

# JMCP

JOURNAL OF MANAGED CARE PHARMACY

## Current Issues and Trends in Medicare Part D

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#### **Learning Objectives**

After reading these articles, participants should be able to do the following:

- Review the current structure, as well as benefit designs and premium, offered by health plans under Medicare Part D.
- Discuss the role of medication therapy management and pay-for-performance as potential tools to improve the overall quality of care for Medicare beneficiaries, decrease health care utilization, and reduce costs.
- Establish the value of electronic health records (EHRs) in providing better coordinated care across multiple providers.
- Address the rapid growth of special needs plans (SNPs) to offer care for specific target populations.
- Overview the auditing and reconciliation procedures required of Medicare Part D plans by CMS.
- Discuss future issues most likely to affect the viability of Medicare Part D.

#### **Disclosures**

Chris R. Cammisa discloses no potential bias or conflict of interest relating to this article. Steven Evans is an advisor for Takeda Pharmaceuticals North America, Inc. Javier Gonzalez is an advisory board member for Takeda Pharmaceuticals North America, Inc., Bayer Healthcare, Abbott Pharmaceuticals, and AstraZeneca Pharmaceuticals.

The following authors disclose no potential bias or conflict of interest related to this article: Thomas C. Fenter, Helen Lee, Sonya J. Lewis, Mark Noga, and Charles Stemple.

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# Introduction:

## Current Issues and Trends in Medicare Part D

Medicare was established in 1965 as a social insurance program to provide health coverage for persons aged 65 years and older, regardless of income or medical history. In 1972, it was expanded to include coverage of those aged younger than 65 years who have permanent disabilities. As of 2007, Medicare provides health insurance coverage to nearly 44 million people: approximately 37 million seniors and an additional 7 million people aged younger than 65 years who have permanent disabilities.<sup>1</sup> Prior to 2003, Medicare consisted of 3 parts: Part A, designed to cover hospital and other inpatient and home care costs; Part B, which covers physician, outpatient, and preventive services; and Part C, or Medicare Plus Choice, which provided financing for beneficiaries to enroll in private health plans, such as health maintenance organizations (HMOs), preferred provider organizations (PPOs), or private fee-for-service (PFFS) plans.

The Medicare Modernization Act of 2003 (MMA) established Part D, the Medicare Prescription Drug Benefit that was launched in 2006, replacing a temporary prescription drug discount card program. Constituting the biggest change in the Medicare system since it was initiated in 1965, Medicare Part D offers beneficiaries the opportunity to remain in traditional Medicare with the drug benefit being offered through a freestanding prescription drug plan (PDP) or to enroll in one of several types of Medicare Advantage prescription drug (MA-PD) plans that integrate all Medicare benefits including prescription drugs.<sup>2</sup>

The Medicare Part D benefit provides prescription drug coverage for more than 24 million Medicare beneficiaries. Administering such a large and complex program, one that ensures its beneficiaries have access to high-quality care while maintaining control of costs, presents numerous challenges. There are many players that contribute to the success (and potential failure) of the Part D benefit, and each is driven by interests that may or may not align with those of the overall program: the Centers for Medicare & Medicaid Services (CMS) are responsible for providing the best possible care for Part D beneficiaries in an

environment where health care costs nationwide are spiraling nearly out of control; the sponsors of the Part D plans share CMS' goal to provide the best care for beneficiaries, but they are also responsible for managing their costs; the providers, including prescribers and pharmacists, are trying to balance the provision of care with increasing demands on their time and resources; and, finally, the beneficiaries themselves are seeking to access the best combination of products and services to meet their needs at a price that they can afford.

Medicare Part D presents both challenges and opportunities to a health care system that is continuously evolving. Among the issues and strategies at the forefront of that evolution and which will be discussed in this supplement are:

- Medication Therapy Management Strategies
- Pay-for-Performance Initiatives
- Electronic Health Records and Health Care Information Technologies
- The Growth of Special Needs Plans
- CMS Oversight of Part D Plans
- The Future of Part D

This publication is not intended to be an exhaustive review of the Medicare Modernization Act but is intended to provide a snapshot of the key issues and trends that promise to shape Part D as it enters its third year. It is based on presentations and discussions from a Part D Summit, which was sponsored by Takeda Pharmaceuticals North America, Inc., and was conducted in December 2007. The summit meeting was attended by leading medical directors and pharmacy directors who are at the forefront of the implementation of these programs at the plan level.

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# Overview of Current Medicare Part D Offerings

Chris R. Cammisa, MD; Steven Evans, MD; Thomas C. Fenter, MD; Javier Gonzalez, PharmD; Helen Lee, PharmD, MBA; Sonya J. Lewis, RPh, MBA; Mark Noga, PharmD, RPh, CGP; and Charles Stemple, DO, MBA

## ABSTRACT

**BACKGROUND:** Since its initiation in 2006, the Medicare Part D drug benefit has resulted in the development of hundreds of privately sponsored drug benefit plans. The evolution of these plans and of the requirements of the Medicare Modernization Act of 2003 (MMA) requires ongoing analysis and evaluation by managed care organizations who have a stake in the success of the drug benefit.

**OBJECTIVE:** To review the current state of plan offerings and highlight recent trends in the design of plans and benefits.

**SUMMARY:** There has been significant growth and change in the number and characteristics of the drug benefit plans available under Medicare Part D since 2006. More than two thirds of beneficiaries currently are enrolled in stand-alone prescription drug plans (PDPs), with increasing numbers moving into Medicare Advantage prescription drug (MA-PD) plans. Although the majority of plans charge tiered flat copayments for drugs, an increasing number are beginning to charge coinsurance for drugs in specialty tiers. Across the United States, the monthly beneficiary premium for Part D coverage is expected to average \$27.93 in 2008. As in 2007, just over one quarter of plans offer some form of gap coverage in 2008. Following the large-scale marketing efforts at the initiation of the Part D benefit, plans currently appear to be less focused on marketing their offerings to potential beneficiaries.

**CONCLUSION:** Although there has been some stabilization among the benefits that are being offered by Part D plans, there continues to be a substantial amount of evolution in the Part D marketplace. Both the PDP and MA-PD markets expanded in 2007, as established plans continued to refine and increase their benefit offerings and new plans entered the market.

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## Plan Availability

Since the initiation of the Medicare Part D drug benefit in 2006, there has been a significant amount of evolution in the type and number of plans that are available to beneficiaries. In 2008, across the 34 prescription drug plan (PDP) regions, a total of 1,824 PDPs will be offered, approximately the same number of plans that were available in 2007.<sup>1</sup> Moreover, beneficiaries in most states choose from among at least 50 stand-alone PDPs and multiple Medicare Advantage prescription drug (MA-PD) plans.<sup>1</sup>

At the same time, the availability of MA-PD plans has continued to grow, with at least 1 MA plan available to 98% of all beneficiaries as of 2007.<sup>2</sup> MA-PD plans are health maintenance organizations (HMOs), preferred provider organizations (PPOs), and private fee-for-service (PFFS) plans that provide a wide range of benefits, including, but not limited to, Medicare-covered services and the prescription drug benefit. The availability of MA plans has increased in recent years as a result of the higher payments from the Centers for Medicare & Medicaid Services (CMS) for services from these plans, which are set according to local cost benchmarks. The benchmarks allow plans to underbid for service contracts, with 75% of the savings returned to beneficiaries in the form of enhanced services or reduced premiums.<sup>3</sup>

In addition, there have been dramatic changes in the availability of offerings in other sectors, with significantly more choices in terms of PFFS plans and the introduction of the first Medical Saving Account (MSA)-type choices.<sup>2</sup>

## Enrollment Trends

The continuing change in the number of plan offerings is also reflected in the evolving trends in beneficiary enrollment. As of January 2008, the U.S. Department of Health and Human Services (HHS) reported that 25.4 million (57%) Medicare beneficiaries were enrolled in Medicare Part D plans. Of those, more than two thirds (17.4 million) are enrolled in PDPs, with the remaining 8 million receiving drug coverage through MA-PD plans (Figure).<sup>1</sup>

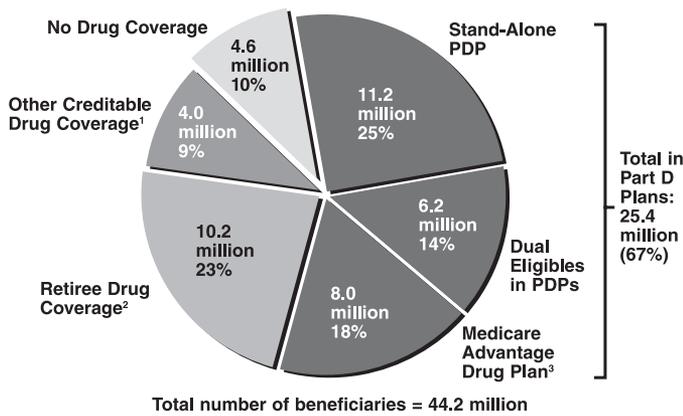
In 2008, 18% (8 million) Medicare enrollees received their benefits through Medicare Advantage plans, a substantial increase from the 5.3 million enrollees in such plans in 2003.<sup>1</sup> As payments to MA-PD plans have increased, enrollees have gravitated toward the enhanced offerings and lower premiums available from these plans.

PFFS plans are the fastest growing type of MA plan. Between 2006 and 2007, the share of beneficiaries with access to a PFFS plan increased from 78% to 97% nationwide.<sup>2</sup> As of early 2007, 86% of Medicare beneficiaries have a choice of at least 3 PFFS plans; 52% can choose from at least 6 PFFS plans.<sup>2</sup> Enrollment in PFFS plans increased 9-fold between March 2005 and November 2006, accounting for 39% of the growth in MA enrollment in

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**FIGURE** HHS Estimates of Prescription Drug Coverage Among Medicare Beneficiaries, 2008



Note: Estimates do not sum to 100% due to rounding

<sup>1</sup>Includes Veterans Affairs, Indian Health Service, state pharmacy assistance programs, employer plans for active workers, Medigap, multiple sources, and other sources.

<sup>2</sup>Includes Retiree Drug Subsidy (RDS) coverage; retiree coverage without RDS; and FEHBP and TRICARE retiree coverage.

<sup>3</sup>Includes 0.4 million enrolled in other Medicare health plan types.

