

# Medicare Part D: Selected Issues for Plan Sponsors, Pharmacists, and Beneficiaries in 2009

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**M**edicare is now the largest public payer of prescription drugs, accounting for 18% of total drug expenditures in the United States in 2006, versus 2% in 2005.<sup>1</sup> Since the inception of Part D, there have been numerous refinements to the benefit; however, its overall purpose and structure remain the same. Most changes have been administrative in nature. Others involved changes in coverage; examples include elimination of coverage for drugs for erectile dysfunction and inclusion of coverage for newer vaccines such as herpes zoster.<sup>2,3</sup> The purpose of this article is to review changes to the benefit for 2009 and to describe the Part D provisions of the Medicare Improvements for Patients and Providers Act of 2008. A question-and-answer format is used, followed by discussion of the implications for providers, patients, and sponsors.

## When will Part D data be available for research purposes?

Effective June 22, 2008, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that allowed the agency to release Part D claims data to other federal government agencies, states, external researchers, and beneficiaries for their personal health records.<sup>4</sup> Data initially will be available for plan year 2006. The final rule balances access to the data with safeguards for beneficiary privacy and commercially sensitive Part D plan information. Updated information on Part D claims data can be found at the CMS Web site.<sup>5</sup> Information also can be obtained from the Research Data Assistance Center at [www.resdac.umn.edu](http://www.resdac.umn.edu).

**Implications.** The availability of Part D claims data in 2009 allows researchers and others to attempt to determine, on a national level, the impact of drugs on overall health outcomes and costs for Medicare beneficiaries in ways not possible before. Part D claims data may be linked with claims data from Part A (hospitalizations) and Part B (physician services) and will offer a rich and robust source of information.

## How did the standard Part D benefit change in 2009?

Most parameters of the standard Part D benefit (defined by CMS as the minimum required plan design) increased in 2009.<sup>6</sup> These changes

are outlined in the **Table**. According to CMS, the overall average increase in the standard drug benefit parameters from 2008 to 2009 was 7.54% versus an average increase of 5.97% from 2007 to 2008. Annual updates to the

**Background:** The Medicare Drug Benefit was designed to provide coverage for outpatient prescriptions to Medicare beneficiaries. Since its inception in January 2006, there have been numerous refinements; however, the overall purpose and structure of the benefit remain the same.

**Objectives:** To (1) review changes to the benefit for 2009 and (2) describe the Part D provisions of the Medicare Improvements for Patients and Providers Act of 2008.

**Methods:** We reviewed policy statements and other communications from the Centers for Medicare & Medicaid Services released between January 1, 2008, and September 30, 2008, and the Medicare Improvements for Patients and Providers Act of 2008.

**Results:** Changes to Part D in 2009 include availability of Part D data, changes in the coverage amounts in the standard drug benefit, outreach to vulnerable populations, the United States Pharmacopeia 3-year cycle, revisions to the best-available-evidence policy, new standards for e-prescribing, and new guidance for medication therapy management programs.

**Conclusions:** Various refinements and clarifications to the benefit have been made to date; however, opportunities for improvement remain. The availability of Part D data will allow researchers to determine the impact of drugs on overall health outcomes and costs for Medicare beneficiaries.

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**Take-Away Points**

Various refinements and clarifications to the Part D benefit were made for 2009; however, the overall purpose and structure of the benefit remain the same.

- In 2009, the Part D standard benefit is more costly to beneficiaries, with increases in the deductible and premium, and a larger coverage gap.
- Part D data now are available for research and other purposes on request through the Centers for Medicare & Medicaid Services.
- Starting in 2009, prescribers will receive incentive payments when they adopt qualified e-prescribing systems.

seek the advice of their pharmacist or physician.

**What efforts are being made to assist vulnerable beneficiaries?**

The LIS provides extra help for individuals who have limited income and resources to help pay Part D costs such as monthly premiums, copayments, and the annual deductible (Table). The

standard benefit design are statutory requirements of the Social Security Act and will continue throughout the life of the program. Plan sponsors can offer the standard benefit design or may vary their design as long as it is actuarially equivalent to the basic coverage.

**Implications.** Medicare Part D is more costly to beneficiaries in 2009. The coverage gap, which is the period of no coverage, continues to be a challenge to beneficiaries and pharmacists. Beneficiaries who may be affected by the coverage gap should consider one of the enhanced Part D plans during their open enrollment period. This option allows some coverage of prescriptions in the coverage gap, albeit at a higher monthly premium, while limiting financial risk to the sponsor. In 2009, 25% of Part D plans offer coverage of some or all generics in the coverage gap.<sup>8</sup> Beneficiaries also might consider the availability of lower-cost generics while in the coverage gap, the low-income subsidy (LIS), or patient assistance programs if they qualify. They should

Centers for Medicare and Medicaid Services has determined that there are approximately 3 million people in the United States who potentially meet the criteria for LIS but have not yet applied. In 2008, CMS permanently removed the late enrollment penalty for anyone who applies for the LIS and qualifies, thus freeing up those who qualify to enroll in Medicare Part D without fear of paying a penalty.

