OVERVIEW

In 2005, an editorial in P&T clearly articulated problems with the then-new Medicare Part D prescription drug benefits program. The editorial noted the severe limitations that were expected to be imposed on both physicians and on patients regarding prescription drug product choices. P&T suggested that this approach, which was supported by health insurance plans, would pave the way for even greater restrictions on access to prescription medications than the restrictions that were then in effect.

The editorial’s caution relating to increasing restrictions on access to prescription medications has been borne out by the numerous difficulties encountered by Part D beneficiaries. The typical problem involves patients who cannot continue using one or more of their prescribed drugs because the agents are not on the Part D formulary. We view these new limitations on access to care as a direct result of Part D formularies that are created with cursory regard to medical concerns and are subject to minimal outside review either before or after implementation.

In addition to providing limited access to pharmaceutical care, congressional estimates suggest that the current drug selection and delivery system under Medicare Part D overspent by nearly $15 billion in 2007 alone.

Unlike traditional Medicare, which is administered by the Centers for Medicare and Medicaid Services (CMS) under uniform standards, Part D uses private insurers to provide prescription drug coverage to beneficiaries. Insurers typically contract with outside pharmacy benefit managers (PBMs) to administer prescription drug plans. Each Part D prescription drug plan is permitted to create its own formulary, a process that is typically delegated to the PBM that administers the drug plan.

The P&T editorial explained how guidelines were being developed under contract between the U.S. Pharmacopeia (USP) and CMS to guide insurers and PBMs, thereby ensuring appropriate access to prescription drugs. The CMS review of plan formularies under the Medicare Modernization Act (MMA) of 2003 was intended to ensure that drug benefit plans offered a broad selection of pharmaceutical agents that reflected the best practices in medicine and in pharmacy. Physicians and pharmacists, in particular, expected these formularies and benefits to include a full range of treatment options then in use by prescription drug plans. Mandates imposed by the MMA included a requirement that Part D was to provide the most clinically appropriate medications at the lowest achievable cost for all Part D beneficiaries.

The MMA also required CMS to acknowledge the specific needs of individuals who were already stabilized with specific drug regimens (e.g., enrollees with HIV infection and AIDS, mental illness, and other cognitive disorders). CMS was also obligated to identify patients who were eligible for prescription drug benefits under both Medicare and Medicaid, the so-called “dual eligible” population.

These dual eligibles were (and continue to be) at increased risk for reduced access to appropriate pharmaceutical care. Dual eligibles were automatically enrolled in Part D prescription drug programs by CMS on a random basis. Neither the dual eligibles themselves nor the prescription plans selected to administer their Part D benefits were informed of the impact that the randomly selected plan and its formulary could have on each patient’s pre-existing drug coverage, continuing drug treatment options, and state of health.

In this article, we examine the barriers to prescription drug access that have arisen under the Medicare Part D prescription drug program since its implementation in 2006. In our view, PBMs play a key role in both the decreased level of pharmaceutical access and excessive costs under Part D.

INTRODUCTION

Evidence-based medicine describes the use of clinical trials and other objective clinical data in the evaluation of medical care and the design of treatment guidelines. The same process, the measured evaluation of objective clinical evidence, can be used to describe the approach that P&T committees traditionally take in their deliberations, which are designed to reach the best decisions concerning drug safety, efficacy, adverse effects, and interactions.

Cost is also a factor in the P&T decision-making process—but only after a drug’s safety, efficacy, effectiveness, side-effect profile, and potential interactions have been considered. Drugs that survive this exhaustive evaluation may be added to the formulary. Although the P&T process was created for inpatient care and evolved in the institutional setting, the method has been widely adopted by health systems and third-party payers to control the delivery of care in outpatient and community settings.

We strongly believe that the displacement of traditional P&T committees and their accompanying formularies, as encouraged by Medicare Part D, has adversely affected the...
drug evaluation, review, and selection process. The result is excessive costs associated with the provision of pharmaceutical care and increasing limitations on access to the most appropriate prescription drug products under Part D.

We also believe that the displacement of P&T committees and their formularies was not an inevitable outcome of Part D. The Department of Veterans Affairs (VA) uses a single formulary nationwide, although most VA facilities also have their own locally appointed P&T committees. The VA's unified approach to formulary design and implementation appears to be effective: Medicare prescription prices are said to be 58% higher than VA prices. Good and Valentino described the steps that the VA took in establishing a pharmacy plan that maintains "a generous drug benefit at a very low cost."

EVOLUTION OF P&T COMMITTEES

Balu et al. have chronicled the historical origins of P&T committees and their natural outgrowth, the formulary system; they discuss the many contributions to the concept of P&T committees over the years that evolved into its modern counterpart in the early 1960s. At that time, the P&T committee's primary purpose was to "maximize rational medication use" and "ensure inventory control." These committees were organized to guide the medical and pharmacy staff of the institutions that they served. Institutions also had the authority to enforce decisions made by their respective P&T committees. As we watch the evolution of P&T committees to the position that they occupy in the American health care system today, we must remember their original purpose and responsibilities.