*The Medicare Prescription Drug Benefit—An Updated Fact Sheet (#7044-08), The Henry J. Kaiser Family Foundation, February 2008.<sup>1</sup> This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, private operating foundation focusing on the major health care issues facing the nation and is not associated with Kaiser Permanente or Kaiser Industries.*

FEHBP=Federal Employees Health Benefits Program; HHS=U.S. Department of Health and Human Services; PDP=prescription drug plan; TRICARE=Department of Defense health system.

that period.<sup>2</sup> Furthermore, enrollment in PFFS plans more than doubled between July 2006 and June 2007, from approximately 765,000 to 1.65 million enrollees.<sup>3</sup>

### Benefit and Premium Design

In 2008, most PDPs (88%) have eliminated the standard drug benefit. The majority (approximately 60%) have no deductible and charge tiered copayments for covered drugs rather than a 25% coinsurance.<sup>1</sup> Since 2006, the most common design uses 3 cost-sharing tiers: (1) for generics, (2) for preferred brand-name drugs, and (3) for nonpreferred drugs.<sup>4</sup> Use of this plan structure has increased since 2006 (from 69% to 74% of plans). In addition to the standard 3 tiers, most plans also offer a specialty tier to cover injectable medications; in 2008, 87% of PDPs have a specialty tier (up from 54% in 2006).<sup>4</sup> A few plans are offering a new plan design for 2008 that designates an additional tier for “value” generic drugs that is positioned below the standard generic tier.<sup>4</sup>

While the majority of PDPs (68%) charge flat dollar copayments for drug costs, the number of plans charging some coinsurance has doubled, from 4 in 2006 to 9 in 2008.<sup>4</sup> Compared

with flat copayments, coinsurance provides plans with greater assurance that, as drug prices rise, enrollee contributions will increase accordingly.<sup>4</sup> Regardless of copayment type, the average cost-sharing for a 30-day supply of nonpreferred drugs has increased 29% between 2006 and 2008 (from \$55.36 to \$71.31), while average cost-sharing for preferred brand-name drugs has increased 11% (from \$26.87 in 2006 to \$29.86 in 2008).<sup>4</sup> As a result, enrollees have to face higher out-of-pocket costs for both preferred and nonpreferred drugs, giving them incentives to switch to lower cost options. Although actual premiums vary across plans and geographic regions, according to the national average bid, the monthly premium for Part D coverage is expected to average \$27.93 in 2008.<sup>1</sup>

As noted, MA-PD plans bid separately for Medicare Part A and Part B services and the Part D drug benefit. Savings that are generated by beating the CMS-established benchmark for Part A and Part B services are shared with beneficiaries, frequently by reducing or eliminating premiums for Part D coverage. This allows MA-PDs to offer lower premiums and better drug coverage than stand-alone PDPs.<sup>3</sup>

PFFS plans pay providers on a fee-for-service basis and work with all providers willing to accept their payment rates. The fee-for-service structure results in better reimbursement for health plans, which is why the availability of these plans is increasing. In a PFFS plan, enrollees are not restricted in terms of the providers that they can use. However, providers may limit their availability to see beneficiaries in such plans. Although payment rates are not required to equal those of Medicare, CMS must consider that the rate will permit adequate access to providers.<sup>2</sup>

### Trends in Gap Coverage

In 2008, roughly the same proportion of PDPs (29%, or 529 plans) provide some gap coverage compared with what was available in 2007.<sup>5</sup> However, the scope of coverage for generic drugs is becoming more limited, with approximately half of PDPs that offer gap coverage in 2008 covering only preferred or some generic drugs.<sup>5</sup> Importantly, the premiums for PDPs that provide gap coverage are approximately double those for plans that do not offer gap coverage in 2008 (\$63.29 for PDPs with some gap coverage vs. \$30.14 for PDPs with basic benefits and no gap coverage).<sup>5</sup>

Although the number of MA-PD plans that offer some gap coverage is growing, most do not cover brand-name drugs in the gap. The proportion of MA-PD plans offering gap coverage has increased from 28% (369 plans) in 2006 to 51% (964 plans) in 2008. This increase is primarily among those plans that cover all generics and “some” brand-name drugs in the gap.<sup>5</sup>

MA-PD plans have greater incentives than PDPs to offer gap coverage, since they provide coverage for the full set of Medicare services. As such, they have more incentive to prevent the negative outcomes (and increased costs) that are potentially associated with enrollees who fail to refill their prescriptions when they reach the coverage gap.<sup>5</sup> The ability of MA-PDs to provide

gap coverage is enhanced by the revenues paid to them by the federal government for the provision of other Medicare services, which enables plans to cross-subsidize their prescription drug coverage.<sup>5</sup> To encourage enrollment by beneficiaries, many PDPs are changing their benefits design by reducing or waiving the standard \$275 deductible. Many are also opting to eliminate the standard Part D benefit for drugs (25% coinsurance) by offering beneficiaries tiered flat-dollar copayments.<sup>4</sup>

### Drug Utilization

Since its inception, Medicare Part D has achieved a relatively high level of generic drug use. Increased use of generic drugs in place of brand-name compounds is one of the tools that Part D has used to minimize costs to beneficiaries and maintain affordable coverage. Because generic drugs as a category are on average 71% less expensive compared with brand-name drugs (2007 data),<sup>6</sup> a higher rate of generic substitution for brand-name drugs can have a significant impact on overall drug costs. In fact, the cost of the Part D prescription drug program for 2006 was lower than originally estimated (\$59 billion), which, in part, was due to greater than expected use of generic drugs.<sup>7</sup> Also, the use of generic drugs has led to a reduction in the estimates of the future cost of the Part D prescription drug program.<sup>8</sup>

### Generic Utilization Rates

According to data from the Office of the Inspector General (OIG), about 56% of all drugs dispensed under Part D in the first half of 2006 were for generic medications.<sup>7</sup> The rates of generic drug use varied widely across Part D plans, ranging from 37% to 83% of drugs across all prescriptions.<sup>7</sup>

Generic drug use is measured by the frequency of generic drug substitution at the pharmacy counter, as well as the prescribing of drugs that do not have generic equivalents (single-source drugs). This study also considered the overall utilization rate of generic drugs based on the percentage of generic drugs that were dispensed for multi-source drugs (i.e., generics and branded agents with generic equivalents).<sup>7</sup> In general, the OIG found that generic substitution rates were similar across Part D plans, between MA-PDs and PDPs, and across specific types of MA-PDs. However, there was wide variation in generic drug substitution rates within specific therapeutic classes. Among the top 10 therapeutic classes of drugs, 8 had a difference of at least 50 percentage points between the lowest and highest generic substitution rates. These classes were: thyroid preparations, anti-coagulants, lipotropics, diabetes therapies, cardiovascular preparations, psychostimulants/antidepressants, narcotic analgesics, and antiulcer/gastrointestinal preparations.<sup>7</sup>

As drug costs continue to rise, Part D beneficiaries are bearing a greater financial burden through increased cost-sharing. For beneficiaries enrolled in a PDP, the average copayments for preferred and nonpreferred brands were \$29.36 and \$63.31, respectively, and these copayments were higher than those of employer

plans, which had average copays of \$25 for preferred brands and \$43 for nonpreferred brands.<sup>4</sup> The differences in average cost-sharing between generics and preferred brands were higher for PDP beneficiaries (\$25), compared with employer-plan enrollees (\$11). This was also true for the differences paid for preferred versus nonpreferred brands, with average cost-sharing of \$34 for PDPs and \$18 for employer plans. Thus, PDPs have a greater financial incentive for switching to generic drugs.<sup>4</sup>

There are some drug classes that were excluded from Medicare Part D, almost all of which are generic, including the benzodiazepines and barbiturates. Other excluded drugs include agents used for cosmetic purposes, drugs used to treat cold symptoms, and prescription vitamin and mineral preparations.<sup>9</sup>

### Plan Marketing Efforts

The marketing of Medicare Part D prescription drug plans appears to be at an uncertain juncture, following the intense marketing push at the start of the Part D program. Although marketing of the first Part D plan offerings was successful in attracting enrollees during the initial open enrollment period in 2005–2006, it is not clear to what degree sponsors will continue to invest in the marketing of newer offerings as they develop.

There are some insights from beneficiaries in 4 states (Maryland, Nebraska, Florida, and California), who took part in a survey commissioned by the Kaiser Family Foundation. This survey monitored the experiences of 35 beneficiaries in Medicare Part D and consisted of 4 rounds of interviews, with the first one held in October/November 2005, and follow-ups conducted in March 2006, October 2006, and September/October 2007.<sup>10</sup> In the final report, the experiences of 17 Medicare Part D enrollees were provided. The report noted that after the deluge of direct mail and other information from Part D plans during that first open enrollment period, there has been a dramatic decline in marketing efforts from plans. Furthermore, beneficiaries note that they do not pay much attention to the materials they receive from the plans or from Medicare.<sup>10</sup> Among those beneficiaries surveyed during the open enrollment season for 2008, most participants were not planning to reassess their plan options. In fact, most were generally reluctant to switch plans, and some respondents were adamantly opposed to doing so. The reasons for this reluctance included satisfaction with their current plan, fear that any plan they switch to may be worse than what they currently have, and the stress of revisiting the complex process of choosing a plan.<sup>10</sup>

Today, marketing efforts seem to be shifting toward member retention by focusing on improvements in benefit design and member services, the qualities that are most apparent to their current members.

### Conclusions

Since its inception, the Medicare Part D drug benefit has continued to evolve in terms of the benefits and services offered to

beneficiaries. This evolution in the number of MA-PD plan offerings is part of plans' efforts to remain competitive in this changing landscape.

One of the more dramatic changes has been the increased availability of PFFS plans and the emergence of MSAs. Part D plans have also changed their benefits structure and premium design to encourage enrollment. In 2008, most plans have eliminated the standard drug benefit, with 60% having no deductible and charging tiered copayments for covered drugs rather than coinsurance.

The implementation of Medicare Part D has also resulted in a relatively high level of generic drug utilization in an effort to minimize costs to beneficiaries and maintain affordable coverage. This strategy is also responsible for a predicted reduction in future drug costs under Medicare Part D.

The proportion of PDPs offering gap coverage in 2008 is similar to those providing such coverage in 2007. However, coverage for generic drugs is more limited, with approximately half of PDPs only covering preferred or some generic drugs. Importantly, the 2008 premiums for PDPs that provide gap coverage are approximately double the premiums for plans not offering gap coverage. While MA-PD plans have greater incentives to offer gap coverage, most do not cover brand name drugs in the gap.

Initially, plans employed aggressive marketing strategies for enrolling beneficiaries, including direct mail. However, as the market changes, plans have placed a greater focus on member retention (i.e., through improvements in benefit design and member services). With these improvements, plans are hoping to increase member satisfaction, improve the overall health of members, and provide quality, cost-effective care.

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# Medication Therapy Management

Javier Gonzalez, PharmD, and Mark Noga, PharmD, RPh, CGP

## ABSTRACT

**BACKGROUND:** A key to efforts in controlling Medicare Part D costs is helping beneficiaries use medications more effectively (i.e., improve patient adherence and reduce adverse drug events). As such, the Medicare Modernization Act (MMA) requires Part D prescription drug plans to establish medication therapy management (MTM) programs. These programs employ pharmacists or other qualified providers to provide counseling and other services to enrollees who have high drug costs due to multiple medications for treating multiple chronic conditions.

**OBJECTIVE:** To review current MTM programs in Part D plans and to provide an overview of the key role that pharmacists play in implementing these programs.

**SUMMARY:** MTM programs are an important part of the MMA's strategy to manage increasing medication costs among Part D beneficiaries. There is a potential to identify additional beneficiaries who qualify for these programs, thus improving the quality of life, cost-effectiveness, and appropriate drug utilization for more enrollees. The approval of permanent Current Procedural Terminology (CPT) codes for MTM services will make it easier for pharmacists to bill for these benefits. A survey published by the Agency for Healthcare Research and Quality (AHRQ) has evaluated the MTM services currently being offered by Part D plans. The services that were most frequently offered included patient education (75% of programs), promoting adherence (70%), and medication review (60%). There is an obvious need for plans to measure therapeutic outcomes with their MTM programs to document the effectiveness of these programs. Although this measurement is not yet required by the Centers for Medicare & Medicaid Services (CMS), it is in the plans' interest to benchmark their MTM programs and determine whether the expense of designing and implementing such programs is justified by improvements in outcomes among beneficiaries.

**CONCLUSIONS:** MTM programs are an increasingly important part of ensuring that Part D plans are providing optimal therapeutic benefit for beneficiaries while managing costs. As such, plans need to consider both how they identify eligible enrollees and how they can target those who are most likely to benefit from MTM. In addition, clear, measurable goals for MTM programs must be established to demonstrate their cost-effectiveness.

