

Reading the Tea Leaves for Medicare Part D

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Much has been printed about the unfortunate difficulties that many patients have been having with enrollment and accessing their medications under the new Medicare Part D benefit. Although every local paper has been full of reported problems with Medicare Part D, very little has been written about how to correct them. To best understand the direction that Medicare Part D is likely to take, one needs to evaluate the legislative landscape to determine its likely course.

The early difficulties occurred mainly as the result of the large volume of Medicare beneficiaries being introduced into an entirely new, untested system. Overall, these problems fell into a few categories, including inaccurate enrollment data, excessive charges for deductibles and copayments, drug plans failing to provide temporary transition medication supplies to beneficiaries already stabilized on certain drugs, and ineffective use of the fallback drug plan (WellPoint).

for weight-related purposes (except when used to treat obesity), fertility problems, cosmetic reasons, and the symptomatic relief cough or colds. This has made access to such medications as Niaspan® (nicotinic acid) and Megace® ES (megestrol acetate), which are frequently used by senior patients, particularly difficult. Table 1 defines some of these gray areas of coverage versus exclusion under Medicare Part D.

Another area of clinical inconsistency is related to the Centers for Medicare and Medicaid (CMS) mandate indicating that “all or substantially all” of the drugs in the antidepressant, an-

In addition to these difficulties, there are several gray areas that have caused considerable confusion and will likely require legislative action for clarification. For example, despite there being significant clinical data to support the use and coverage of specific medications, the Medicare Modernization Act (MMA) excludes certain medications from coverage under Medicare Part D, based on their class and use. Specific excluded classes of medications include over-the-counter medications, barbiturates, benzodiazepines and vitamins (with the exception of prenatal vitamins). Specifically excluded medications that are not covered under Medicare Part D because of how they are utilized include those used

Table 1.
Gray Areas of Coverage Under Medicare Part D

	Covered	Excluded
Agents for anorexia/weight gain	Used for weight gain due to a long-term disease such as cancer, AIDS, heart failure, lung, kidney, or liver disease	All other uses
Agents to promote weight loss	Morbid obesity (BMI >40)	Cosmetic purposes (BMI <39)
Electrolytes	K, Na, Ca, Mg	Potassium iodide products
Heparin	Therapy	Flushes
Vitamin D analogs	Calcitriol, doxercalciferol, paricalcitol, dihydrotachysterol	Ergocalciferol, cholecalciferol
Niacin products (Niaspan®, Niacor®)	Optional plan coverage until May 31, 2006	No coverage after June 1, 2006

tipsychotic, anticonvulsant, anti-retroviral, immunosuppressant, and antineoplastic categories must be included on Medicare prescription drug formularies. “All or substantially all” means all drugs in these categories are expected to be included with a number of specific exceptions. However, the exceptions to the “all or substantially all” policy undercut the very purpose of CMS guidance designed to accommodate the varying responses to medications for people with any of these 6 chronic health conditions. In particular, CMS has informed plans that Lexapro® (escitalopram) did not need to be included in their formularies because another drug, Celexa® (citalopram), could be used as an alternative.¹ However, several studies have demonstrated that patients who did not achieve a good response to citalopram have had a good response to escitalopram.²⁻⁴ Although this fulfills a medically accepted criterion by which antidepressants are demonstrated not to be interchangeable, CMS guidance allows prescription drug plans (PDPs) to cover only the less expensive citalopram at the exclusion of escitalopram. This has resulted in many patients being switched from escitalopram to citalopram, resulting in adverse consequences and disruptions in health care.

While such needed clinical changes could occur with CMS regulatory guidance, given the agency’s reluctance to change, it is more likely that legislative actions will be required to make needed changes.

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Legislative Actions

Currently there are over 50 pieces of legislation written to correct the difficulties within Medicare Part D. These legislative actions fall

within the following categories: enrollment issues, cost-sharing issues, access issues, and process issues (Table 2).

