* the CRC has established the clinical foundation and rationale for a given drug therapy. Wellpoint utilizes a separate VAC for its Medicaid, Medicare Part D and commercial markets. Wellpoint’s VACs have some specific rules:

- The VACs must take into account the CRC’s clinical designations to recommend drugs for the Drug List/Formulary.
- The VACs determines *tier assignments*, or coverage levels, based on designations assigned by the CRC, as well as financial data (average wholesale price, rebates, ingredient cost, cost of care, patient cost sharing), and market factors.

Although the Medicare Prescription Drug Benefit has been criticized for the “doughnut hole” in the plan design, Mr. Seidman believes that this coverage gap creates a unique opportunity to engage patients and providers around the issue of prescription drug costs. Although there are roughly 100,000 drug industry sales representatives speaking to doctors exclusively about brand name medications, when patients hit the coverage gap, they are faced with the full price of these drugs. Mr. Seidman characterizes the “doughnut hole” as the “great equalizer” as it creates a dynamic of price sensitivity where many patients begin to seek out lower cost alternatives – specifically generics. If there were no coverage gap in Part D, such discussions would be far less likely. Wellpoint has had strong success working with patients and providers to increase utilization of generic drugs. Wellpoint’s generic utilization rate in Medicare Part D is 77 percent, which compares closely to its Medicaid generic utilization rate. This is significantly higher than its commercial generic utilization rate of 57 percent.

The Medicare Part D model will likely get amended as we move past implementation. Mr. Seidman believes that other changes necessary to enhance the Medicare Part D program include a need for improved patient and provider education, and increased dialogue on cost and value among all stakeholders (notably between payers and manufacturers).

Mr. Seidman also believes that there is a pressing need to work more effectively with network doctors and manufacturers and foster more conversations between patients and

⁵ Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. Arch Intern Med. 1997;157:1531-1536.

doctors. Only 1 in 4 Americans discuss the cost (and value) of medicine with their doctor. Additionally, 20 percent of pharmaceutical use is off-label; two-thirds of off-label use is not supported by science. Finally, when patients do not adhere to prescribed drug regimens, this adds costs to the system by increasing the use of inappropriate medicine. This may lead to safety problems, quality of life issues, and loss of productivity. For example, premature discontinuation of medication for depression results in a 77 percent increase in the rate of relapse or recurrence, and an estimated 93 percent of adults with diabetes do not adhere fully to all aspects of their diabetes treatment plan.⁶

Several steps can be taken to reduce Medicare Prescription Drug expenditures. Mr. Seidman suggests that Medicare Part D beneficiaries and CMS could save over \$23 billion for the 14 major brand name drugs that lose patent protection if generic alternatives are prescribed over the next five years. Increasing use of over-the-counter products in common therapeutic categories as alternatives to prescription drugs could provide further savings opportunities. From a care management perspective, electronic medical records that combine both full pharmacy and medical records would improve providers' capabilities. Expanded use of e-prescribing could save 8 to 15 percent of drug spending, and increases generic utilization. Furthermore, e-prescribing decreases adverse customer service encounters by 21 to 33 percent. These represent a variety of cost-saving initiatives that health care industry stakeholders could pursue.

Stephen Soumerai, Ph.D.
Harvard Medical School

Our final speaker focused on the importance of ensuring that pharmaceutical benefit management strategies do not create barriers to appropriate and cost effective utilization. Research conducted on utilization changes in a variety of government health care programs, including state Medicaid programs have demonstrated that placing caps or other barriers on prescription drugs can create unintended consequences. Caps that limit the number of prescriptions covered can lead to increased medical costs and is associated with adverse outcomes. Research generated throughout the past three decades demonstrates that many cost sharing strategies reduce both appropriate *and* inappropriate utilization, even at low dollar amounts.

To avoid discouraging appropriate use, a careful analysis of changes in utilization is important to monitor the effects of changed cost-sharing strategies. Additionally, certain drugs should not be subject to substitutions or hard edits at the pharmacy level. In one state Medicaid program, members changed utilization response with just a one dollar co-payment (adjusted to today's dollar value). This small co-payment significantly reduced inappropriate *and* appropriate use, thereby nullifying the anticipated benefits of this policy. So, as a general rule, severe payment caps and fixed high cost sharing should be avoided, particularly for vulnerable populations. In general, modest cost sharing seems reasonable except for the lowest income groups. Prior authorization as a tool towards

⁶ Nichols-English G, Poirier S. Optimizing adherence to pharmaceutical care plans. J Am Pharm Assoc. 2000;40(4):475-485.

better care management, tiered co-payments, are generally good tools for plan sponsors. Additionally, Dr. Soumerai suggests that reference pricing with safety values seems like a good strategy to employ.

In general, pharmacy benefit managers still use reactive tools because we haven't found a way to get physicians to better manage prescription drugs to maximize value. One suggestion from a Forum participant was that we should consider instituting a new rule in Medicare. In order to write a prescription drug for Medicare beneficiaries, physicians would have to participate in focused, (and short) continued education courses on a variety of drug therapy topics. Although the question of funding such continuing education efforts was not solved, there was consensus that such costs should not be borne by providers, and perhaps could be subsidized by payers. Another participant suggested using the Australian model of sending public detailers or purchasers to physicians in order to provide non-bias evidence-based education. More evidence is needed to determine if physician education might be a better way to increase value and appropriate use of drugs than the alternative of higher cost sharing, restricted formularies, prior authorizations, and other traditional pharmaceutical benefit management tools.

More cooperation is needed among the major stakeholders to get a better handle on prescription drug benefits, as the stakes are quite high for all involved. Payers don't want to pay blockbuster prices for incremental innovations, patients need access to life-saving therapies, and drug manufacturers need sustainable business models. Finding a balance for these competing and vital interests is imperative.

The Health Industry Forum

The Health Industry Forum is based at Brandeis University and is devoted to developing practical, actionable, market-oriented strategies to improve the quality and value of the U.S. healthcare system. The Forum's charter members include Aetna Inc., Johnson & Johnson, HIP Healthplan of New York, Lifemasters Supported Selfcare Inc., Merck & Company, and Novartis Pharmaceuticals. The Forum also receives generous support from Blue Cross & Blue Shield of Massachusetts, Cigna Healthcare, Kaiser Health Plans, Partners Healthcare, Pfizer, Inc., Sanofi-Aventis, and Wyeth. This synopsis was prepared by Garen Corbett based on the Forum's July 13, 2006 meeting on Pharmaceutical Benefit Management under Medicare Part D.