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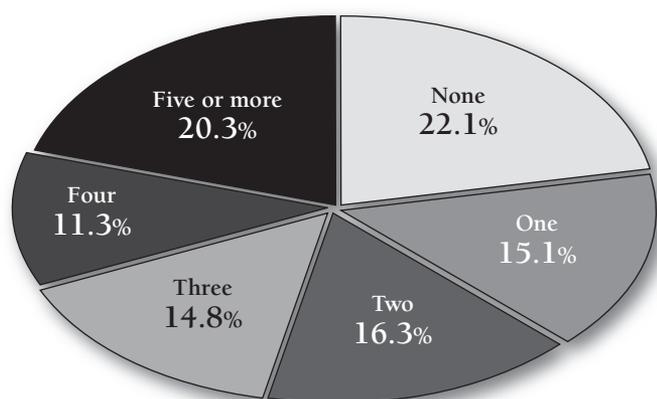
## Introduction

The Medicare Modernization Act (MMA) was initiated to help Medicare beneficiaries afford the increasing cost of prescription drugs by subsidizing drug costs through stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans. A key part of the MMA's strategy for managing the increases in medication costs includes the use of medication therapy management (MTM) programs that employ the services of pharmacists and other health care professionals to help ensure appropriate and cost-effective drug use among beneficiaries. The MMA requires Part D prescription drug plans to operate cost-effective MTM programs that provide counseling and other assistance to enrollees who have multiple chronic diseases (e.g., diabetes, asthma, hyperlipidemia, and congestive heart failure), who use multiple medications, and who incur high drug costs. MTM programs, which are broadly defined by the Centers for Medicare & Medicaid Services (CMS), can include a variety of methods (e.g., mailed letters, telephone conversations, face-to-face interactions) that promote better understanding of appropriate medication use, improved adherence to therapy, and the reduction of adverse events, all with the goal to improve the overall quality of medication use. These programs are funded according to a negotiated contract between drug plans (MA-PDs or PDPs) and CMS.

## Which Beneficiaries Qualify for MTM?

Beneficiaries that qualify for MTM services are individuals with multiple chronic diseases taking multiple medications, and who are consequently likely to incur annual Part D drug costs in excess of a standard amount specified by the Secretary of Health and Human Services. Data from the 2002-2003 Medical Expenditure Panel Survey (MEPS) indicate that beneficiaries aged 65 years and older who met the expenditure threshold (adjusted to \$3,810 in 2003 dollars) report an average of 11 unique medications, 82 prescriptions, and 5 chronic conditions.<sup>1</sup> Approximately 9.2% of adults aged 65 years or older met the expenditure threshold. Women made up a higher percentage of the group that met the threshold compared with those that did not. The factors that predicted meeting the expenditure threshold included age, requiring help with daily activities, having functional limitations, receiving military health care services, and being a Medicaid beneficiary.<sup>1</sup> Additional factors that predicted meeting the threshold included having mental health disorders, ulcers, diabetes, dyslipidemia, cardiac disease, chronic obstructive pulmonary disease (COPD), and the number of chronic conditions. Among older adults meeting the expenditure threshold, more than 60% reported 5 or more chronic conditions, while those who reported between 1 and 3 chronic conditions did not meet the threshold.<sup>1</sup> Investigators noted that 97% of the older adults who exceeded the expenditure threshold had 2 or more chronic diseases, while all had filled at least 3 unique prescriptions during the year.<sup>1</sup>

**FIGURE** Percent of Medicare Beneficiaries With Varying Numbers of Chronic Conditions, 1999



Permission to reprint figure from the National Health Policy Forum. Super N. Medicare's Chronic Care Improvement Pilot Program: What Is Its Potential? NHPF Issue Brief, No. 797; May 10, 2004.<sup>3</sup>

Recently, the Academy of Managed Care Pharmacy (AMCP) sponsored a study to assess and validate the *Sound Medication Therapy Management Programs*, version 1.0.<sup>2</sup> Field studies conducted by the National Committee for Quality Assurance (NCQA) reported for 13 PDP and 18 MA-PD MTM programs that beneficiaries selected for inclusion into the program had on average 2.6 chronic conditions, 5.6 medications, and annual drug expenditures  $\geq$ \$4,000.<sup>2</sup> Among the PDP and MA-PD plan members in this study, on average, only 11% (range 3%–27%) qualified for MTM programs according to CMS reportable criteria.<sup>2</sup>

Thus, opportunities to better identify patients who may benefit from MTM programs represent a challenge to plan sponsors. More than 60% of Medicare beneficiaries are afflicted with 2 or more chronic conditions and may benefit from MTM initiatives (Figure).<sup>3</sup>

In the authors' opinions, (a) expanding the population eligible for MTM programs at various levels of intensity could improve quality of life, cost-effectiveness, and appropriate utilization of medication therapies for these beneficiaries, which could have a positive effect on lowering overall medical utilization for plan sponsors, and (b) the CMS may place additional requirements on plan sponsors to extend MTM program eligibility as a mechanism to increase quality and encourage more appropriate cost-effective management initiatives to help mitigate rising health care costs in Medicare.

### The Role of Pharmacists in MTM

The implications of MTM for pharmacists and pharmacy practice are significant, providing an opportunity for an increasing role for

pharmacists in direct patient care. With their knowledge of pharmacotherapy, as well as a thorough understanding of insurance coverage and pharmacy benefit design, pharmacists are ideally suited to provide MTM services. The convenience and accessibility of being able to talk to a pharmacist about drug therapy are important benefits of pharmacist-provided MTM.<sup>4</sup> In addition, there is increasing evidence that MTM services provided by pharmacists can improve medication adherence and clinical outcomes.<sup>4,5</sup> For example, the Asheville Project demonstrated improvements in both clinical outcomes and patient-reported adherence to American Diabetes Association-recommended behaviors among patients with diabetes who received ongoing consultations with community-based pharmacists.<sup>5</sup>

One challenge that pharmacists have faced relative to this evolving role is how they are able to bill for the patient care services they provide. Toward that end, in 2005, 3 Current Procedural Terminology (CPT) codes for pharmacists were made available to bill third-party payers for face-to-face MTM services (Table).<sup>6,7</sup> Initially introduced as temporary codes to allow the profession time to demonstrate their therapeutic value, new

**TABLE** CPT Codes for MTM Payments

MTM includes the following documented elements, as stated in guidelines established by the Pharmacist Services Technical Advisory Coalition (PSTAC), an organization that was founded to support billing for pharmacists' professional services:

- Review of the pertinent patient history
- Medication profile (prescription and nonprescription)
- Recommendations for improving health outcomes and treatment compliance

Additional information is also available on the coalition's website at: <http://www.pstac.org/>.

The codes are not to be used to describe the provision of product-specific information at the point of dispensing or any other routine dispensing-related activities.

Temporary Code	Permanent Code	Description
0115T	99605	Initial 15 minutes of medication therapy management service(s), including assessment and intervention if appropriate; for a new patient
0116T	99606	Initial 15 minutes of medication therapy management service(s), including assessment and intervention if appropriate; for an established patient
0117T	99607	Each additional 15 minutes; used in addition to 99605 or 99606

Adapted from Thompson CA. *Am J Health-Syst Pharm.* 2007; 64:2410-12 and the Pharmacist Services Technical Advisory Coalition. Available at: [www.pstac.org/services/mtms-codes.html](http://www.pstac.org/services/mtms-codes.html).<sup>6,7</sup>

CPT = Current Procedural Terminology; MTM = medication therapy management.

permanent codes were introduced in late 2007 for use starting on January 1, 2008. The codes were upgraded to permanent status based largely on the recognition that many pharmacists are providing MTM services. However, pharmacists can only use these CPT codes to bill payers according to criteria established by the health plan, and these criteria can vary considerably among individual plans. The next step in the process will be to establish payment rates for these services.

### **MTM Programs in Medicare Part D: A Survey**

A useful picture of the breadth of MTM programs recently being offered by Part D prescription drug plans is available from a survey of MTM programs published by the Agency for Healthcare Research and Quality (AHRQ) in early 2007. Data were obtained for 70 health insurance plans, representing 50 different PDPs and 221 MA-PDs that cover at least 12.1 million Medicare enrollees.<sup>8</sup>

### **MTM Enrollment Criteria**

With 1 exception, nearly all of the 20 MTM programs included in the survey imposed restrictions on beneficiary eligibility. These 19 programs represent 90.5% of the MTM programs surveyed and account for roughly 11.2 million enrollees.<sup>8</sup>

Among the 19 MTM programs with eligibility restrictions, all restrict enrollment to individuals with a predefined number of diseases, with a median number (range) of disease states of 3 (2 to 5).<sup>8</sup> In addition, many MTM programs limit enrollment to patients with specific chronic diseases. Twelve MTM programs in the survey (57.1%, representing 4.0 million enrollees) restrict services on this basis, while 8 of the programs specify only that the conditions be chronic.<sup>8</sup> The diseases most commonly included in the restrictions were diabetes mellitus (12 programs), congestive heart failure (10 programs), asthma (8 programs), hypertension (8 programs), and hyperlipidemia (8 programs).<sup>8</sup>

According to the MMA, MTM services should be offered to Medicare beneficiaries whose annual Part D drug expense exceeds a dollar amount specified by the Secretary of Health and Human Services, which in 2006 was \$4,000.<sup>8</sup> Nearly all the programs surveyed (95.2%) required beneficiaries to meet a spending threshold before being offered enrollment in an MTM. They also required that a patient fill a certain number of prescriptions for chronic medications (median number of medications=6) in order to qualify for enrollment.<sup>8</sup> A challenge these programs face is getting support from chain pharmacies, some of which may consider MTM a challenge to implement given resource demands associated with achieving maximum efficiency in prescription dispensing.

### **MTM Benefit Design**

In addition to differences in enrollment criteria among the MTM programs, there were also notable differences in the services offered to beneficiaries, both between and within individual MTM programs. Six MTM programs (28.6%) offered a tiered

MTM service benefit, while 15 programs (71.4%) provided the same services to all eligible enrollees.<sup>8</sup>

The services that were offered most frequently included patient education (75% of programs), patient adherence (70%), and medication review (60%). In programs with tiered benefits, some services may be offered only to a subgroup of eligible enrollees, although it was not disclosed in the survey results how these tier assignments were determined.<sup>8</sup>

An important aspect of MTM programs involves how such services are provided to patients. Typically, services can be provided by mail, telephone, or face-to-face interactions with a clinician. As expected, each option provides specific benefits, with mailings being the least expensive option and direct clinician contact likely to be the most effective.<sup>8</sup>

In 75% of the plans surveyed, some or all MTM services were provided by mail. Among the most popular methods for providing services, in-house telephone call centers were used by 90.4% of programs.<sup>8</sup> In contrast, relatively few programs reported the use of in-house case managers or the use of contracted pharmacies. Nineteen percent of programs provided face-to-face services via contract with pharmacies.<sup>8</sup>

The frequency of MTM service provision also varied among the programs. Fourteen percent of programs provided services monthly and another 14% provided them annually. Nearly 25% of the programs did not specify a frequency for providing MTM services, but described their frequency as individualized according to patient need.<sup>8</sup>

Given that the MMA stipulates that MTM may be provided by a pharmacist and developed in cooperation with practicing pharmacists and physicians, it is not surprising that most of the programs (95.2%) employed pharmacists to provide MTM to their beneficiaries. Nearly half the programs (47.6%) also employed nurses, with physicians used by 14.3% of programs.<sup>8</sup>

### **Documenting Outcomes of MTM Programs**

Since MTM programs are aimed at improving therapeutic outcomes for patients, there is an obvious need for plans to measure those outcomes and document the effectiveness of the MTM programs they provide; however, many plans are not yet doing this, or at least have not reported results of their evaluations. According to a survey by the American Pharmacists Association (APhA), numerous plans initially began MTM programs without plans to evaluate their effectiveness.<sup>9</sup> The APhA also convened a task force to look at outcome measures that might be used by plans (as well as CMS) to evaluate MTM programs.<sup>9</sup> The task force made a number of recommendations regarding the development of outcomes research for MTM services. It was recommended that outcomes analyses should include both short-term and long-term measures, as well as metrics to assess the economic impact of MTM services. In addition, there ought to be measures of adherence to established treatment standards and guidelines, monitoring of therapeutic outcomes, and monitoring to determine appro-

appropriate use of medications (e.g., the Beers criteria).<sup>8</sup>

According to data from the AMCP/NCQA study, all 20 programs included in the study report quality measurements that look at all patients eligible or enrolled in MTM programs.<sup>2</sup> In addition, all programs used information technology and extensive pharmacy data to evaluate their own performance, which underscores the value of utilizing pharmacy data.<sup>8</sup> Analytical tools in MTM will serve a critical role in ensuring that MTM programs can remain scalable and efficient since the database analysis requirement is intensive.

