Shifting the Focus From Cost to Value: A Government Perspective

BABETTE S. EDGAR, PharmD, MBA

ABSTRACT

OBJECTIVE: To examine the federal government's current health care initiatives in the Centers for Medicare and Medicaid Services (CMS) to improve quality of care and cost-effectiveness around the prescription drug benefit.

SUMMARY: The government has a unique perspective on quality and outcome. Pharmacists need a working knowledge of 3 areas: (1) Medicare Part D, (2) medication therapy management efforts, and (3) demonstration projects. All of these will make demands on health care providers but should result in better outcomes data and patient care. All of these areas also have value components, and all have strategic implications as 2006 moves into 2007.

CONCLUSION: CMS does not consider managing cost and providing value to be mutually exclusive and is attempting to move America's health care toward a value-based program.

KEYWORDS: Healthy workforce, Integrated health care, Value, Benchmarks, Disability, Prevention

J Manag Care Pharm. 2006;12(6)(suppl S-b):S11-S15

The government has a unique perspective on quality and outcome. Some issues are particularly controversial and labor-intensive for stakeholders in the health care environment, such as Medicare Part D, demonstration programs conducted by the Centers for Medicare and Medicaid Services (CMS) that examine the outcomes and values equation, and medication therapy management (MTM) programs. All of these have value components, and all have strategic implications as 2006 moves into 2007.

Medicare Part D

Medicare Part D has been a development and implementation challenge to health care providers, including pharmacists, physicians, health plans, long-term care institutions, and home health care providers. Congress designed a challenging benefit with many moving pieces. Developers of Part D plans have designed creative benefits, taking into account government rules and regulations while making sure that the benefits were cost effective and provided overall quality of care for beneficiaries. Organizations offering Part D plans have had to go through a multistep process to get their plans approved by CMS. These steps include filling out a complicated application, submitting formularies that are regulated by CMS guidelines, and submitting bids (how much the beneficiary, plans, and government are willing to pay for the benefit) for approval. Plans can charge the same amount for all drugs; can charge different amounts for drugs based on whether they are generic, brand, or a preferred brand for that plan; or can charge a percentage of the cost of the drug. Beneficiaries who have limited income or who also qualify for Medicaid (dual-eligibles) can be charged less than beneficiaries who have more robust incomes.

Health care plans have found the workload created by Medicare Part D to be somewhat taxing, and because this is the program's first year, they (like the federal government) have had to learn quickly and make adjustments when and where necessary. The need to plan for 2007 while dealing with requirements for 2006 has complicated things further. Current concerns include the following:

1. deciding whether dual-eligibles will need to be moved to new plans again in 2007 if their current plans' bids are not low enough,
2. reconciling Medicare payments for plans and pharmacies,
3. transitioning patients' medications covered in old plans to Part D plans, and
4. handling last-minute enrollments that could overwhelm current plan systems.

Existing plans prepared for the next wave of enrollment, which was locked in on May 15, 2006. This lock-in is statutory, and beneficiaries may only change plans after this date for the remainder of the calendar year if they are dual-eligibles (who can change

Author

BABETTE S. EDGAR, PharmD, MBA, is vice president, strategic development, Gorman Health Group, LLC, Washington, DC

AUTHOR CORRESPONDENCE: Babette S. Edgar, PharmD, MBA, Vice President, Strategic Development, Gorman Health Group, LLC, 2176 Wisconsin Ave., NW, Washington, DC 20007. Tel: (202) 364-8283, (410) 560-9952; Fax: (202) 244-8324; E-mail: bedgar@gormanhealthgroup.com

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monthly) or have a status change, such as diagnosis of a chronic disease. Also, in mid-2006, some employers who are on mid-year benefit cycles may end up “dumping” their retirees into Part D (dropping current retirees into the government entitlement for an economic advantage to the parent company); this will create additional opportunities and challenges for Part D plans.

For health care providers attempting to implement Medicare Part D, operational issues abound. Numerous agents and brokers are operating, and CMS is starting to intensify its crackdown on unwanted marketing practices in terms of compliance. This could lead to sanctions on the Part D plans. Examples of these practices include the selling of plans door-to-door by agents or the setting up of sales tables for plans too close to areas of clinical practice. In addition, pharmacies are not allowed to steer beneficiaries to a plan based on financial gain for the pharmacy. Pharmacists can make recommendations based on specific patient data, such as the patient's medication profile and match the patients to plans with formularies that offer their medications. CMS has provided a detailed document that outlines which marketing practices are acceptable and which are not.