As health care costs escalated in the final decades of the 20th century, the traditional fee-for-service model gave way to third-party providers. Managed care organizations (MCOs) such as Kaiser Permanente and health maintenance organizations (HMOs) such as Blue Cross were created in an attempt to moderate the growth in health care spending by introducing cost containment and the resources available within the organization.

MCOs such as Kaiser provide essentially all of the health care needs of their patient subscribers. Kaiser typically owns the facilities that patients use, including acute-care hospitals, physician offices, satellite clinics, and pharmacies. These facilities are staffed by physicians, nurses, nurse practitioners, pharmacists, medical technicians, and support personnel. Most of these personnel are Kaiser employees, although some specialty services may be outsourced to other health care providers, depending on the needs of the local patient population and the resources available within the organization.

Kaiser's subscribers are covered for all of their medical care, including prescription drugs, for which they pay monthly premiums. The system has provided fine care to its subscribers and has contained costs through effective management strategies. Although Kaiser's P&T committees and their formularies are generally uniform throughout the entire system, each local patient care unit has its own P&T committee and formulary to address the concerns of its staff.

Unlike MCOs, HMOs are basically insurance entities that coordinate health care services from independent providers to their subscribers. Services and benefits vary but usually include acute hospitalizations, laboratory procedures, physician fees, and, more recently, prescription drugs. The addition of prescription drug coverage to HMO plans is important, because many HMOs manage their drug benefit by contracting with a PBM.

The involvement of PBMs is a key development in the delivery of health care. Even though HMO subscribers can take their prescription to a local community pharmacy to be filled, community pharmacies can dispense only a 30-day drug supply under most circumstances. But when an HMO contracts with a PBM to administer HMO drug benefits, patients can typically receive a 90-day supply through contracted dispensing pharmacies such as Next Rx or Caremark. These 90-day prescription fills are typically delivered by mail, a service usually referred to as "mail order."

Patients recognize two advantages from obtaining their medications through a PBM. The cost per dose is less because patients make only one co-payment for a 90-day supply rather than three co-payments for three successive 30-day prescription fills. Second, the patient's drug supply lasts three times as long and may not require a drugstore visit, saving time, effort, and transportation costs.

Each HMO and its related PBM has a P&T committee. The P&T committee and formulary design are typically delegated to the PBM as one of the administrative tasks needed to create and administer a prescription drug benefit. Although organizational designs and responsibilities can vary greatly among PBMs, the membership and deliberations of P&T committees are seldom open to scrutiny by the public or by the HMOs on whose behalf PBMs work. As a practical matter, it is nearly impossible to identify the members of a PBM's P&T committee, their qualifications, or the precise content of its formulary. This lack of transparency makes it difficult for prescribers and patients to decide which drugs to choose.

As an example, if a physician needs to prescribe a drug for a neurological problem, it would be helpful to know which of several potential neurological agents are on the formulary and covered by the patient's prescription drug benefit. Under the current system, a physician may prescribe the most appropriate pharmacological agent, only to discover that the specific drug is not covered by the patient's prescription drug plan because it is not on formulary. It could also be helpful to know whether one or more neurologists was on the P&T committee that selected neurological agents for the plan formulary in order to judge the appropriateness of the formulary and the potential need to request special authorization to use a non-formulary agent.

PART D RESTRICTIONS

Prescribers, patients, and pharmacists have found that the same lack of transparency has become part of Medicare Part D.

The Congressional actions that originally established Medicare Part D authorized the USP to create guidelines for Part D P&T committees and formularies. The guidelines, P&T committees, and formularies envisioned by Congress and by the USP were expected to be implemented by CMS by the time Part D prescription drug benefits began on January 1, 2006. These USP guidelines were not adopted, because a central P&T committee with a uniform formulary to regulate

Failures of Medicare Part D Delivery

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all Part D pharmacy operations—whether PBMs and their pharmacy providers, chain drugstores, or community pharmacies—was never adopted by CMS.

Instead, the Bush administration and Congress allowed each pharmacy provider accepted into the Medicare Part D program to establish its own P&T committee and to create its own formulary. These pharmacy providers were not required to reveal either the identities or qualifications of persons serving on their P&T committees or the criteria used to select drugs for formularies. More important, the pharmacy provider’s formulary drug list was not adequately disclosed. This near-total nondisclosure of formularies has denied prescribers, patients, and pharmacists adequate knowledge of the drug-selection process. In California, for example, there are at least 47 pharmacy providers under Part D. Each provider has its own P&T committee and its own formulary. Regulatory oversight for all of these providers is delegated to only one CMS pharmacy consultant.