Some programs perform quality measurements across their entire populations, while half of the programs reported using Healthcare Effectiveness Data and Information Set (HEDIS) measures.<sup>2</sup> However, the AMCP report notes that quality measurement to date is not yet sufficient across programs to enable comparisons of different programs based on quality or performance.<sup>2</sup> Among their findings was the recommendation that MTM programs measure performance not only among those beneficiaries who are eligible for MTM services, but across the entire populations of their plans. This will make it possible for plans to identify benchmarks among programs and contribute to the establishment of best practices in the field.<sup>2</sup>

### Conclusions

MTM programs, which employ pharmacists and other health care professionals, represent a growing strategy to ensure appropriate and cost-effective drug use to ensure optimal outcomes. Under the MMA, Part D prescription drug plans are required to provide counseling and other assistance to enrollees who have multiple chronic diseases, require multiple medications, and incur high drug costs.

Identifying patients who may best benefit from participation in MTM programs is a challenge for plan sponsors. However, these programs offer beneficiaries an opportunity to improve the quality of life, cost-effectiveness, and appropriate drug utilization, thus reducing their health care utilization and costs to the MA-PD plan sponsors.

The growth of MTM programs also enables pharmacists and pharmacy practices to play a greater role in providing direct patient care. Their knowledge of pharmacotherapy, insurance coverage, and pharmacy benefit design, makes them an ideal choice as MTM service providers.

The eligibility criteria and services offered for MTM programs vary significantly. Eligibility can be based on a predetermined number of chronic diseases or limited to those with specific

chronic diseases. Many MTM programs provide the same services to all eligible enrollees, but others offer a tiered benefit to MTM-eligible enrollees. Additionally, some plans offer MTM services monthly, while others are available only annually.

It is important that plans assess and document the therapeutic outcomes achieved through their MTM programs. Unfortunately, many plans are either not performing this evaluation or not reporting their results, despite an APhA task force's recommendation that plans analyze the economic impact of MTM programs via short-term and long-term outcomes. The task force also recommended measurement of adherence to established treatment standards and guidelines and the monitoring of therapeutic outcomes and adverse drug events.

The establishment of measurable goals will enable both payers and CMS to assess the value of expanding MTM programs across populations. Although they are not yet required to document MTM outcomes, PDPs and MA-PDPs would find these data beneficial in determining whether the return on investment from their MTM programs justifies program design and implementation costs.

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# Pay-for-Performance Initiatives

Thomas C. Fenter, MD, and Sonya J. Lewis, RPh, MBA

## ABSTRACT

**BACKGROUND:** Improving the quality of care provided to beneficiaries while reining in costs, is a key goal for Medicare programs. The emerging pay-for-performance (P4P) movement is a reimbursement strategy that provides incentives to improve the overall quality care provided to patients, which can lead to improved clinical outcomes and reduced health care utilization and costs.

**OBJECTIVE:** To review current P4P initiatives from Medicare as well as the results of select national P4P programs.

**SUMMARY:** P4P strategies are an attempt to link financial incentives to increase efficiency and quality of care, improve clinical outcomes, and provide disincentives for providing care that does not achieve adequate outcomes. The Centers for Medicare & Medicaid Services (CMS) has developed numerous P4P initiatives to support improvements in the care of Medicare beneficiaries. CMS-sponsored initiatives include hospital demonstration projects that focus on a set of 10 quality measures and link reporting of those measures to payments that hospitals receive. In addition, there are demonstration projects aimed at physician group practices and the use of health information technology (IT). Another aspect of P4P is the movement toward nonpayment for nonperformance, which is intended to provide a negative incentive toward preventable complications resulting from medical errors or improper care.

**CONCLUSION:** P4P programs represent an attempt to harness the potential of health care payment structures to motivate quality-enhancing and cost-saving changes in the behavior of physicians, pharmacists, and other health care professionals, as well as in the health care systems where they practice.

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## Introduction

Like any large health care provider, The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring that its beneficiaries receive high-quality care. As a result, Medicare has advanced the development and use of quality measures, as well as the standardization of appropriate care guidelines. CMS has developed regulatory standards so that providers are required to have quality improvement systems in place.

In addition to ensuring high-quality care for beneficiaries, CMS is charged with reining in health care costs so that its programs can provide the best care to all eligible beneficiaries. In reality, there continues to be financial disincentives to improving quality of care, which was the basis of traditional Medicare coverage resulting from the fee-for-service payment system. Traditionally, CMS has paid all health care providers without discriminating based on quality of care. As a result, there has been little incentive for providers to improve the quality of care. This has caused an inefficient use of Medicare resources, which perpetuates substandard care for some beneficiaries and does not reward providers who do offer high-quality care. In fact, such an arrangement may even reward poor-quality care by providing additional payments to cover further treatments when patients' initial therapies fail to resolve their problem.

It is in this context that the movement toward P4P programs has emerged. P4P is a reimbursement strategy that links payment to the quality of care provided by clinicians, offering financial incentives for improvements in care, as well as disincentives for care that does not achieve adequate outcomes. An effective P4P program rewards providers for meeting or exceeding care benchmarks and uses these financial incentives to push for increased efficiency in the delivery of health care services to beneficiaries.

## Medicare Pay-for-Performance Initiatives

CMS is developing a set of P4P initiatives to support quality improvement in the care of Medicare beneficiaries. These initiatives include programs for hospitals, physicians, and physician groups. In addition, CMS is exploring potential performance-related programs for nursing home care, as well as for home health care providers. These CMS demonstration projects are intended to assess whether the use of financial incentives can improve the quality of care provided to Medicare beneficiaries.

## Hospital Demonstrations

The *Hospital Quality Initiative* is part of the broader National Quality Initiative that focuses on a set of 10 quality measures and links reporting of those measures to payments that hospitals receive. Nearly all the eligible hospitals are complying with the requirements of this provision. The *Premier Hospital Quality Incentive Demonstration* provides financial incentives for high-quality care and is aimed at improving the quality of inpatient care for Medicare beneficiaries. CMS is collecting data on 34 specific

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clinical measures that relate to 5 clinical conditions, including acute myocardial infarction, coronary artery bypass graft, heart failure, community-acquired pneumonia, and hip and knee replacement.<sup>1</sup> For hospitals that score in the top 10%, this demonstration program will provide a 2% bonus payment on top of the standard diagnostic related group (DRG) payment for relevant discharges.

**Physician and Group Practice Demonstrations**

The first P4P initiative for physicians under the Medicare program, the *Physician Group Practice Demonstration (BIPA 2000)* rewarded physicians for improving the quality and efficiency of health care services for Medicare fee-for-service beneficiaries. It involved 10 large group practices (>200 physicians), which earned performance-based payments as a reward for achieved savings compared with a control group.<sup>2</sup>

The *Medicare Care Management Performance Demonstration (Medicare Modernization Act [MMA] section 649)* is a 3-year P4P demonstration that will promote the use of health IT to improve the care of chronically ill patients. Bonuses will be paid to doctors who “meet or exceed performance standards ... in clinical delivery systems and patient outcomes,” as defined by CMS.<sup>2</sup> This program is focused on small- and medium-sized practices in Arkansas, California, Massachusetts, and Utah. A second 5-year demonstration mandated by MMA section 646 (the *Medicare Health Quality Demonstration*) will examine projects that enhance patient safety and reduce variations in utilization through the use of evidence-based care and best practice guidelines. It will include physician groups and local or regional integrated health systems.<sup>2</sup>

**Disease Management Demonstrations**

CMS has also implemented a number of demonstrations to look at the management of patients with chronic complex disease states, such as congestive heart failure, diabetes, end-stage renal disease, or coronary artery disease. The *Chronic Care Improvement Program (MMA section 721)* is a pilot program to evaluate disease management programs aimed at particular patient populations (i.e., those with congestive heart failure and/or complex diabetes) and will include companies specializing in disease management, as well as larger organizations such as insurance companies. Participating organizations are required to guarantee CMS a savings of at least 5% plus the cost of monthly fees compared with a similar population of beneficiaries. Additional disease management demonstrations include programs aimed at patients with end-stage renal disease, those with severe chronic illnesses, and chronically ill dual beneficiaries.<sup>2</sup>

**Results from National Pay-for-Performance Projects**

A number of provider groups across the United States have been reporting results from their P4P initiatives. These results represent the broad applicability of P4P programs as a means of improving the quality of care that beneficiaries receive.

Now in several markets around the United States, Bridges to Excellence (BTE) is the largest employer-sponsored P4P initiative that rewards physicians for meeting specific quality benchmarks. Through its P4P program, BTE has found that physicians who are rewarded for providing high-quality care are able to deliver that care at costs that are 15% to 20% lower than physicians who do not participate in such programs. BTE notes that while financial incentives can influence physician practices, it is necessary for the reward to be large enough to have an effect.<sup>3</sup>

The Integrated Healthcare Association (IHA) is a California-based coalition of health plans, physicians, health care systems, purchasers, and consumers that has issued a public scorecard that compares the performance of physician groups. These efforts have led to across-the-board improvements in every quality measure they use. In some plans, this has resulted in a 40% increase in patient visits and reduced hospitalizations, with particular improvements among patients with diabetes.<sup>3</sup> As with many such initiatives, the innovative use of technology has proven to be a key to the program’s success, demonstrating a direct correlation between the use of tracking technology and improvements in care quality. In fact, physician groups who adopted IT to track outcomes had average clinical scores that were 9 percentage points higher than physician groups that did not (60% vs. 69%).<sup>4</sup>

**TABLE** Conditions for Which Medicare Will No Longer Pay More If Acquired During an Inpatient Stay<sup>a</sup>

Condition	No. of Medicare Cases in Fiscal Year 2006	Average Medicare Payment for Admission in Which Condition Was Present
Object left in patient during surgery	764	\$61,962
Air embolism	45	\$66,007
Blood incompatibility	33	\$46,492
Catheter-associated urinary tract infection	11,780	\$40,347
Pressure ulcer	322,946	\$40,381
Vascular catheter-associated infection <sup>b</sup>	Unknown	Unknown
Mediastinitis after coronary artery bypass grafting	108	\$304,747
Fall from bed	2,591	\$24,962

<sup>a</sup> Data taken from the Federal Register.

<sup>b</sup> Data unknown due to a unique code for this condition, which was introduced for fiscal year 2008.

Rosenthal MB. *N Engl J Med.* 2007;357(16):1573-75.<sup>5</sup> Copyright © 2007 Massachusetts Medical Society.

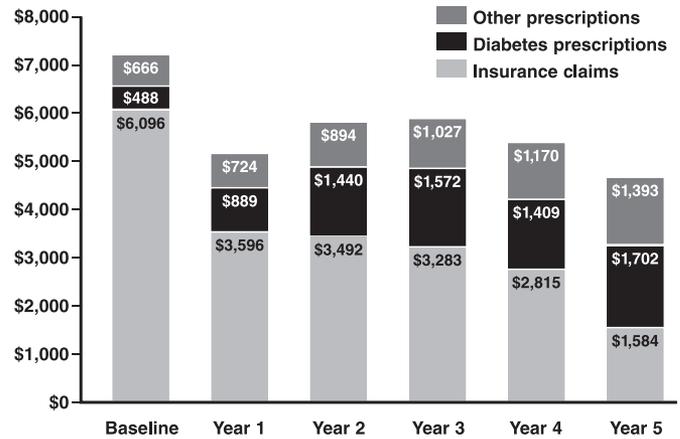
**Nonpayment for Nonperformance**

The other side of P4P as an incentive for improvements in quality of care is the movement toward nonpayment for nonperformance. Intended as an antidote to the counterproductive incentives built into health care reimbursement, nonpayment for nonperformance provides a negative incentive against preventable complications that sometimes result from medical errors or improper care.<sup>5</sup>

As a result of evaluating conditions that are high cost and/or high volume and which have until now resulted in a higher payment as a secondary diagnosis, CMS has identified 8 conditions for which Medicare will no longer pay if they are acquired during an inpatient stay (Table).<sup>5</sup>

Although the change in payment for these preventable secondary conditions will not result in large amounts of money being withheld from hospitals, the new rule is expected to have a disproportionate effect on hospital behavior, since it is viewed as an indication of things to come as CMS continues to reform provider payment toward an increasingly P4P model.<sup>5</sup>

**FIGURE** Direct Medical Costs Over Time: The Asheville Project



Cranor CW, et al. *J Am Pharm Assoc.* 2003;43(2):173-84.<sup>6</sup> Copyright American Pharmacists Association (APhA). Reprinted by permission of APhA.