Plans are also dealing with pharmacy benefit management (PBM) oversight from a subcontractor's perspective. For Medicare Advantage (MA) organizations, formerly known as Medicare+Choice organizations, mastering risk adjustment before 2007 will be a challenge as risk corridors (limits to the profits or losses plans incur if their basic Medicare drug benefit costs are lower or higher than they had estimated based on beneficiaries' disease states) are shrinking. Medicare will begin to reimburse plans more for sicker patients and less for healthy patients.

If plan developers still want to include 3 plans per organization per region, which may position the plans better in the marketplace, they will need to alter their benefit design. Last year, organizations were allowed 3 plans per region, and that number will be reduced to 2 in the coming year, unless plans choose to submit 1 plan with some drug coverage in the coverage gap (or donut hole, resulting from requirements in the Medicare benefit law that cause a gap: Medicare pays 75% of initial drug costs up to \$2,250 after a \$250 deductible for most seniors but then pays nothing until total drug expenses reach \$5,100, after which the government pays 95% of all costs). Most plans that offer some coverage in the gap are doing so for generic drugs at the generic drug copayment rate. Plan developers will seriously need to rethink their marketing and product strategies for this year given the changes in the marketplace.

Demonstration Projects

CMS is coordinating several demonstration projects related to outcomes. These data will be made publicly available to help the plan developers and other stakeholders deal with the most crucial health care issues facing the nation.

For most stakeholders, the Section 641 demonstration is most familiar. Known as the Medicare Replacement Drug Demon-

stration, this initiative paid for certain drugs and biologics self-administered by the patient at home, replacing the traditional approach that covered Medicare Part B drugs only when given in a doctor's office. In addition, newer, more effective medications for rheumatoid arthritis, multiple sclerosis, pulmonary hypertension, and a variety of cancers were also covered. Specific drugs were selected based on criteria developed by physicians and other experts who consulted with CMS.

CMS enrolled 3,200 participants and examined the following patient outcomes: patient perception of benefits, costs of self-administration versus office visits, number of physician visits, administration costs, and emergency department visits. While pharmaceutical companies and others expected that all of the demonstration project drugs would be required to be on the Medicare plan formularies this year, this did not occur. The project is now complete and the outcomes data are being tabulated. The data should be available later this year.

The Section 646 demonstration project tests major system changes to improve quality of care while increasing efficiency across the whole system. It looks primarily at physician compliance with treatment guidelines but also examines variations in utilization and outcomes measurement and research, shared decision making between providers and patients, and culturally and ethnically sensitive health care delivery. CMS intends to use this demonstration to identify, develop, test, and disseminate major, multifaceted improvements to the entire health care system.

CMS's 1-year 2006 Oncology Demonstration Program is also under way. Program developers are looking at specific outcomes: controlling pain, minimizing nausea and vomiting, and reducing fatigue. These 3 areas are significant concerns for patients who undergo chemotherapy. To facilitate the project, CMS has established new G-codes (temporary national codes for items or services requiring uniform national coding between one year's update and the next) for physicians, enabling a \$130 payment in addition to the encounter fee to physicians when they report the data.

CMS is sponsoring numerous other projects, but 2 are of great interest to pharmacists. The CMS E-prescribing demonstration will test initial electronic medication prescribing standards with health care practitioners, Medicare Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PDP) sponsors, and pharmacies. Medicare plans must have established programs using these standards (which will be released in 2008) in 2009 if they plan to participate in E-prescribing. To be prepared for this, stakeholders (e.g., plans, pharmacies) will need to start thinking about this now.

CMS's reinsurance project looks at new methods of providing reinsurance and offers payments that remove disincentives for private-sector plans to offer additional prescription drug benefits to their enrollees. This should demonstrate the effect of filling the gap in coverage by reimbursing participating plans. The capitated payment is equivalent to the amount plans would otherwise

receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point (\$3,600 of out-of-pocket costs).

Medication Therapy Management

CMS has defined an MTM program as one that helps ensure that drugs are used to “optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug reactions,” in certain high-risk patients. MTM is a clinical quality and utilization program related to drugs and their outcomes that can be furnished through multiple different distribution mechanisms, such as direct pharmacist contact or mailings to targeted beneficiaries. Plans must offer MTM to all beneficiaries who meet their inclusion criteria although beneficiaries can decline the offer. MTM costs are included in the administration costs of bids. CMS intentionally left the criteria for eligibility (see Table 1) vague to encourage innovative programs. Although there are no criteria requiring programs to have measurable outcomes at this point, plans will need to have the ability to measure their outcomes. It is anticipated that measurable outcomes will be required at some point by CMS, and these are necessary to administer a successful program.