**Implications.** If beneficiaries are having difficulty paying for their medications, the first question a pharmacist or physician should ask is whether the beneficiary has applied for LIS. Providers should be aware that individuals can apply for LIS at any time during the year. Applications are available through the Social Security Administration ([www.ssa.gov](http://www.ssa.gov)) or by calling 800-772-1213.

**What is the USP 3-year cycle?**

At the inception of Part D in 2006, CMS requested that the United States Pharmacopeia (USP) develop a model for-

■ **Table.** 2009 Changes to the Medicare Part D Standard Benefit<sup>a</sup>

Benefit Parameters	2008	2009
Annual deductible	\$275	\$295
Initial coverage limit	\$2510	\$2700
OOP threshold	\$4050	\$4350
Total covered Part D drug spending at OOP threshold	\$5726	\$6154
Coverage gap <sup>b</sup>	\$3216	\$3454
LIS copayments	<b>Generic/Brand</b>	
Institutionalized beneficiaries	\$0/\$0	\$0/\$0
Up to or at 100% FPL <sup>c</sup>	\$1.05/\$3.10	\$1.10/\$3.20
Other LIS	\$2.25/\$5.60	\$2.40/\$6.00

FPL indicates federal poverty level; LIS, low-income subsidy; OOP, out-of-pocket.

<sup>a</sup>The standard benefit design includes the annual deductible, which is the amount of money a beneficiary must spend on medications before the plan starts to pick up any portion of medication expenses. Once the member has satisfied the annual deductible, the member enters the initial coverage phase. As part of the standard benefit design, the plan pays 75% of prescription costs, and the member pays 25% during the initial coverage phase up to the initial coverage limit, or an actuarially equivalent amount, above which there is a coverage gap in which the beneficiary pays 100% of medication costs until the OOP threshold pushes the beneficiary into catastrophic coverage. For costs above the catastrophic threshold, the beneficiary is responsible for only a small portion of cost sharing for the remainder of the benefit year.

<sup>b</sup>The coverage gap is a period of no coverage in which the beneficiary pays the full price of covered Part D drugs. The coverage gap is equal to the difference between the total covered Part D drug spending at the OOP threshold and the initial coverage limit.

<sup>c</sup>The FPL is defined as an annual income in 2009 below \$10,830 for an individual and \$14,570 for a couple. The LIS is available to beneficiaries with an annual income below 150% of the FPL (ie, \$16,245 for an individual or \$21,855 for a couple) and resources below \$12,510 for an individual or \$25,010 for a couple.<sup>7</sup>

mulary containing drug classes, categories, and drug types.<sup>9</sup> All plan sponsors must include coverage for at least 2 drugs from each therapeutic category and class, unless only 1 drug exists. It is not a requirement that all plans use the USP formulary design for their formularies, but it is considered the gold standard to which all plans will be compared. On May 20, 2008, USP announced that they reached an agreement with CMS to move from an annual time line for revision of the model formulary to a 3-year cycle.<sup>10</sup> Revisions will occur, although less frequently, to reflect changes in therapeutic uses of existing medication and additions of new medications to the market. The Centers for Medicare and Medicaid Services will use the current version 4.0 without changes through 2011.

**Implications.** The change in review cycle may benefit Part D plans slightly. Once plans satisfy the minimum category and class requirement the first year of a new USP model formulary release, they will not have to worry about this requirement for 2 more years, unless they modify their formularies significantly.

### What is the new best-available-evidence policy?

*Best available evidence* (BAE) is a phrase used to describe the specific information plans use to update their eligibility records when an eligibility dispute occurs and a member is assessed an incorrect copayment. A class action lawsuit was filed against CMS by full-benefit, dually eligible Medicare beneficiaries who were unable to receive the full benefits of Medicare Part D prescription drug coverage.<sup>11</sup> On June 19, 2008, a settlement was reached, and on August 4, 2008, CMS released a clarified BAE memorandum.<sup>12</sup> The relevant revisions to the new BAE policy are outlined in **eAppendix A** and **eAppendix B** available at [www.ajmc.com](http://www.ajmc.com).

**Implications.** The new BAE policy will help prevent beneficiaries from being turned away from pharmacies when they are entitled to a subsidized copayment. This policy also will benefit pharmacies, especially those that provided patients with necessary medication and held the difference in copayment as an account receivable in hopes that the eligibility issues would get resolved and the claims could be reprocessed. Although this policy is good for beneficiaries and pharmacies, it may have a negative short-term impact on plan sponsors. The new requirements place an administrative burden on sponsors that was not previously required, and they may need to increase staffing or reallocate existing staff to fulfill these guidelines.