**The Asheville Project**

An important precursor of other P4P programs, the Asheville Project, was a longitudinal cohort study designed to evaluate the maintenance of outcomes for up to 5 years following the initiation of community-based pharmaceutical care services (PCS) for patients with diabetes. It included an examination of how long-term PCS impacts direct medical costs.<sup>6</sup>

The study included patients with diabetes who were covered by 1 of 2 employer-funded health care plans. Patients were offered a health care benefit that consisted of consultation with a community-based pharmacist with whom they could meet (at no cost). Pharmacists provided diabetes education, helped establish and track treatment goals, and offered training for in-home blood glucose monitoring, as well as information about adherence.<sup>6</sup> They also evaluated patients' feet, skin, blood pressure, and weight. In addition, an important component of the intervention included the pharmacist's referral of patients to their physicians or a diabetes education center as needed. Patients were provided with a free home blood glucose monitor and had their copayments for diabetes-specific drugs and supplies waived.<sup>6</sup>

The investigators evaluated the economic outcomes of

the PCS project by monitoring the change in direct medical costs during the study. According to analyses of insurance and prescription claims, the mean total amount paid for all diagnoses decreased with each year of follow-up (Figure). This was accounted for by shifting costs from insurance claims for emergency department, inpatient, and physician visits to prescription claims.<sup>6</sup> In fact, mean insurance claim costs decreased by \$2,704 per patient per year (PPPY) in the first year and by \$6,502 PPPY in the fifth year. Mean prescription costs increased during the same period by \$656 in the first year and by \$2,188 PPPY in the fifth.<sup>6</sup> Overall, the payers saw decreases in total direct medical costs that ranged from \$1,622 to \$3,356 PPPY.

This demonstration project found that patients with diabetes who received PCS in community pharmacies achieved and maintained clinically significant improvements in hemoglobin A1cs over the length of the study. At the same time, third-party payers benefited from decreases in average total direct medical costs for each year of the study. Based on these results, employers who sponsored the program have adopted it as part of their health plan benefit.

### ■ Conclusions

To ensure that its beneficiaries receive high-quality care, CMS has advanced the development and use of quality measures and appropriate care guidelines. In addition to ensuring high-quality care for beneficiaries, Medicare is charged with controlling health care costs so that its programs can provide the necessary care to all eligible beneficiaries. Traditionally, Medicare has reimbursed its health care providers without discriminating based on quality of care. As a result, there has been little incentive for providers to improve the quality of care. This has caused an inefficient use of Medicare resources, which perpetuates substandard care for some beneficiaries and does not reward providers who do offer high quality care.

P4P is a reimbursement strategy that links payment to the quality of care provided by clinicians, offering financial incentives for improvements in care, as well as disincentives for care that does not achieve adequate outcomes. An effective P4P program rewards providers for meeting or exceeding care benchmarks and uses these financial incentives to push for increased efficiency in the delivery of health care services to beneficiaries.

Based on the success of other performance-based programs (e.g., BTE, the IHA, and the Asheville Project), CMS is currently developing a set of P4P initiatives to assess whether the use of financial incentives can improve the quality of care provided to Medicare beneficiaries. These initiatives include programs for hospitals, physicians, and physician groups. CMS is also exploring potential performance-related programs for nursing home care, as well as for home health care providers.

On the other side of P4P is the movement known as nonpayment for nonperformance. This movement serves as an antidote to the counterproductive incentives built into health care reimbursement by providing a negative incentive against preventable complications resulting from medical errors or improper care. In

fact, CMS has now identified 8 conditions for which Medicare will no longer pay if they are acquired during an inpatient stay.

P4P programs represent an attempt to harness the potential of health care payment structures to motivate quality-enhancing and cost-saving changes in the behavior of physicians, pharmacists, and other health care professionals, as well as in the health care systems where they practice. As such, they rely on the gathering and analysis of quantifiable quality and cost data. The need for data that can lead to objective assessments of P4P initiatives points to the important role that electronic health records may play in furthering the quality and cost-effectiveness of health care services.

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# Electronic Health Records and the Value of Health IT

Steven Evans, MD, and Charles Stemple, DO, MBA

## ABSTRACT

**BACKGROUND:** An important component of improving the quality of care provided to Medicare beneficiaries involves the development of integrated medical records, which provides all of a patient's medical information in 1 easy-to-access location. As a result, electronic collection and reporting of health information has become a key focus of the Centers for Medicare & Medicaid Services (CMS).

**OBJECTIVES:** To explore the potential benefits of electronic health records (EHR) and the use of integrated health information technology (IT) in the provision of quality care to Medicare beneficiaries.

**SUMMARY:** The use of EHR has the potential to lead to improved patient outcomes, increased efficiency, improved communication with payers and hospitals, and improvements in billing and reimbursement. However, the substantial costs of creating EHR systems have limited their adoption at many smaller practices and institutions. According to 1 study, which evaluated the investment required of solo and small physician practices, initial costs averaged \$44,000 per physician with ongoing costs averaging \$8,400 per physician per year. Therefore, it is critical for organizations with limited resources to assess the value of such an investment. As with pay for performance (P4P), CMS is developing a number of demonstration projects to reward the provision of high-quality care that is supported by the use of EHR by physicians. Among the electronic recordkeeping projects being promoted by CMS, electronic prescribing (E-Rx) is perhaps the area that has received the most attention, due, in part, because CMS has proposed standards for E-Rx that are scheduled for implementation as early as 2009.

**CONCLUSIONS:** CMS has identified the electronic collection and reporting of health-related information in the form of EHR as a key to overall efforts to improve the quality, effectiveness, and cost of health care in the Medicare system. With such support from CMS, it is anticipated that the United States will increase the use of health IT as part of the overall focus to improve patient outcomes and efficiencies in health care delivery.

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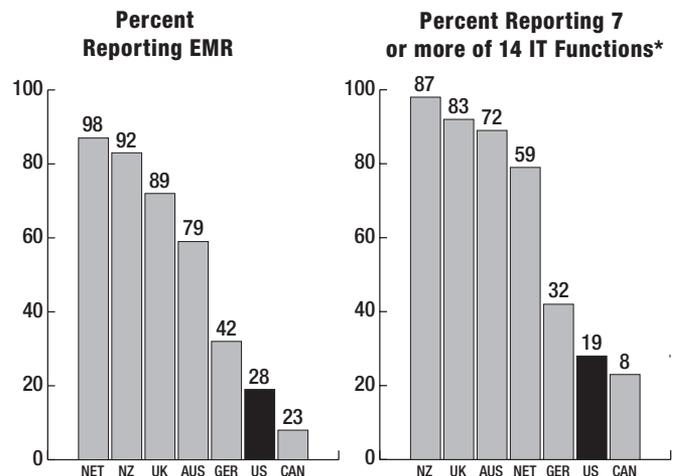
## Introduction

Among the keys to improving the quality of care that is provided to Medicare beneficiaries is the development of an integrated medical record, so that all of the patient's medical information is available in one location and easily accessible to all clinicians providing care to that patient. Therefore, the Centers for Medicare & Medicaid Services (CMS) has identified electronic collection and reporting of health-related information in the form of electronic health records (EHR) as a central objective in the effort to improve the quality, effectiveness, and cost of health care in the United States.

The presumed benefits of EHR are substantial: improved patient outcomes, increased efficiency, improved communication with payers and hospitals, and improvements in billing and reimbursement. However, many practitioners have hesitated to purchase electronic medical record systems because they believe the cost of adopting such systems far outweighs the financial benefits likely to be realized at the local level.<sup>1</sup> Therefore, the United States continues to lag behind other

**FIGURE** Status of Health IT in the United States

**Only 28% of U.S. primary care physicians have electronic medical records (EMRs), and only 19% have advanced IT capacity.**



\*The 14 functions are: EMR, EMR access other doctors, outside office, patient; routine use electronic ordering tests, prescriptions, access test results, access hospital records; computer for reminders, Rx alerts, prompt test results; easy to list diagnosis, medications, patients due for care.

*The Commonwealth Fund. A high performance health system for the United States: an ambitious agenda for the next president. Commission on a High Performance Health System. November 2007. Available at: [www.commonwealthfund.org/usr\\_doc/Ambitious\\_Agenda\\_1075.pdf?section=4039](http://www.commonwealthfund.org/usr_doc/Ambitious_Agenda_1075.pdf?section=4039). Accessed February 25, 2008.<sup>1</sup> EMR=electronic medical records; IT=information technology; Rx=prescription.*

developed countries in the use of health information technology (IT) (Figure).<sup>1</sup> According to a report from the Commonwealth Fund Commission on a high performance health system, all health care providers should be required within 5 years to use an EHR and participate in information exchange networks that will link health information across clinical settings.<sup>1</sup>

### Assessing the Value of Health Information Technology

Implementation of an EHR system requires a significant expenditure of resources regardless of an organization's size. Assessing the value of investing in an EHR system is critical, particularly at small- and medium-sized organizations with more limited resources. According to a study that looked at the cost benefit of implementing EHR in 14 solo or small-group practices, initial costs averaged \$44,000 per physician with ongoing costs averaging \$8,400 per physician per year.<sup>2</sup> Despite these costs, Miller et al. estimate that the average practice would cover the expense of the EHR within 3 years and begin profiting from the cost savings generated by the system.<sup>2</sup> Savings came from 2 main sources: increased coding levels that led to improved billing and greater efficiency from a decrease in personnel costs.<sup>2</sup>

### CMS Demonstration Projects

In 2008, CMS is developing a new, 5-year demonstration project intended to reward the provision of high-quality care that is supported by the adoption and use of EHR by physicians. CMS hopes that this initiative will broaden the implementation of EHRs and health IT and transform the way medicine is practiced.<sup>3</sup> All practices involved in this project must have an EHR system that is Certification Commission for Health Information Technology (CCHIT)-certified within 2 years. For this demonstration, physician practices must use EHR for procedures that benefit patient care (e.g., clinical documentation, ordering and recording lab tests, ordering prescriptions).<sup>3</sup> They will receive financial incentives according to how they perform on a series of specific clinical quality measures (not specified) and will receive bonuses based on the degree of health IT functionality used to manage patient care. Payments for all 5 years may reach up to \$58,000 per physician or \$290,000 per practice.<sup>4</sup> The project is recruiting practices in locations where the demonstration is likely to enhance existing or planned private sector projects related to health IT and quality-reporting initiatives.<sup>4</sup>

Electronic prescribing (E-Rx) is a part of electronic record keeping that has received the most attention from CMS. In fact, CMS has proposed standards for E-Rx that were released April 2008 for implementation in 2009. These standards cover 6 areas, including formulary and benefits information, exchange of medication history, structured and codified sig (to ensure standardized codes for patients' instructions for medication taking), fill status notification, clinical drug terminology, and prior authorization.<sup>5</sup> CMS anticipates that savings of \$95 million to \$410 million will be realized due to increased use of generics

with E-Rx implementation.<sup>6</sup> In addition, CMS has predicted that community pharmacy would save as much as \$65 million to \$242 million of costs with E-Rx, as a result of reduced administrative and dispensing costs at 25% implementation of E-Rx.<sup>5</sup>

### Challenges for Integration

As noted, many clinical settings have been slow to adopt EHR. According to a national survey of 2,758 physicians, only 17% reported having an electronic health records system in their practice as of 2007–2008.<sup>7</sup> This stems primarily from the financial barriers to purchasing these systems and physician concern about return on the initial investment.<sup>7</sup> For some clinicians, EHR systems are viewed as a source of potential legal liability in that they may facilitate inappropriate access to patients' medical information.<sup>7</sup>

From the perspective of the health plans, implementation of an EHR system can bring challenges in terms of integrating the technology into clinical workflow, the costs of technology upgrades, and providing sufficient training and support to help clinicians and staff make the transition from paper to electronic records. For implementation to succeed, clinical staff must accept and use EHR.