CMS has very specific reporting requirements for MTM programs: the number of beneficiaries in the program who met the criteria for the MTM program, the number of beneficiaries who participated in the program, the number of beneficiaries who dropped out of the program, the number of beneficiaries who declined the offer to participate, and total prescription costs. Quality measures are not included in 2006 but will probably be added in 2007.

Plans have implemented various MTM programs, including mandatory generic programs, prior authorization, step therapy, quantity limits, drug utilization review, polypharmacy and disease-specific clinics, brown bagging, adherence/compliance programs, programs similar to the Asheville project (in which pharmacists run in-depth clinical patient consultations), and case management/call center programs. Program complexity ranges from the simple, like utilization management strategies, to the complex, like one-on-one patient and pharmacist interaction. Generally, however, the stronger the direct patient interaction the more expensive the program, and since these interventions are charged to administration costs, funds are usually limited.

Outcomes analyses will require data integration, and CMS Parts A, B, and D data are not going to be integrated until early 2007. So integrated outcomes data will probably not be available from CMS until at least mid-2007, and it is still uncertain how and if CMS will present the results. Plans may be able to do this on their own if they have the sophisticated systems or contractors to do so. Reporting requirements are the focus of 2006 and include the areas of grievances, financial data, exceptions and appeals, overpayment and reversals, generic dispensing rates, call center measures, and disenrollment numbers. Benchmarking and trend

TABLE 1 Required Criteria for Eligibility in an MTM Program

A beneficiary must meet ALL 3 criteria to be eligible for a plan's MTM program:

1. A beneficiary must have multiple chronic diseases
2. A beneficiary must have filled multiple covered Part D drugs
3. A beneficiary must be likely to incur annual costs of at least \$4,000 for all covered Part D drugs

The program must have measurable outcomes and the plan must have the ability to measure them!

MTM = medication therapy management.

analysis will be focus areas for 2007. Although CMS has not released details, some of these areas may be subject to pay-for-performance measures (particularly related to generic dispensing rates) and call center measures.

Benefit Structure: Outcomes

MA plans with MA-PDPs are probably best able to perform outcomes studies. They control both the medical data and pharmacy data, although some plans may not be capable of integrating all data. Often, their PBM companies have the capability to do this for them. The concept of budget siloing—where the pharmacy director and medical director are responsible for their costs in isolation—is a barrier to effective and overall disease and patient management. Disease management (DM) theory suggests that increasing drug costs sometimes decreases medical costs. MA, MA-PDP, and special-needs plans (SNPs; specialized management plans that limit Part D enrollment to dual-eligibles, institutionalized individuals, and those with specific chronic health conditions) are in the best position to implement DM and improve outcomes. In the case of stand-alone PDPs, where the beneficiary can be enrolled in a private fee-for-service (FFS) plan, the incentive is to keep drug costs low. There is little incentive to collaborate with the FFS plan and do perhaps what is best for the patient in terms of improving outcomes and lowering overall health care costs.

This suggests that MTM programs need to be integrated with DM programs and other care management programs to provide the best patient outcomes. If MTM manages medication therapy and DM manages disease, the only thing not being managed is the patient as a whole. A patient-centric approach integrates the DM program with MTM. This approach enhances patient care and is likely to be cost effective. In the Medicare population, it is critical to address polypharmacy, multiple doctors, and coordination-of-care issues. In the current commercial population, care management is difficult because patients do not stay in one plan long enough to measure health outcomes. Dual-eligibles also create an additional problem since Medicare allows them to switch plans every month, making DM and MTM very difficult.

Formularies

The formulary process for Medicare beneficiaries is predicated on 2 basic principles of the statute. It requires that formularies provide broad access to all patients and that they are nondiscriminatory. The Medicare Part D formularies were to mimic best-practice commercial formularies for the Medicare population while maintaining the principles of the statute.

Medicare Part D formularies differ from traditional commercial managed care formularies considerably. They include injectables and vaccines, have dosage forms required by a broad variety of populations (e.g., nursing home residents), and must contain drugs included in certain clinical best-practice guidelines. In addition, there are drugs that can sometimes be covered under Part B and sometimes covered under Part D (depending upon the circumstances); this can also increase administration costs.