With regards to enrollment, recently introduced legislation includes provisions to extend the initial enrollment period from May 15, 2006 until December 31, 2006. This is meant to provide seniors with time to educate themselves about Medicare Part D and make the best decisions for enrolling in plans. Legislation has been proposed that would eliminate the late enrollment penalty fee during the first year of the program and allow for every person

Table 2.
Federal Legislation to Correct Medicare Part D Issues

Enrollment

- Extension of the initial enrollment period from May 15, 2006 to December 31, 2006
- One-time change of plan enrollment during 2006
- One-time go-back to employer-sponsored plan

Cost-sharing

- Beneficiary
 - Elimination of cost-sharing for nursing-eligible seniors living outside of long-term care (LTC) facilities
 - Ensure that dual eligibles are not overcharged
- Pharmacy
 - Cover medications given to dual eligibles
- State
 - Reimbursement for 2006 transition costs
 - State coverage of nonformulary prescription drugs for dual eligibles

Access

- Formulary transition
- Coverage for benzodiazepines
- Coverage for barbiturates, which are sedative agents that are clinically effective in treating seizures associated with epilepsy and head injuries; in addition, they are utilized to treat insomnia

Process

- Customer service
- Standardize authorization process

Figure 1.
CMS Appeals and Exceptions Template⁵

REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION

This form cannot be used to request antineoplastic, benzodiazepines, fertility drugs, drugs for weight loss or weight gain, drugs for hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).

Enrollee's/Requestor's Information

Enrollee's Name _____ Enrollee's Date of Birth _____
 Enrollee's Medicare Number _____ Enrollee's Part D Plan ID Number _____
 Requestor's Name (if not enrollee) _____
 Requestor's relationship to Enrollee (attach documentation that shows authority to represent enrollee, if other than prescribing physician) _____ City _____ State _____ Zip Code _____
 Enrollee/Requestor's Address _____
 Phone _____
 Name of prescription drug you are requesting (if known, include strength, quantity and quantity requested per month): _____
Prescribing Physician's Information
 Name _____ Medical Specialty _____ City _____ State _____ Zip Code _____
 Address _____ Office Contact Person _____
 Work Phone _____ Fax _____
Type of Coverage Determination Request
 I need a drug that is not on the plan's list of covered drugs (formulary exception).
 I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).
 (attach physician's supporting statement, if applicable)
 Date _____
 Note that your Medicare drug plan may have materials for more information.

with Medicare to make a one-time change in plan enrollment at any point during 2006. Another provision would protect beneficiaries from being dropped by their employer-sponsored plans during the first year of implementation so that they have time to correct enrollment mistakes.

Legislation also has been proposed that would assist beneficiaries, pharmacies, and states in issues related to cost sharing. Currently, benefits are based on the site of care, rather than specific patients needs. For beneficiaries, legislation would clarify cost sharing for copayments for dually eligible beneficiaries (those with Medicare and Medicaid) or eliminate copayments for these patients, regardless of where they live. Another problem with regard to copayments has been the overcharging of beneficiaries as a result of their not being recognized by the system as being dually eligible. Legislation would work to correct this problem to ensure that the dually eligible are not overcharged.

Legislation would also require CMS to ensure that pharmacies receive payment for providing medications for dually eligible beneficiaries. States have found themselves in a similar situation where they needed to provide coverage for their dually eligible citizens through the transition period as they move from Medicaid to Medicare. In addition, legislation would make sure that states would receive matching federal funds for providing coverage of nonformulary prescription drugs for dual eligibles.

Although many of the initial problems were the result of the large volume of patients being in-

troduced to the new system, access issues have surfaced that involve medications specifically excluded from coverage under Medicare Part D, as well as the off-label use of medications. To ensure access to medications that a patient has already been taking, legislation would mandate that plans cover medications for a prolonged transition period. In addition, coverage would be made available for some of the excluded medications, in particular, benzodiazepines and barbiturates.

