
Medicare Part D: Legislative Help for Patients, Pharmacists, and Physicians

Richard Stefanacci, DO, MGH, MBA, AGSF, CMD, and Danielle Pouliot

The Medicare Modernization Act (MMA) of 2003 unleashed major changes in Medicare with the introduction of Part D. With over 50 pieces of legislation introduced to change Medicare as we know it today, plus legal and marketing activities, and the impact of the baby-boomers, profound changes to the Medicare are likely.

When Medicare Part D was signed into law in December 2003, President Bush remarked, “With this law, we’re giving older Americans better choices and more control over their health care, so they can receive the modern medical care they deserve.”¹ However, this has been difficult to realize. Seniors must first navigate the complexities of enrollment, and then the process for gaining access to their medications. The fact that problems are surfacing should come as no surprise with such a massive and complex federal program.

Problems fall into 2 primary areas: enrollment and medication access. Enrollment has to do with the failure of Medicare beneficiaries to enroll in any plan or in the right plan. The level of complexity of the benefit design, as well as the sheer number of plan choices, have made enrollment a difficult decision for many, especially given the restrictions that the Centers for Medicare and Medicaid Services (CMS) has placed on providers in assisting in this process.

General difficulties inherent in dealing with medication access include restrictive formularies with prior authorization requirements, tiering, and quantity limits. In addition, the original legislation that excluded certain medications from

coverage, as well as CMS’ evaluation of therapeutic equivalents, have made access to some of the most frequently prescribed geriatric medications difficult.

Proposed Legislation **Patients**

During the initial enrollment process, seniors had a difficult time deciding which plan to select. The US Government Accountability Office (GAO) recently evaluated prescription drug plan (PDP) help desks and found that relatively few customer service representatives were able to accurately identify the least costly plan and calculate its annual costs.² Other findings from the report are illustrated in Figure 1.

This has left over one-third of seniors without prescription drug coverage. Seniors left uncovered by Medicare Part D will face a late enrollment penalty unless legislation, such as S.2810—The Medicare Late Enrollment Assistance Act of 2006, introduced by Senator Grassley (R-IA)—is passed and signed into law (Table 1). This legislation would waive the enrollment penalty for Medicare beneficiaries who did not sign up during the initial enrollment period.

Assistance in managing enrollment process issues may come in the form of simplifying the process. Currently, seniors in Pennsylvania have over 200 plans to select from, each with very different offerings and all difficult to evaluate. S.2665—The Medicare Prescription Drug Simplification Act, introduced by Senator Baucus (D-MT)—would require companies to group their plans into 1 of 5 categories based on certain characteristics (Table 1). This would create a standardized platform for comparing all plan offerings, as Medigap has done with the lettering of similar plans from A through J.

Another enrollment issue has to do with the fact that benefits are tied to a patient’s location of care rather than to the patient. This is most evident with regard to the problem caused by the limited

legal definition of long-term care (LTC) facilities, due to which nursing home-eligible seniors living outside a skilled nursing facility, an assisted living facility, or any other alternative care setting likely will not receive several important benefits available to especially frail seniors. These benefits include access to an extended enrollment period, special packaging through institutional pharmacy providers, no cost sharing for those covered by both Medicare and Medicaid, and greater access to nonformulary medications. Although extending and refining the definition of LTC might correct this problem, a better solution would be to develop a system in which benefits follow the patient, regardless of their location of care. S.2409—The Home and Community-based Services Copayment Equity Act, introduced by Senator Smith (R-OR)—would reduce the cost sharing now applied to non-institutionalized, full-benefit, dual eligibles (Table 1).

Once enrolled, the complexity for seniors and providers shifts to accessing needed medications. Restrictions on certain drugs that make it difficult for beneficiaries to receive their needed medication include quantity limits, prior authorization, and step therapy. Dr. Jeffrey A. Kerr, Medical Officer for the Center for Beneficiary Choice, stated that, “Medicare drugs plans have created significant hurdles that patients and physicians must jump over before getting their medications. The prescription drug plans are playing a dangerous game.”³