Despite these challenges, it is anticipated that greater all-around support for EHR will increase the use of health IT in the United States as part of an overall strategy to improve patient outcomes and efficiencies in health care delivery.

### Conclusions

Developing integrated medical records is an important strategy toward quality of care improvement for Medicare beneficiaries. EHR enables all clinicians to easily access a patient's medical information. CMS has recognized the potential of EHR to improve the overall quality and effectiveness of health care delivery and also reduce costs, and has made it a key focus to enhance patient care. Despite the potential benefits of electronic medical records, many practitioners/practices are hesitant to adopt and purchase these systems because they believe that the cost far outweighs the financial benefit. As such, the United States continues to lag behind other developed countries in the use of health IT.

Nevertheless, CMS has developed a new, 5-year demonstration project that will reward physicians/practices for high-quality care supported by the use of EHR. CMS hopes that this initiative will broaden the implementation of EHRs and health IT and transform how medicine is practiced. CMS' final standards for E-Rx were released April 2008 and identified 6 key areas for implementation, which are scheduled to take effect in 2009.

The adoption/use of EHR faces numerous challenges from both providers and payers. As of 2007–2008, only a small percentage of physician practices (17%) have invested in EHR technology due to the costs in purchasing these systems. Despite these challenges, it is anticipated that increased support for EHR

in the United States will result in an uptake of health IT in an effort to improve patient outcomes and efficiencies in health care delivery.

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# Special Needs Plans

Chris R. Cammisa, MD

## ABSTRACT

**BACKGROUND:** Privately sponsored special needs plans (SNPs) are growing rapidly in Medicare and are seen as a way to access patient populations that have been served primarily through traditional Medicare (not Medicare Advantage), private plan programs, or Medicaid. It remains to be seen if such plans are able to provide improved care while controlling costs.

**OBJECTIVE:** To review current trends in the development of Medicare Advantage (MA) SNPs.

**SUMMARY:** Medicare Advantage SNPs are designed to address the health care needs of specific target populations that include some of the most vulnerable patients in the Medicare system. SNPs differ from other types of plans by virtue of the fact that they are defined by the specific populations they serve rather than by the type of contract. SNPs are permitted to restrict enrollment to 3 specific target populations: dual eligibles, institutionalized beneficiaries, and those with serious, chronic disabling conditions. Plans can design special clinical programs to provide services for groups with distinct health care needs, with the goal of reducing hospitalizations and institutionalizations. An important attribute of the SNP model is the potential to modify care patterns and provide greater disease management that can lead to improved outcomes while reducing costs.

**CONCLUSIONS:** The 3 types of SNPs authorized by CMS have the potential to provide added value for beneficiaries and plans compared with other Medicare Advantage prescription drug (MA-PD) plans. At present, however, most SNPs have not been in operation long enough to make a clear determination about how well that potential will be realized.

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## Introduction

Medicare Advantage (MA) special needs plans (SNPs) are an important development in the health care marketplace. Designed to address the health care needs of specific target populations, they promise to improve care for some of the most vulnerable types of patients, while controlling costs through economies of scale and better coordination of care. SNPs are growing rapidly in Medicare, with 772 SNPs expected to be offered in 2008, up from 477 in 2007.<sup>1</sup> More SNPs are being offered because the insurance industry sees them as an attractive growth opportunity, providing access to populations that were previously served primarily through traditional Medicare (not MA plans), private plan programs, or Medicaid.<sup>1</sup> Effectively, SNPs are an attempt to see if coordinating care according to specific population characteristics will help to provide better quality care while controlling costs. The authority for limiting enrollment to specific subgroups was originally set to expire at the end of 2008 and required the Centers for Medicare & Medicaid Services (CMS) to submit an evaluation of SNPs to Congress at the end of 2007. It remains to be seen whether SNPs will fulfill the promise of their initial mandate.

## Types of Special Needs Plans

SNPs are different from other types of MA plans in that they are tailored to the needs of the populations they serve.<sup>2</sup> In contrast with other Medicare health plans that are required to market to the general Medicare population, SNPs are permitted to restrict enrollment to 1 of 3 target populations:

1. Dual eligibles—persons who are eligible for both Medicare and Medicaid, including low-income beneficiaries who receive subsidies from state Medicaid programs for their Medicare cost-sharing.
2. Institutionalized beneficiaries—those who reside for at least 90 days in a long-term care facility or those who require a level of care equivalent to those living in a long-term care facility.
3. Those with serious chronic or disabling conditions—those individuals with cardiovascular disease, diabetes, congestive heart failure, osteoarthritis, mental disorders, end-stage renal disease, and HIV.<sup>3</sup>

By focusing their efforts on these special groups, plans can design special clinical programs that will provide services for groups with distinct health care needs, reducing hospitalizations and institutionalizations. Because patient populations targeted by a SNP can be more homogeneous than the general Medicare population, plans can tailor benefit packages to cover more of the drugs that these patients require. Some plans may choose to offer enhanced benefits, such as transportation and home safety evaluations designed to improve outcomes for these vulnerable populations. They are particularly valuable in that they can target resources for early identification of specific symptoms and can

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implement specialized disease management protocols. In addition, they can improve the management of polypharmacy to reduce the risk of negative effects.<sup>1</sup>

### SNP Trends

According to February 2008 data from CMS, there are 769 SNPs serving more than 1.1 million beneficiaries.<sup>4</sup> The most common types of SNP are those for dual-eligible enrollees (270 contracts offering 439 plans), with 241 plans being offered for enrollees with chronic or disabling conditions and 89 for institutionalized beneficiaries.<sup>4</sup> Among the most common chronic care SNPs currently being offered are those for end-stage renal disease, cardiovascular disease, pulmonary disease, and diabetes.<sup>4</sup>

One important attribute of the SNP model is the potential to modify care patterns and provide greater disease management that will improve outcomes while reducing costs. Among the goals of an effective disease management program are facilitating primary care interventions, reducing the use of hospitalization and urgent care visits, and reducing the use of medications with improved health outcomes.<sup>1</sup>

Because chronic condition SNPs are permitted to choose the conditions in which they specialize, they have the potential to reduce the use of more expensive services by providing better overall management of the conditions unique to their population.<sup>1</sup> Specialization provides an opportunity to focus a plan's efforts and benefit design in a particular direction, rather than having to spread resources over the entire range of the Medicare population. However, the actual gains that may be achieved through specialization may be limited based on how specialized the needs of the population are.<sup>1</sup> In addition, those SNPs that include multiple, diverse disease categories may have more difficulty taking advantage of the benefits of specialization that are possible in a more homogeneous population.<sup>1</sup>

Institutional SNPs may have the greatest potential and incentive to modify care patterns since they are at risk of incurring the hospitalization and medication costs that their enrollees may incur.<sup>1</sup> They also may have more opportunity to use the savings that are realized from keeping enrollees out of hospitals to pay for services within the institution that can reduce additional hospital visits.<sup>1</sup> These services can include the services of on-site nurse practitioners and consulting clinical pharmacists to improve the use of prescription drugs, as well as more intensive on-site services that enable the management of conditions that might

otherwise require hospitalization.<sup>1</sup>

In addition to disease management strategies, active case management is essential to ensure that beneficiaries are receiving the appropriate care at all times. Effective case management requires coordinating the efforts of clinicians, pharmacists, clients, and support staff so that enrollees achieve the best possible outcomes. In addition, plans are able to offer social case management services, providing members with psychosocial assistance to augment what is offered by the patient's health care providers. These services can be particularly valuable to vulnerable patients who may need assistance navigating the health care system.

### Conclusions

Medicare Advantage SNPs are designed to address the specific health care needs of vulnerable patient populations by improving the delivery of care, while controlling costs. An important development in the health care marketplace, Medicare SNPs are growing rapidly, because the insurance industry views them as an attractive growth opportunity. SNPs are different from other MA plan types because they are tailored according to the needs of the populations they serve. As of February 2008, there are 769 SNPs serving more than 1.1 million beneficiaries. Among the most common chronic care SNPs currently being offered are those for end-stage renal disease, cardiovascular disease, pulmonary disease, and diabetes.

By focusing their efforts on special patient groups, plans can design targeted clinical programs that provide services for those who require specific health care needs, which may reduce both hospitalizations and institutionalizations. Plans also have an opportunity to tailor benefit packages by covering more of the drugs that patients require, thus increasing the attractiveness of the plan to enrollees.

It appears that the 3 types of SNPs offered by CMS may provide added value for beneficiaries and plans compared with other MA-PD plans. This potential, however, has not yet been realized because most SNPs have not been operating for a long period of time. The original authorization for SNPs was scheduled to expire in 2008, but was extended to 2009 (with a 1-year moratorium on new SNPs). This additional time will enable plans to fully evaluate whether their SNPs have contributed to greater efficiencies and improved outcomes in providing care to beneficiaries with special needs.

### **CMS, NCQA Propose Quality Measures for Medicare Special Needs Plans**

In a continuing effort to improve the quality of care being provided to Medicare beneficiaries, CMS is working with the National Committee for Quality Assurance (NCQA) to develop a set of structure and process measures for Medicare SNPs. The measures are intended to begin a process of evaluating the structure, process, and performance of SNPs in relation to the care they are providing to enrollees.

NCQA President Margaret E. O'Kane commented that because they care for some of the country's most vulnerable citizens, it is imperative that SNPs demonstrate that they are

providing quality care and protecting the rights of Medicare and Medicaid beneficiaries.<sup>5</sup>

The proposed measures evaluate how SNPs set up case management programs for members with complex needs and how the programs work to improve patients' clinical care. The CMS will require SNPs to start reporting on 13 Healthcare Effectiveness Data and Information Set (HEDIS) measures that assess clinical performance (measures are yet to be defined by CMS and NCQA).<sup>5</sup>

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# CMS Oversight

Helen Lee, PharmD, MBA

## ABSTRACT

**BACKGROUND:** Medicare Part D plans are subject to strict oversight by the Centers for Medicare & Medicaid Services (CMS) to ensure that they are meeting all the statutory and regulatory requirements of Medicare Part D programs. Oversight includes CMS auditing and reconciliation procedures.

**OBJECTIVE:** To provide a brief overview of the auditing and reconciliation procedures required from Medicare Part D plans by CMS.

**SUMMARY:** Because Medicare Part D plans are required to meet all of statutory, regulatory, and program requirements that govern the Medicare Advantage program, CMS oversees the operation of both Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDPs). This oversight requires effective record keeping and reporting procedures by plans so that they can provide CMS with the necessary accounting of cost, utilization, and availability/accessibility of their services. Plans that are unprepared for adequate accounting face stiff penalties, including civil monetary penalties. In the event of noncompliance, CMS may also issue a request for a corrective action plan that will address concerns within 2 to 6 months. CMS reconciliation involves the submission of data to CMS in order for a plan to receive the drug benefit payment to cover the costs of drugs provided to beneficiaries. Reconciliation occurs with CMS itself, or with another Part D contractor that may have paid for drugs for a beneficiary covered under the plan. Reconciliation is a critical component in how plans are reimbursed for the services they provide to beneficiaries.

**CONCLUSIONS:** Although compliance with the auditing and reconciliation procedures required by CMS represents a substantial burden for plan sponsors, it is necessary for continued participation in Part D. In addition, much of the data that are needed to meet CMS auditing and reconciliation requirements are also important to the plans themselves as they evaluate the management of their programs and assess the quality and profitability of their benefit offerings.

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## Introduction

Medicare Part D plans are subject to strict oversight by the Centers for Medicare & Medicaid Services (CMS) to ensure that they are meeting all statutory and regulatory requirements. From the perspective of the plans themselves, CMS oversight can represent substantial administrative and financial burdens. However, successfully meeting the CMS requirements of auditing and reconciliation provides the platform for continued participation in Part D. As such, it is a necessary component of the administration of all Part D plans.