As implemented in 2006, Part D prescription drug programs must employ private insurers to administer drug coverage to Medicare beneficiaries. Proponents of this approach claim that private prescription drug coverage provides broader drug selection at a lower cost. Opponents question how private organizations can be more efficient than such governmental organizations as the VA. As previously noted, Part D costs are almost 58% higher than similar outpatient drug costs under the VA system. To attempt resolve these different points of view on private versus governmental administration of prescription drug coverage, Henry Waxman, Chairman of the House Committee on Oversight and Government Reform, authorized a study to analyze costs from the private insurers operating Medicare Part D. The final report included data from 12 leading insurers offering Part D coverage to more than 18 million Medicare beneficiaries. This figure represents almost 75% of enrollees in Part D.

The committee findings indicated that the use of private insurers to deliver Medicare Part D drug coverage was driving up costs and producing only limited savings on drug prices. Taxpayers and Part D beneficiaries might have been able to save almost $15 billion in 2007 alone if administrative expenses had been reduced to levels achieved by traditional Medicare programs and if drug prices had been lowered to Medicaid levels. We are not aware of any large or persuasive studies demonstrating that PBMs can either reduce drug costs or improve the quality of pharmaceutical care.

Prescribers, pharmacists, and Part D beneficiaries do recognize that private firms such as PBMs and insurers must be profitable in order to survive, but the drive for higher profits should not eclipse the business practices that earn a company respect for its products and the fairness of its dealings with consumers. Private firms list many reasons why they cannot change their business practices, including the cost of developing and marketing new drugs, fierce competition from other drug manufacturers, and positions by the VA as well as other countries, such as Canada, that deny formulary access to manufacturers that refuse to lower prices.

As the P&T editorial in 2005 suggested, patient access to medications will face even greater restrictions if health insurance plans and their PBMs continue to write the rules of prescription drug access. PBMs claim that on-line access to the many PBM formularies is straightforward and simple. This has not been our experience, or the experience of CMS staff we have consulted, or the experience of patients. The insurance plans and their PBMs need to recognize that they must supply the most efficacious drugs, not the least expensive drugs, to their patients and subscribers as a precondition to earning a reasonable profit. Formulary selection must be based, first and foremost, upon efficacy, safety, side-effect profiles, potential interactions, and similar clinical factors. Only if all clinical factors are equal should cost be considered in the formulary decision.

RECOMMENDATIONS

The following are our recommendations to improve access to prescription drugs under Medicare Part D:

1. PBMs must disclose full details about the methods they use to select prescription drugs for their formularies. The qualifications of those individuals chosen to serve on P&T committees and their formulary deliberations should be accessible to Congress, to CMS, to all health care professionals, and—most of important of all—to patients. PBM operations would become more transparent if CMS were allowed to do what it was mandated to do by the MMA and actively manage the Part D prescription drug benefit.

2. When P&T committee members add a drug to the formulary or delete a drug from the formulary, they must act only after they have carefully evaluated safety, efficacy, adverse effects, drug interactions, and other medically relevant data. Drug costs, rebates from drug manufacturers, and similar economic factors must be secondary to medical and therapeutic considerations.

3. Because cost is a relevant consideration in formulary design, multisource agents should be selected when available. If two drugs appear to be equivalent in therapeutic value, cost must be considered in deciding which agent to add to the formulary. This step can be accomplished only if CMS, operating with Congressional support, requires PBMs to fully disclose their financial relationships with drug manufacturers. A recent bill that failed in the Senate would have required that the federal government negotiate prices that Medicare pays for prescription drugs. There was some suggestion of change in the latter half of 2007 as more than a dozen PBMs agreed to reveal more about what they pay for drugs.

4. Patients should have the option of obtaining a 90-day fill for their prescriptions at a local pharmacy without the financial penalties of multiple copays and multiple pharmacy visits even if a 90-day fill is available via mail order or via any other pharmacy channel. Community pharmacies typically provide timely, error-free service and sound pharmacological advice. In addition, patients have an informed, professional advocate in a local pharmacist who knows them and their personal health needs. This relationship can build the patient’s trust in the professional who dispenses prescriptions written by the physician, reinforcing confidence that prescription drugs are dispensed and used as intended and at a fair price.

continued on page 181
CONCLUSION

The economic influence of PBMs has usurped the well-established role of P&T committees and the formularies they have created for use in the outpatient setting. We call for more openness and transparency on the part of PBMs in order to understand how they create, design and implement formularies under Medicare Part D.

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Editor’s note: We invite readers with any other viewpoints on this topic to submit their comments or manuscripts to Sonja Sherritze: ssherritze@medimedia.com.