S.2255—The Medicare Drug Formulary Protection Act, pro-

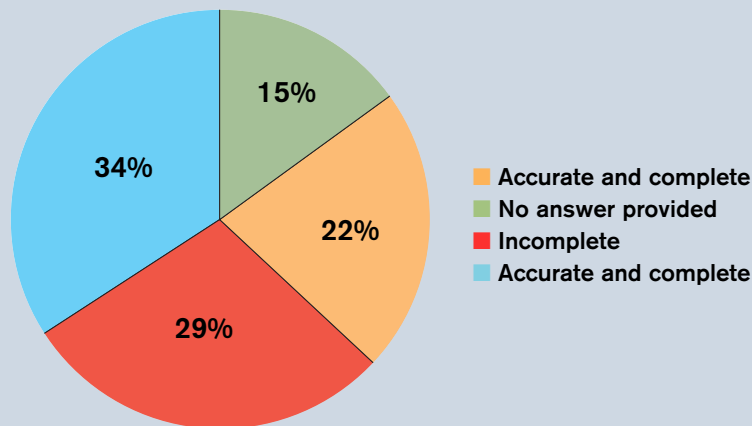
posed by Senator Feinstein (D-CA)—would prohibit the removal of covered Part D drugs from a plan’s formulary during the course of the plan year (Table 2). Currently, plans can make changes to their formularies provided that they give members 60-day notice, while the members remain locked into that plan and, in most cases, are unable to change to a different plan for the entire calendar year.

Medicare Part D medications that are not on a plan’s formulary can be accessed through the exceptions and appeals process. However, not all medications are covered under Medicare Part D. By law, specific medications that are excluded from coverage include over-the-counter medications, barbiturates, benzodiazepines, vitamins (except prenatal), weight-related drugs (except to treat obesity), fertility agents, cosmetic drugs, and medications for the symptomatic relief cough or colds. The lack of coverage for benzodiazepines is especially problematic because of their use in treating conditions such as anxiety disorders, which affect 11% of the population over the age

of 55. These medications cannot be covered by Medicare Part D funds, but PDPs can choose to provide them at no cost using other sources of funding. While most states will cover some or all benzodiazepines and barbiturates for dual eligibles, Tennessee is an exception.⁴

A social worker in Tennessee reported that 10 of her patients have been rushed to an emergency department since the state discontinued coverage of benzodiazepines.⁵ Health care professionals in the state are warning that many more Medicare beneficiaries may be admitted to hospital emergency departments due to benzodiazepine withdrawal symptoms. People with mental and cognitive disorders can spend months or even years developing stable medication regimens. For these individuals, discontinuing any medication could result in serious clinical setbacks and painful efforts to regain function and stability.⁶ Denying beneficiaries access to effective medication causes unnecessary danger and hardships to them, as well as their families and loved ones. HR.3151—The Medicare

Figure 1. Percentage of 864 Calls to Plan Help Desks With Accurate and Complete, Incomplete, or Inaccurate Responses, and Those Where No Answer Was Provided²



D

Denying beneficiaries access to effective medication causes unnecessary danger and hardships to them, as well as their families and loved ones.

Subvention Fairness Act, introduced by Congressmen Ben Cardin (D-MD) and Jim Ramstad (R-MN)—was designed to correct this issue, but has yet to move forward (Table 2). This legislation would amend the MMA by removing the exclusion of benzodiazepines from coverage under the Medicare Part D program.

Another piece of legislation focuses on the removal of the MMA restriction on the ability of CMS to negotiate directly with pharmaceutical companies for discounts.

S.2354—The Medicare Prescription Drug Gap Reduction Act, proposed by Senator Nelson (D-FL)—would allow Medicare to negotiate directly for discounts on medications (Table 2). Thus, patients’ ability to pick the right plan and gain access to medications at affordable prices is now dependent on several pieces of pending legislation.

Pharmacists

Pharmacists have been caught in the difficult position of providing medications to seniors on the as-

Table 1.

Proposed Legislative Action Directed at the Patient Enrollment Process

Bill No.	Sponsor	Summary	Status
S.2810 – The Medicare Late Enrollment Assistance Act	Grassley (R-IA)	Waives the enrollment penalty for beneficiaries, allowing them to enroll during the annual enrollment period without a penalty	Introduced 5/16/06; placed on the Senate calendar
S.2665 – The Medicare Prescription Drug Simplification Act	Baucus (D-MT)	Groups plans into 1 of 5 categories based on their characteristics	Introduced 4/27/06; referred to the Senate Finance Committee
S.2409 – The Home and Community-based Services Copayment Equity Act	Smith (R-OR)	Reduces cost sharing under Part D for certain noninstitutionalized full-benefit dual eligibles	Introduced 3/14/06; referred to the Senate Finance Committee

Table 2.