Legislation would also help to improve process issues. Providers have received numerous reports that plans' customer service representatives are not aware of their plan's transition policies and that plans are inappropriately denying some prescriptions. Since each plan has its own authorization process, legislation would call upon plans to adhere to a standardized authorization process. CMS has already tak-

en a step in this direction by developing an appeals and exemptions template (Figure 1).

State Actions

Early in January 2006, over 2 dozen states continued to provide coverage for their dually eligible beneficiaries. CMS initially announced that they would not provide reimbursement to states for these lapses in coverage. However, CMS has since stated that they would, in fact, provide reimbursement to states for this coverage. Beyond this, each state is developing their own strategy to cover their dually eligible beneficiaries as best as possible. In New York, the State Legislature unanimously voted to override Governor George Pataki's veto of a bill that would indefinitely provide a safety net or "wrap-around" benefit for New York residents covered by Medicaid who were unable to get their medications through their

Medicare Part D plan. Because this program is not eligible for matching federal funds, New York State estimates it will cost an additional \$68 million per month.

Pennsylvania has already approved legislation to require LTC pharmacies to re-package drugs received from other pharmacies. The bill was motivated by a retiree in an LTC facility who received drugs from the Veteran's Administration. Due to this legislation, the resident was instead able to use the LTC facility's preferred pharmacy.

Most of the pending Pennsylvania legislation deals with the state's pharmacy assistance programs, known as PACE and PACENET. Older Pennsylvanians can now apply for new federal Medicare prescription drug benefits without adversely impacting their Pennsylvania PACE and PACENET prescription drug benefits. It is felt that many of the states that offer State Pharmacy Assistance Plans (SPAP) will move in this same direction (Table 3).

Other states such as New Jersey are taking steps to correct inconsistencies ahead of legislative action. Realizing the disincentive for frail elderly patients who utilize home- and community-based waivers instead of living in a nursing facility, New Jersey has made arrangements to pay for similar benefits for these residents regardless of the site of care.

Pharmaceutical Marketing

Besides actions directly related to Medicare Part D, now that the federal government has become the principle payor of medications, it is taking aim at direct-to-consumer marketing efforts by pharmaceuti-

Table 3. Pennsylvania State Pharmacy Assistance Plans	
Coverage	<ul style="list-style-type: none"> • Payment of Part D premiums for PACE enrollees • Coverage of drugs specifically excluded from Part D coverage and for prescriptions during the deductible phases and "donut hole" • Coverage for copayments up to current PACE and PACENET amounts • Elimination of the PACENET deductible <ul style="list-style-type: none"> – PACENET enrollees would pay Part D premiums that are at or below the regional benchmark premium (currently \$32.54)
Process	<ul style="list-style-type: none"> • PACE and PACENET would act as the representative for their enrollees: <ul style="list-style-type: none"> – Assessing eligibility and applying for limited income subsidies – Selecting and enrolling beneficiaries in the most appropriate Part D plan – Undertaking appeals from Part D plans • Real-time on-line coordination of benefits between PACE and appropriate Part D plans <ul style="list-style-type: none"> – Pharmacists continue to fill prescriptions at their pharmacies – Eliminate additional costs, delays, and paperwork

Table 4. Features of the Bridge Rx Patient Assistance Program	
• Eligibility:	<\$18,620 annual income
• Period:	Coverage gap
• Coverage:	>50% discount on specific medications
• Copayments:	15%
• Companies:	Johnson & Johnson, AstraZeneca, Novartis, Bristol-Myers Squibb
• Budget:	\$30 million (500,000 participants)
• OIG issues:	Must include generics and a significant range of branded medications to avoid being viewed as a kickback to promote use of specific medications

cal companies. The concern is that current marketing practices encourage greater use of expensive branded products. Other areas of concern involve rebates to LTC pharmacy providers, pharmaceutical patient assistance programs, and professional sampling.