## CMS Auditing

Medicare Part D plans are required to meet all statutory, regulatory, and program requirements that govern the Medicare Advantage program. As a result, CMS oversees the operations of Part D plans—both Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDPs)—to assess if plans are in compliance with all federal requirements. This is done through the monitoring of day-to-day activities, periodic performance audits, and ad-hoc compliance events. CMS uses a risk assessment approach to determine which organizations it audits; not all MA-PDs and PDPs are audited each year.

According to the Medicare Prescription Drug, Improvement and Modernization Act (MMA), each part D sponsor is required to maintain effective record keeping and reporting procedures to enable it to provide statistics indicating:<sup>1</sup>

1. the cost of its operations;
2. the patterns of utilization of its services;
3. the availability, accessibility, and acceptability of its services;
4. information that demonstrates it has a fiscally sound operation; and
5. other matters as required by CMS.

The data provided are used by CMS to monitor the prescription drug benefit being provided to Medicare beneficiaries. In addition, each Part D sponsor is required to provide the “necessary data to CMS to support payment, program integrity, program management, and quality improvement activities,” as well as supplementary reporting requirements as indicated in additional guidance documents throughout the year.<sup>1</sup>

## CMS Audit Process

Approximately 9 weeks before a scheduled audit, CMS will contact the part D sponsor to schedule an acceptable date for the audit and review audit logistics.<sup>2</sup> Within 3 weeks of that initial contact, CMS will provide a written notification that will identify the chapter(s) that will be covered in the audit and initiate a request for documentation. According to CMS, Part D audits are likely to be conducted as desk audits (outside the sponsor’s site) and will take no more than 1 month to complete (from the entrance conference to the exit conference).<sup>2</sup> Audits held onsite generally last no more than 1 week, during which time, the spon-

sor is expected to make available key staff responsible for compliance in the selected areas.<sup>2</sup>

A critical component of the audit process is the ability of the plan's sponsor to provide the CMS audit team with sufficient documentation to demonstrate compliance with CMS requirements.<sup>2</sup> To be prepared for the potential CMS audit and to keep in compliance, plans usually have an internal auditor and compliance officer for Part D.

Plans that are not prepared face stiff penalties, including civil monetary penalties of as much as \$25,000 per error.<sup>3</sup> CMS may also issue a request for a corrective action plan, then return in 2 to 6 months to determine if the errors have been corrected.<sup>3</sup>

When CMS determines that a plan is not complying with Medicare program requirements, it issues a corrective action requirement (CAR) letter from CMS. Corrective action requirement letters are posted on the CMS Web site and updated monthly. If the errors identified in the corrective action plan are not addressed within 2 to 6 months, it is likely that CMS will suspend the plan's enrollment.<sup>3</sup>

Common problems reported during audits include a lack of testing, out-of-date policies and procedures that do not reflect current guidelines, and incomplete training.<sup>3</sup> Plans can best be prepared for CMS audits by developing effective internal and external monitoring procedures well before the audit is requested.<sup>3</sup> Components that are critical to monitor include enrollment, coverage determinations, exceptions to coverage determinations, direct and indirect remuneration, prescription drug event (PDE) transaction data, CMS's complaint tracking module, grievances, and pharmacy benefit manager (PBM) data.

Plans that are working with a PBM are strongly encouraged to perform periodic formal audits of their PBMs, as well as updating their contracts with PBMs. Contracts ought to address updated requirements for rebate disclosure, claim reporting statistics, low-income cost-sharing adjustments, and mail-order administrative pricing.<sup>3</sup>

### **CMS Reconciliation Processes**

Reconciliation is the process by which a plan submits data to CMS in order to receive drug benefit payments to cover the costs of drugs provided to beneficiaries. Reconciliation occurs with CMS itself or with another Part D contractor that may have paid for drugs for a beneficiary covered under the plan.

#### **Reconciliation: Prescription Drug Events**

PDE is the name given to the fulfillment of a prescription that is covered under Part D. Each time a beneficiary fills such a prescription, the Part D plan must submit a summary record of that event (called the PDE record) to CMS. The PDE record contains the data that make it possible for CMS to provide payment to the plan and administer the Part D benefit. The PDE record includes covered drug costs above and below the out-of-pocket threshold and records payments by Part D plan sponsors, other payers, and

beneficiaries. These data, submitted by the plan, fit together to allow the calculation of payment under the following 4 legislated payment mechanisms: direct subsidies; premium and cost-sharing subsidies for qualifying low-income individuals (low-income subsidies); federal reinsurance subsidies; and risk sharing.<sup>4</sup>

In 2007, initial PDE reconciliation turned out to be a huge administrative burden to plans, many of which were not prepared nearly well enough to meet the deadline. Many plans did not have a database to track PDEs and to provide the information needed to reconcile with CMS. As a result, the reconciliation process led to plans having to pay CMS huge sums of money—a total of more than \$4 billion among all of the parent organizations that sponsor plans.<sup>5</sup> Of all the parent organizations, 80% owed money to CMS. Twenty-nine percent of the parent organizations were required to pay less than \$1 million, while 22% had to pay in excess of \$10 million back to CMS.<sup>5</sup>

Some of the key challenges that were identified in this process included a variety of operational issues. Perhaps most important was the issue of plans not having valid membership data. In addition, many plans experienced a high level of PDE rejections.

Part D plans are now recognizing how important it is to understand how enrollment reconciliation is connected with PDE data. A key element of PDE reconciliation is having access to valid membership data so that PDE data can be tied to enrollment data. A critical first step in this process is to build a platform for reconciliation: a system that can track weekly, monthly, and special transaction reports, along with monthly membership reports.<sup>3</sup>

In addition, sponsors must identify membership discrepancies and rejected PDEs. This can be done by categorizing members according to their active status both according to the records of CMS and in the plan's records.<sup>3</sup> Discrepancies also need to be categorized and prioritized by whether members were active in 1 or more plan benefit packages (PBP) in a given year, as well as those members with and without breaks in coverage over the calendar year.<sup>3</sup>

Once the discrepancies are categorized, sponsors should develop clear procedures for reconciling the discrepancies, including start-to-finish research that identifies which entity (the plan or CMS) can fix the discrepancy, the steps necessary to fix it, and confirmation that it has been corrected.<sup>3</sup> At that point, it is time to do the actual reconciling, which can consist of processing transactions to CMS, updating plan systems, and providing necessary correspondence.

#### **Plan-to-Plan Reconciliation**

The Plan-to-Plan (P2P) financial reconciliation process provides a means by which the contracted plan of record pays any other Part D contract that reimbursed Part D drugs in good faith when Part D plan enrollment data were not current. P2P reconciliation has 2 primary objectives: it corrects payment discrepancies that occurred during program start-up, and it enables Part D payment reconciliation.

P2P reconciliation has taken place in 2 phases. The first phase emphasized the reconciliation of PDE data for any dates of service between January 1, 2006, and April 30, 2006, which was the initial start-up period for Part D plans. Phase II extended the reconciliation process between Part D plans to those claims that occurred after April 30, 2006. In this period, although plans should have been notified of beneficiary disenrollments before the effective date of enrollment in another plan, there were lag times associated with the enrollment process, which in combination with lags in CMS information system updates, resulted in instances where a plan continued to pay for covered prescription drugs after the effective date of disenrollment. As a result, the plan may have paid drug costs for a beneficiary who was no longer covered under that plan, precluding the possibility of receiving compensation directly from CMS for those costs.

### ■ Conclusions

Medicare Part D plans are subject to strict oversight by CMS to ensure that they are meeting all statutory and regulatory requirements. Although this oversight can be a substantial administrative and financial burdens for health plans, the CMS auditing and reconciliation procedure is a necessary component for the plan's continued participation in Part D.

In order to comply with CMS oversight, each part D sponsor is required to maintain "effective" record keeping and reporting procedures to demonstrate the cost of its operations; show utilization patterns for its services; disclose the availability, accessibility, and acceptability of its services; and provide information that demonstrates it has a fiscally sound operation. In addition, each Part D sponsor is required to provide data to support payment,

program integrity, program management, and quality improvement activities. Without this information, plan enrollment is subject to suspension. Consequently, plans need to have effective internal and external monitoring procedures in place well before an audit is requested.

Oversight of Medicare Part D providers, although perhaps viewed as burdensome by health plans, is critical to ensure plans meet the standards set by CMS. From a plan's perspective, however, the data required to meet CMS's auditing and reconciliation requirements can be beneficial in evaluating the management of programs and for assessing the quality and profitability of their benefit offerings.

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# Looking to the Future of Medicare Part D

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## ABSTRACT

**BACKGROUND:** The future of the Medicare Part D benefit is of concern for all parties who are stakeholders in the health care system. There are a number of issues that are likely to emerge in the coming years that will have a significant impact on the future of Medicare Part D.

**OBJECTIVE:** To explore some issues that are most likely to affect the future viability of Medicare Part D.

**SUMMARY:** Medicare is one of the largest and fastest growing federal entitlement programs, and given the rapid increases in the cost of medical care, the long-term viability of the system is an ongoing concern. At the same time, the Medicare Part D marketplace is undergoing rapid change that is likely to continue for some years. While the initial design of Part D was intended to provide a wide choice of drug benefit plans, it is not clear whether the variety of plans will continue as the program evolves from the initial enrollment period. It is probable that the number of stand-alone prescription drug plans (PDPs) will decline as plans consolidate and merge into larger organizations that are better able to compete with the more cost-effective plans. Among the changes that are being investigated by the Centers for Medicare & Medicaid Services (CMS) are the mandatory enrollment of complex patients, such as the disabled, blind, and aged, the introduction of medical savings accounts, and increasing focus on the needs of low-income beneficiaries.

**CONCLUSIONS:** As the Medicare Part D drug benefit evolves beyond the initial roll out, there are significant concerns about how the benefit will be structured and financed in the future. The financial viability of Medicare is a major concern for all players in this market and financial constraints will continue to drive policy decisions at all levels.

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## Introduction

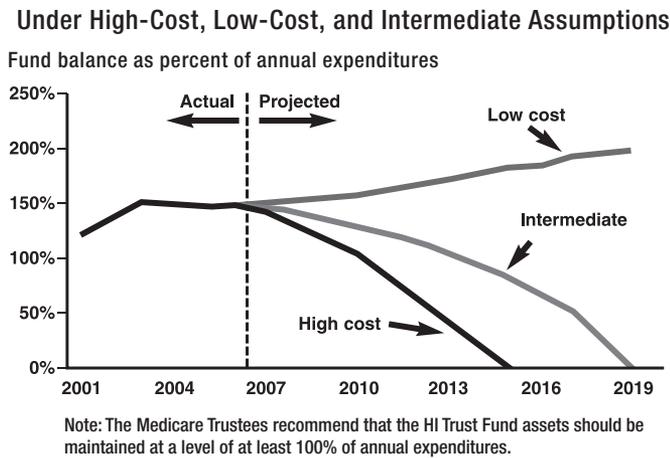
The Medicare Part D benefit was initiated to help Medicare beneficiaries access the prescription drugs they need through privately run health plans. The drug benefit helps enrollees with out-of-pocket drug costs, which is particularly important for those with low incomes, individuals who lack other sources of drug coverage, and those who face catastrophic drug costs. The future of the Medicare prescription drug benefit is a concern for all of those with a stake in the success of the system: this includes the beneficiaries themselves, the federal government, the private plans that are charged with providing the drug benefit to beneficiaries, and the providers, including physicians and pharmacists.

In this section, we look at some issues that are likely to have a significant impact on the future of Medicare Part D. Perhaps most important, particularly in a period of economic uncertainty, is the financial viability of Medicare overall. In addition, as the Part D benefit continues to evolve, plans will re-evaluate strategies in efforts to improve the quality of benefits while increasing the potential for greater revenue. Finally, the Centers for Medicare & Medicaid Services (CMS) is also exploring changes to the Part D system in an attempt to address current gaps and improve quality and efficiency.