Proposed Legislative Action Directed at Patient Access to Medications

Bill No.	Sponsor	Summary	Status
S.2255 – The Medicare Drug Formulary Protection Act	Feinstein (D-CA)	Prohibits plans from removal of covered Part D drugs or imposing restrictions during the plan year	Introduced 2/8/06; referred to the Senate Finance Committee
HR.3151 – The Medicare Subvention Fairness Act	Cardin (D-MD) Ramstad (R-MN)	Removes the exclusion of benzodiazepines from the list of covered Part D medications	Introduced 6/30/05; referred to the Energy, Commerce, and Ways and Means Committee
S.2354 – The Medicare Prescription Drug Gap Reduction Act	Nelson (D-FL)	Allows Medicare to negotiate for discounted drug prices	Introduced 3/06; referred to the Senate Finance Committee

Medicare Part D prescription drug coverage has created a financial crisis for pharmacists.

sumption that insurers would eventually grant physicians' requests to cover specific medications. This delay in payment to pharmacies is a problem that is compounded by the delay in recovery of payments for medications covered by the plans. The shift from receiving reliable payments from Medicaid, which typically were made every 2 weeks, to private PDP reimbursement has caused major cash flow issues, especially for smaller independent pharmacies and pharmacies in low-income and rural areas.⁷

Many times pharmacists are not able to confirm a patient's enrollment in Medicare Part D because the PDP's data files are incomplete. This is the result of the lag time between when a beneficiary enrolls in a new plan and when the plan recognizes their status, especially with regard to their eligibility for the low-income subsidy. Life-sustaining drugs can cost thousands of dollars for the pharmacist, who many times is paying out-of-pocket to supply the drugs until the plan will cover them. This situation has forced many pharmacists to take out loans to help supply their elderly customers with needed medications.

Many pharmacist organizations, including the National Community Pharmacists Association (NCPA), have written to CMS, asking them to relieve the financial pressure being put on pharmacies and pharmacists. Bruce Roberts, NCPA Executive Vice President and CEO, has stated that "Although the source of these problems comes from many elements of this complex new ben-

efit program, it is the nation's community pharmacists who are bearing the brunt, along with their patients."⁸

CMS has done little to help the nation's pharmacists. S.2664—The Pharmacy Access Improvement Act, sponsored by Senator Baucus (D-MT)—would require PDPs and organizations offering Medicare Advantage drug plans to reimburse pharmacies more quickly and conveniently (Table 3).

In addition to helping pharmacists with payment issues, S.2173—The Medicare Dual Eligible Identification and Enrollment Facilitation Act, introduced by Senators Clinton (D-NY) and Rockefeller (D-WV)—would direct the Secretary of the Department of Health and Human Services to provide for outreach and education to pharmacies, particularly independent pharmacies. This legislation recognizes the important role of pharmacists in directing Medicare beneficiaries to the right plan and ensuring access to needed medications. Unfortunately, this legislation fails to take into account the equally important role of physicians.

Physicians

Besides being prohibited from participating in the educational initiatives that have focused on grass

roots organizations (eg, State Health Insurance Assistance Programs [SHIPs]), physicians have had restrictions placed on their ability to speak freely to their patients regarding specific plans. Unfortunately, help for physicians is less likely to come in the form of legislative actions than from competitive market pressures and the courts. CMS' marketing guidelines that place strong restrictions on physician' abilities to direct their patients to the PDP that is best for them have been called unconstitutional. In an extensive analysis of this matter, Ronald D. Rotunda, a Professor of Law at the George Mason University School of Law in Arlington, VA, questioned CMS' ability to restrict physicians' free speech, especially when looking out for the best interest of their patients, and concluded that these restrictions are vulnerable to constitutional challenge.⁹