While there has been no legislative action restricting current pharmaceutical marketing practices, both the Office of the Inspector

General (OIG) and CMS have released statements in different formats to restrict these activities. This position is based on the belief that where a manufacturer offers subsidies tied to the use of their own products, the subsidies are associated with the risk of fraud, abuse, and kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial

Take-Away Message

- Early issues that involved enrollment and access to medications were related to the difficulty in handling a large volume in a short time frame and will resolve; however, those involving access will remain.
- A move to give physicians the ability to write, "Specific medication medically necessary," rather than going through a prior authorization or appeals and exceptions process, would improve access.

ROI

- Understanding the gray areas of coverage will reduce denied prescriptions.
- Utilizing the CMS appeals and exceptions template will improve efficiency.
- Keeping abreast of the legislative changes will be important to help answer questions for patients and staff about enrollment and access issues, as these will be changing in the near future.

advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs. It is likely that if these actions do not achieve the results that OIG and CMS believe are needed to decrease the encouragement of branded products, legislative action is probable.

In a move to decrease some of the OIG's concerns over pharmaceutical patient assistance programs, some drug companies are developing a plan to evolve their current patient assistance programs to a program called "Bridge Rx" (Table 4). Currently, only 4 pharmaceutical companies have committed to participation in this program, but many more are evaluating their participation options. Eligibility in the program is such that it is accessible to many more individuals than those who receive the low-income subsidy, which has income requirements and asset restrictions for single individuals and married couples. For example, those eligible for the low-income subsidy cannot have assets in excess of \$11,500 for a single individual and \$23,000 for a married couple, whereas the Bridge Rx program has no asset restrictions and

provides higher income allowances. By structuring the Bridge Rx program in this manner, beneficiaries could be enrolled in a Part D plan and still receive benefits from a patient assistance program. However, under the current structure, the OIG is concerned that access will be limited to specific branded products, while discouraging less expensive generic drug use.

Again, now that the federal government is the major payor of medications under Medicare Part D, Veteran's Administration and other military benefit programs, as well as federal employee and retiree pharmaceutical benefit programs, it is likely that if the OIG and CMS are not satisfied that pharmaceutical products are promoted and utilized in an efficient and effective manner, legislative action is likely.

The Ultimate Solution

Perhaps the most sweeping legislative change is that which would allow providers to simply write "specific medication medically necessary." The push for this change has been building momentum because of the significant difficulties for providers in utilizing the appeals and exceptions process and

the prior authorization process to gain access to needed medications. Currently, PDPs are obligated to provide all medications that are medically necessary, a situation that has not been defined by CMS. As such, in allowing providers to make this determination through the prescribing process rather than a separate plan-driven process, patients could receive their medically necessary medication in a much more timely manner.

Clearly, changes are needed to allow patients to receive medically necessary medications in a timely fashion. These changes will occur through both CMS regulations and federal legislation. *MPM*

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References

1. CMS Guidance: Why is CMS requiring "all or substantially all" of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant, and HIV/AIDS categories? June 20, 2005. Available at: <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidanceAllorSubAll.pdf>. Accessed February 12, 2006.
2. Gebhart F. Long-term care pharmacies unhappy with Part D limits. *Drug Topics*. November 21, 2005. Available at: <http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=200926&pagelD=1&sk=&date=>. Accessed February 10, 2006.
3. Graham J. Drug program problems hit sickest of sick: Medicare woes plague nursing home patrons. *Chicago Tribune*. January 24, 2006. Available at: http://www.chicagotribune.com/news/nationworld/chi-0601240022jan24_1_5923467.story?coll=chi-newsnationworld-hed. Accessed February 10, 2006.
4. Levine S. Stability of mentally ill shaken by Medicare drug plan problems: some prescription denials have heightened distress. *Washington Post*. February 6, 2006, p. A01. Available at: <http://www.washingtonpost.com/wp-dyn/content/article/2006/02/05/ar2006020501163.html>. Accessed February 10, 2006.
5. Centers for Medicare and Medicaid Services. Medicare prescription drug coverage determination request form. Available at: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp. Accessed February 11, 2006.