## Sustainability Issues

The long-term financial viability of Medicare continues to be an issue of significant concern as Medicare is one of the largest and fastest growing federal programs. The combined effects of the high rate of growth in health care costs and emerging demographic trends are presenting a serious challenge to the future fiscal health of Medicare. At present, funding for Medicare Part D comes primarily from general revenues, the premiums paid by beneficiaries, and state payments for dual eligibles who previously received drug coverage under state Medicaid programs.<sup>1</sup> As the U.S. population increases in age, the decreasing ratio of workers to beneficiaries promises to exert significant pressure on Medicare finances.<sup>1</sup>

According to the Medicare actuaries' most recent estimates (and based on "intermediate" assumptions about future economic and demographic factors and health care costs), annual payments from the Hospital Insurance (HI) Trust Fund will exceed annual income to the Trust Fund beginning in 2011, and by 2019 the Trust Fund will not have sufficient funds to cover the cost of inpatient hospital care and other Medicare Part A services (Figure).<sup>2</sup> While this does not mean that Medicare will be "bankrupt" and unable to pay for Medicare benefits, it does mark the point at which there will be insufficient funds to meet all Trust Fund obligations. This shortfall will continue to accumulate each year unless some adjustment is made that either increases the revenue coming into the Trust Fund or decreases total Trust Fund expenditures.<sup>2</sup>

**FIGURE** HI Trust Fund Solvency, 2001–2019

*Financing Medicare: An Issue Brief*, Henry J. Kaiser Family Foundation, January 2008.<sup>2</sup> This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation, based in Menlo Park, California, is a nonprofit, private operating foundation focusing on the major health care issues facing the nation and is not associated with Kaiser Permanente or Kaiser Industries.

HI = Hospital Insurance (as in HI Trust Fund).

These funding issues have the potential to impact future subsidies provided by the CMS. Although the federal contribution to premiums is based on an average of the bids submitted by plan sponsors, in 2007, CMS adjusted its computation such that it artificially raised subsidies, effectively reducing average premium costs to beneficiaries.<sup>3</sup> At some point in the future, CMS has indicated that it will return to the federally mandated system wherein subsidies will be entirely based on average bids for basic benefits, which could mean that there will be increases in beneficiary premiums at that time.<sup>3</sup>

Another factor that could impact future costs of the program is the possibility that some plans are temporarily maintaining artificially low premiums to increase their market share. The average stand-alone prescription drug plan (PDP) increased its premium by less than 4% between 2006 and 2007.<sup>3</sup> Compared with CMS' projection of the increase in per enrollee drug costs (close to 7%), if plans are charging artificially low premiums to attract enrollees, they are likely to significantly raise premiums in the coming years.<sup>3</sup> Further, there is uncertainty about what proportion of employers who are currently providing drug benefits to retirees will continue to do so in the future. Some may decide to discontinue drug coverage and begin instead to help retirees cover Part D premiums. It is argued that it is those employers whose retirees have the highest drug costs will be the most likely to shift enrollees to Part D programs, resulting in increases in average plan costs.<sup>3</sup>

Fortunately, employer-sponsored health care plans continue

to make a substantial contribution to the health care costs of Medicare beneficiaries, with 1 in 4 Medicare beneficiaries receiving retiree benefits from either employer or union-sponsored plans.<sup>1</sup> It is estimated that 10.3 million beneficiaries receive prescription drug benefits from such plans, while 2.6 million working beneficiaries have employer plans as their primary health insurance coverage.<sup>1</sup> While retiree health benefits are declining overall, the proportion of large companies offering retiree health benefits has fallen by more than half since 1988 (from 66% in 1988 to 35% in 2006); therefore, the Part D drug benefit does not appear to have further accelerated the erosion of employer-sponsored retiree health coverage.<sup>1</sup>

Ultimately, it will take years before it is clear whether the Part D program is truly sustainable, since future costs of the program (both to beneficiaries and to the federal government) will depend on the actions of numerous players, including plan sponsors, CMS, and the beneficiaries themselves.

### Evolving Structures and Strategies

As Medicare Part D evolves, plans are looking at ways to provide quality benefits while increasing the potential for greater revenue. This translates into the likelihood of significant changes in the market over the next few years. One of the goals of Part D was to provide a wide choice of drug benefit plans. While this goal was met with the availability of many more plans than originally anticipated, it is not clear whether the wide variety of plans will continue as the program moves from the initial enrollment period. For example, it is likely that the number of PDPs will decline as plans consolidate and merge into larger organizations that are better able to compete with the more cost-effective plans.<sup>4</sup> In addition, analysts predict that as the market consolidates, enrollees in search of better overall health benefits will migrate into Medicare Advantage (MA) plans from stand-alone PDPs.<sup>4</sup> In fact, this may have been a strategy for some sponsors: to offer inexpensive stand-alone PDPs to attract enrollees with a longer-term plan to shift them into more profitable Medicare managed care plans, which cover physician and hospital bills, as well as drugs, and also receive higher payments from CMS for their services, as determined by local cost benchmarks.<sup>5</sup>

However, it is uncertain how the ongoing mergers and acquisitions of companies offering MA-PDs will proceed. The Department of Justice has expressed concern over managed care companies acquiring too much market share in individual regions, recently filing suit (and a proposed settlement) to require UnitedHealth to divest itself of MA assets in order to acquire Sierra Health Services, a seller of MA plans in the Las Vegas area.<sup>6</sup>

One potential new area of growth in that field will be in customized prescription drug plans aimed at employers. As the sponsors of current Medicare PDP plans develop a better understanding of the needs of employers, they will be positioned to leverage their PDP infrastructure to compete for that segment of the market with official Medicare plans. Medicare Advantage

plans may also begin to see increased interest from employer groups looking for better coverage offerings for their retiree populations.<sup>4</sup>

### **Potential CMS Changes**

In addition to the evolving strategies being advanced by the Part D plans currently providing benefits, CMS is also exploring changes to the Part D system in an attempt to address current gaps and improve quality and efficiency.

### **New Populations**

Among the potential developments in the coming years will be the mandatory enrollment of disabled, blind, and aged Medicaid beneficiaries into managed care plans as a means of controlling costs. While this complex group of patients makes up only 16% of beneficiaries in Medicaid, they account for more than 45% of state Medicaid expenditures and may present an opportunity for a new type of special needs plan.<sup>7</sup>

### **Medical Savings Accounts**

One area that is attracting greater attention among plan sponsors is the introduction of Medicare medical savings accounts (MSAs). Authorized in 2003 under the Medicare Prescription Drug, Improvement and Modernization Act (MMA), these accounts provide tax-sheltered investment funds that can be used to cover expenses not covered by Medicare Advantage plans with high deductibles and low monthly premiums. In 2007, 3 MSA plans were offered within Medicare Advantage: 2 are MA-MSA plans and 1 is an MA-MSA Demonstration plan. As of February 2007, 2,238 beneficiaries were enrolled in these plans.<sup>8</sup>

### **Comparative Effectiveness Movement**

A recurring theme in any discussion of Medicare is the importance of improving the value of the health care that it pays on behalf of its beneficiaries. As the costs of paying for benefits begin to outpace financing of the system, Medicare is increasingly turning its attention to not only the overall costs of providing benefits, but to the quality of the care and the outcomes that are achieved. This emphasis on quality is playing out via the implementation of comparative effectiveness initiatives that attempt to provide a “head-to-head” look at drugs, procedures, and devices in an effort to offer guidance on choosing between different therapeutic options.<sup>9</sup>

As stated in its own strategic plan, CMS stresses the importance of supporting only high-value health care, in part by creating a system in which patients and clinicians are empowered to make informed decisions about the most effective medical care, “based on timely access to the latest evidence, and in a way that delivers the highest value care.”<sup>10</sup> This includes promoting the use of secure electronic health records; electronic prescribing; increased system transparency based on immediate, accurate, and comparative quality and cost information; new plan designs

and innovative prescription plan approaches; disease management and prevention programs; and value-driven payments.<sup>10</sup>

However, it is important to acknowledge that comparative effectiveness is only one part of the quality and value decision making process—providers and payers also have to know what additional cost is required for the improved benefit. In other words, cost-effectiveness also must be taken into consideration to prevent the risk of uncontrolled spending in pursuit of the most effective therapy.<sup>11</sup>

### **Focus on Low-Income Beneficiaries**

With nearly half of all Medicare beneficiaries earning incomes that are below 200% of the federal poverty level, the Medicare system is compelled to address the provision of services to low-income beneficiaries. Part D includes substantial assistance for those with low incomes to help cover the costs of plan premiums and cost-sharing (e.g., the costs of copayments, coinsurance, and gap coverage). As of January 2008, it is estimated that 12.5 million beneficiaries are eligible for low-income assistance; of these, CMS estimates that 21% (2.6 million) are not receiving low-income subsidies.<sup>12</sup> If beneficiaries are not automatically deemed eligible for low-income subsidies, they must apply through the Social Security Administration (SSA) or their state Medicaid programs. However, because SSA is not required to screen for Medicare Savings Program eligibility and does not automatically refer applicants to state Medicaid agencies, it is possible that beneficiaries may be unaware that they qualify for the Medicare low-income benefits.<sup>12</sup>

CMS stipulates that all individuals who are eligible for the low-income subsidy (LIS) and who do not choose a plan on their own, will be automatically enrolled in PDPs that have premiums at or below the regional average.<sup>13</sup> In addition, Medicare Advantage organizations are charged with identifying both full benefit eligibles to be auto-enrolled and other LIS eligibles who are to be enrolled into a stand-alone PDP.<sup>14</sup>

From the plans’ perspective, the enrollment of LIS recipients may be viewed either as an opportunity or a liability. A potential incentive for plans that offer premiums at or below the subsidy level is the automatic enrollment of LIS beneficiaries without having to spend additional marketing dollars.<sup>3</sup> However, plans may also have reservations about enrolling beneficiaries who can be particularly costly to cover. Although Part D risk provides higher payments for beneficiaries who are eligible for subsidies (8% for those with Medicaid and 5% for other subsidy recipients), it is more difficult for plans to control drug utilization in this population, which pays little or no cost-sharing.<sup>3</sup>

### **Conclusions**

Medicare Part D was initiated to help Medicare beneficiaries access prescription drugs through privately run health plans and stand-alone PDPs. This benefit helps enrollees to reduce out-of-pocket drug costs, which is particularly important for individuals

with low incomes, who lack other sources of drug coverage, and those facing catastrophic drug costs.

The long-term financial viability of Medicare is a significant issue. Increasing health care costs and emerging demographic trends present serious challenges to the future fiscal health of Medicare. As the U.S. population continues to age, the decreased ratio of workers to beneficiaries will exert considerable pressure on Medicare finances, which by 2019 will not have sufficient funds to cover the cost of inpatient hospital care and other Medicare Part A services. In addition, future program costs could be affected by other factors, including decreases in the number and scope of privately financed retiree benefits.

As Medicare Part D evolves, plans are constantly assessing how to provide quality benefits while increasing the potential for greater revenue. This could lead to some potentially significant changes in the market over the next few years, including a decline in the number of PDPs, as plans consolidate and merge into larger organizations in order to compete with more cost-effective plans. Additionally, analysts predict that more enrollees will migrate from stand-alone PDPs to MA plans in search of better overall health benefits.

In addition to the evolving strategies being advanced by Part D plans, CMS is exploring changes to address gaps in the current Part D system and to improve quality and efficiency. One of these changes is the mandatory enrollment of disabled, blind, and aged Medicaid beneficiaries into managed care plans to control costs, which may be an opportunity for a new special needs plan. Furthermore, Medicare Advantage organizations are now charged with identifying beneficiaries eligible for low-income subsidies, which from the plans' perspective, may be viewed either as an opportunity or a liability.

Clearly, the long-term financial viability of Medicare is a major concern for all stakeholders in this market, and these financial constraints will continue to drive policy decisions at all levels. In response, both MCOs and CMS are looking to manage costs more efficiently while continuing to provide quality benefits to enrollees. This undoubtedly will lead to significant structural changes in the future for Medicare Part D.

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