CMS has created other barriers that physicians need to overcome to provide access to needed medications. With regard to CMS' guidance on therapeutic equivalents, federal regulators or PDPs made the decisions, rather than clinicians actually working with patients. For example, in their efforts to encourage the use of generic medications, CMS stated that escitalopram (Lexapro[®]) and citalopram (Celexa[®]) are therapeutically equivalent, which allowed plans to cover citalopram at the exclusion of escitalopram. This situation arose late during the formulary review process when CMS added guidance that formularies must include "substantially all" medications in 6 drug classes, which included the antidepressant

class. The reason for their use of the term “substantially all” and not simply “all” is that CMS stated that plans did not need to include escitalopram on their formularies because another drug, citalopram, was an effective and less expensive alternative.¹⁰ This despite the fact that escitalopram is currently being taken by hundreds of thousands of LTC residents. In reality, citalopram is not the generic equivalent of escitalopram, and the drugs are structurally different with different clinical effects. While both drugs have FDA approval for the treatment of depression, only escitalopram is also approved for the treatment of anxiety. In clinical studies, citalopram was less effective and associated with more adverse side effects. While CMS has stated that they want formularies to follow clinical guidelines, estab-

Physicians recently have had restrictions placed on their ability to speak freely to their patients regarding specific plans.

lished American Psychiatric Association treatment guidelines for depression unequivocally state that drugs to treat depression are not interchangeable.

This example illustrates that CMS is best leaving issues of clinical concern to the FDA and other medical and research professionals, rather than forcing the exclusion of widely used medications from plan formularies that will cause disruption to care and numerous problems. As CMS be-

comes more involved in formulary management, similar actions are likely to increase as a means to control costs. It is not entirely clear how patients, especially the frail elderly, will respond to forced nonequivalent therapeutic interchanges. Careful physician involvement to ensure that adverse consequences of such actions are minimized will be critical.

Prior authorization requirements placed on certain prescriptions also have delayed access to many medications. The process of prior authorization is unique but equally complex for different PDPs. Each PDP requires physicians to verify that no other drug on their formulary would be as effective as the drug in question or that the use of formulary drugs would cause adverse consequences. With some plans having 25 to 30 different forms for

Table 3.

Proposed Legislative Action Directed at Pharmacists

Bill No.	Sponsor	Summary	Status
S.2664 – The Pharmacy Access Improvement Act	Baucus (D-MT)	Requires drug plans to reimburse pharmacies more quickly and conveniently	Introduced 4/27/06; referred to Senate Finance Committee
S.2173 – The Medicare Dual Eligible Identification and Enrollment Facilitation Act	Clinton (D-NY) Rockefeller (D-WV)	Directs the Secretary of DHHS to provide for outreach and education to pharmacies	Introduced 12/21/05; referred to Senate Finance Committee
S.2563 – The Pharmacist Access and Recognition in Medicare Act	Cochran (R-MS)	Requires prompt payment to pharmacies under part D, restricts pharmacy co-branding on prescription drug cards, and provides guidelines for Medication Therapy Management Services programs offered by PDPs and MA-PDs	Introduced 4/6/06; referred to Senate Finance Committee
S.2723 – The Pharmacists Medicare Relief Act	Lautenberg (D-NJ)	Requires the PDP or an organization offering an MA-PD to promptly pay claims submitted under Part D	Introduced 5/4/06; referred to Senate Finance Committee

D= Democrat; DHHS=Department of Health and Human Services; MA-PD=Medicare Advantage prescription drug plans; R=Republican.

PROVIDER ACTION

Impact to You

The structure of Medicare Part D directly affects health outcomes for senior patients and, as a result, affects the physicians and pharmacists who serve them. As more responsibility for producing positive health outcomes is placed on providers, understanding and directing reform for positive effects will be critical.

What You Need to Know

Legislation is pending that will have a profound impact on the delivery of pharmaceutical services to seniors. Keeping informed of these changes is important so that providers can best manage their practices.

What You Need to Do

Advocating for patients to enroll in plans that understand the importance of prescribed medications is an important step for ensuring positive outcomes. Having processes in place to manage prior authorization and appeals efficiently and effectively, and applying political pressure to ensure that legislation is passed that will improve access to medications for our seniors.

obtaining prior authorizations, the diverse requirements are onerous and can delay or deny access to needed medications for many beneficiaries. However, many insurance companies stand by their complex system of forms, stating that prior authorization is a way to prevent the overuse of high-cost medications and ensure that equally effective, less expensive agents are used instead.