In 2007, some trends can be expected. Theoretically, plan administrators know what to expect from a formulary review, as well as how many and what their bids are going to look like. Based on this, it is expected that fewer formularies and benefit designs may be available. Also, the number of SNPs is expected to increase, as will the specialized formularies that accompany them. Hypothetically, managing a particular population, such as diabetics, should lead to better outcomes because the focus is on a particular type of care and the specialized needs of this patient population. Formularies for these specific populations may be unique, containing a broader array of agents for the specific condition or population. Plans will start to move away from the United States Pharmacopeia categories and class system and toward their own categorization systems in order to allow for enhanced manufacturer contracting strategies.

Part D: PBM Issues

For several years, plans and employers have asked for greater transparency from PBMs. Part D is accelerating the rebate transparency issues for plans and CMS because of its reporting and Web requirements. The CMS Web site now allows anyone to see drug pricing, and astute observers will be able to estimate plan rebates. Part D plans also have significant reporting requirements to CMS. Part D reporting requirements include the following:

- For each rebate, provide the contracting manufacturer's name.
- For each rebate, provide the brand name.
- For each unique manufacturer/brand-name combination, provide the rebate amount received in the reporting period specified.
- For each unique manufacturer/brand-name combination, provide the rebate amount requested but yet unpaid for the reporting period specified.
- For each unique manufacturer/brand-name combination, provide the rebate amount received that is associated with a prior reporting period.

From a contracting standpoint, pharmaceutical manufacturers may decide to promote access-based contracts as opposed to

market-share-based contracts; the reasoning is that, from the standpoint of market share, a plan would have had to list the highest potential cost of the drug on the Web site. By doing so, plans may not look quite as competitive as those plans having access rebates.

Strategic Considerations for 2007

Plans used various strategies to be successful in the Medicare Part D marketplace. For example, some plans this year decided to operate at cost or at a loss to create low premiums and attract beneficiary market share. This strategy also capitalized on the way that plans were displayed on the Web site, with lowest premium programs listed first. This could be a strategy again in 2007, but many plans will have to increase premiums to avoid going out of business in 2008.

Sponsors now face the end of aggregate reinsurance, so the loss of higher payments will dictate decreasing costs to maintain profit margins. This will increase the importance of control mechanisms, like step therapy, prior authorization, quantity limits, and strict formularies.

With SNP plans expected to blossom, plans will attempt to achieve total risk adjustment and increase enrollment. Again, dual-eligibles have no lock-out period—they can change plans anytime. In addition, Medicaid reforms will also move A/B/D populations to mandatory managed care plans, and managed long-term care will probably become popular.

In 2006, about 9% of employers moved their retirees into Part D. A little enrollment bump is expected in Part D midyear as a few more employers follow suit. As time goes on, more employer groups are expected to transfer retirees into Part D, with unions, nonprofits, and the public-sector employers probably leading the way because of lack of tax benefits. This is likely to occur because many employers are analyzing their retiree benefits and concluding that they are no longer financially able to support retiree drug coverage even with the employer subsidy of 28%.

Conclusion

Successful Medicare drug programs demand a dedicated staff and a supportive infrastructure. Medicare must be an organizational priority for them since reporting and compliance requirements are onerous. Individual and group sale strategies will be needed, as will aggressive revenue and reconciliation recovery strategies. Most important from an outcomes perspective are aggressive member retention programs; it is less expensive to keep a member than it is to lose one and have to recruit another.

Partnership between manufacturers, health plans, PBMs, grassroots organizations, and patient advocacy organizations is needed to develop a consensus about the meaning of value and to establish outcomes programs.

CMS does not consider managing cost and providing value to be mutually exclusive. Medicare Part D is moving America's health care toward a value-based program. CMS mandates certain

activities, and plans will have to collect outcomes data and report on quality indicators. This should lead to improvements in the quality of data that document outcomes and quality. In the end, patients will benefit.

DISCLOSURES

This article is based on the proceedings of a symposium held on April 5, 2006, at the Academy of Managed Care Pharmacy's 18th Annual Meeting and Showcase in Seattle, Washington, which was supported by an educational grant from sanofi-aventis and sponsored by the Benefit Design Institute. The author received an honorarium from sanofi-aventis for participation in the symposium. She reports no affiliations with or financial interest in any commercial organization that poses a conflict of interest with the presentation on which this article is based.