Along with physicians' verification, PDPs may require clinical evidence (eg, bone density levels for authorization of osteoporosis drugs, mental health test results for antimentia drugs, as well as white blood cell counts for certain AIDS drugs). While these tests promote the proper use of certain drugs, they are often time-consuming and add extra costs. Since the initiation of Medicare Part D, 3 of the nation's largest PDPs have required prior authorization for all Alzheimer's drugs. In response, the Alzheimer's Association wrote a letter to CMS, detailing the problems that this requirement was causing for thousands of dementia patients. As a result, Medco changed its policy, and since July 15, 2006, no longer requires prior authorization for antimentia agents. This shows how pressure from the medial community can cause a PDP's policy to change, resulting in greater access to critical medications.

Reforming Medicare

Rather than simply modernizing the current Medicare Program, what is needed is a more thoughtful process that involves continuous quality improvement, where clinicians lead the way to system redesigns that op-

imize outcomes. The history of changes to Medicare demonstrates that this is not an easy path. The most recent attempts include the catastrophic Medicare bill of 1986 and the Clinton health care plan of 1993, both of which lacked clinician involvement and failed successful implementation.

Clearly, tomorrow promises even more changes. Hopefully, by working together with all stakeholders, providers will play a key role in ensuring that Medicare reform produces positive results for senior patients. **MPM**

Richard G. Stefanacci, DO, MGH, MBA, AGSF, CMD, is Editor-in Chief of Medicare Patient Management and the Founding Executive Director of the Health Policy Institute of University of the Sciences in Philadelphia, PA. He also held the position of CMS Health Policy Scholar 2003-2004.

References

1. The White House, President George W. Bush. President Signs Medicare Legislation. Available at: <http://www.whitehouse.gov/news/releases/2003/12/20031208-2.html>. Accessed August 5, 2006.
2. US Governmental Accountability Office. *Medicare Part D: Prescription Drug Plans Sponsor Call Center Responses Were Prompt, But Not Consistently Accurate and Complete*. Washington, DC: US Governmental Accountability Office; June 2006. Publication GAO-06-710.

Available at: <http://www.gao.gov/new.items/d06710.pdf>. Accessed August 5, 2006.

3. Pear R. Rules of Medicare drug plans slow access to benefits. *New York Times*. February 14, 2006. Available at: <http://www.seniors.org/doc.asp?id=2042>. Accessed August 5, 2006.

4. Centers for Medicare and Medicaid Services. Excluded drug coverage by State Medicaid program. Available at: <http://www.cms.hhs.gov/States/EDC/list.asp>. Accessed August 5, 2006.

5. America's Senior Care Pharmacists[®]. Federal and state news. *ASCP Update*. March/April 2006, p 3. Available at: <http://www.ascp.com/publications/update/>. Accessed August 5, 2006.

6. Medicare Rights Center. Critical coverage: benzodiazepines under Medicare Part D. June 2005. Available at: <http://www.medicarerights.org/benzoreport.pdf>. Accessed August 5, 2006.

7. Pugh T. Medicare mess for druggists. *Philadelphia Inquirer Washington Bureau*. February 9, 2006. Available at: <http://www.philly.com/mld/inquirer/business/13825249.htm>. Accessed August 7, 2006.

8. National Community Pharmacists Association. Medicare Part D causes cash flow crisis for community pharmacy: NCPA calls for help to ease burden created by claims processing problems. Available at: http://www.ncpanet.org/news_press/press_releases/2006/medicare_part_d_causes_cash_flow_crisis_for_01-24-2006.shtml. Accessed June 29, 2006.

9. Rotunda RD. CMS information policy under Medicare "Part D" creates 1st Amendment problems. *Washington Legal Foundation*. 2006;21:1-4. Available at: http://www.ncpanet.org/news_press/press_releases/2006/medicare_part_d_causes_cash_flow_crisis_for_01-24-2006.shtml. Accessed August 5, 2006.

9. Centers for Medicare and Medicaid Services. CMS guidance. Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories? Available at: http://www.amcp.org/data/nav_content/Formulary%20QA%20final%20mm%20-%20revised.pdf. Accessed August 3, 2006.