### What is the final rule for e-prescribing?

CMS released 4 new e-prescribing standards that became effective on April 1, 2009.<sup>9</sup> These standards are listed in the **Box**. They supplement the basic e-prescribing program that was introduced at the inception of Part D. The standards

apply to all Part D sponsors, prescribers, and dispensers that electronically transmit prescriptions and prescription-related information for Part D-eligible individuals. Although plans and pharmacies are required to adhere to the CMS standards, prescribers are not yet required to prescribe electronically. In an effort to encourage prescribers to adopt e-prescribing, the Medicare Improvements for Patients and Providers Act of 2008 provides Medicare Part B incentive payments for providers to use qualified e-prescribing systems.<sup>13</sup> The payments are 2% in 2009 and 2010; 1% in 2011 and 2012; and 0.5% in 2013. Providers will be required to e-prescribe starting in 2011. Payments to providers who fail to e-prescribe will be reduced by 1% in 2012; 1.5% in 2013; and 2% thereafter.

**Implications.** The hope for e-prescribing is that it will reduce the number of adverse drug events. The Centers for Medicare and Medicaid Services estimates that more than 500,000 adverse drug events per year occur for Medicare beneficiaries. In addition, e-prescribing is expected to reduce prescription errors, provide information to prescribers on formulary coverage so they can make better prescribing decisions, and decrease the time it takes for a patient to receive necessary medications.

### What changes have been made to medication therapy management programs?

In August 2008, CMS released a memorandum reaffirming that sponsors have the flexibility to develop and implement medication therapy management programs (MTMPs) that best meet the needs of their specific patient populations.<sup>14</sup> Although CMS did not change any of the criteria for members to qualify for an MTMP, they did outline the permissible changes to a sponsor's program. This policy is outlined in **eAppendix C** available at [www.ajmc.com](http://www.ajmc.com). The Centers for Medicare and Medicaid Services also announced that they entered into a contract with Optimal Solutions Group to monitor MTMPs and to ensure that sponsors are evaluating their programs in compliance with the outcome measures stated in their CMS-approved MTMP application.<sup>15</sup>

**Implications.** The types of allowable changes for MTMP are consistent with CMS-allowable changes in other areas such as plan formularies. For example, changes made in the beneficiary's favor always are allowed, whereas more restrictive changes are not. In addition, most Part D sponsors would agree that a deeper analysis of MTMP plan data by CMS has been anticipated. This is a step towards more rigorous program standards that are tied directly to patient outcomes.

### Looking Ahead

Future changes are planned for Medicare Part D. The Medi-

■ **Box. New e-Prescribing Standards**

**1. Formulary and Benefits.** This standard will allow prescribers to communicate with Part D sponsors about formulary coverage on a specific drug level. This information will assist prescribers in identifying which drugs have restrictions and what lower cost alternatives may be available.

**2. Medication History.** This standard will allow prescribers, as well as dispensers and Part D sponsors, to communicate about prescribed medications a beneficiary has taken or is taking, including those prescribed by other providers. This information can help identify and potentially prevent adverse drug events, therapeutic duplications, and excessive use that can result from patients using multiple prescribers as well as multiple pharmacies.

**3. Fill Status Notification.** This standard will allow prescribers to receive an electronic notice from the pharmacy telling them that a patient's prescription has been picked up, has not been picked up, or has been partially filled. This information will assist prescribers in monitoring patient compliance.

**4. Provider Identifier.** The final rule requires providers, dispensers, and Part D sponsors to use the National Provider Identifier to identify individual healthcare providers in Part D e-prescribing transactions.

Source: Reference 9.

care Improvements for Patients and Providers Act of 2008 was enacted on July 15, 2008, after Congress overturned a veto by then President Bush.<sup>13</sup> The legislation contains provisions that pertain to Medicare Part D. The provisions that are effective in 2009 have been outlined in this article. Other provisions will be effective in 2010 and beyond, and they are described below.

**Protected Classes of Drugs.** Starting in 2010, the current Part D policy on coverage of protected classes of drugs will be codified, or enacted into legislation. Through rule-making, the Secretary of Health and Human Services will identify protected categories and classes of drugs. These drugs will be protected either (1) because restricting their use would have a major or life-threatening clinical effect or (2) because individuals need access to multiple drugs in a category or class (eg, cancer drugs) because of unique chemical actions and pharmacologic effects. Part D sponsors will be required to cover all drugs in the category or class that the secretary identifies as a protected class unless there are exceptions based on scientific evidence and medical standards of practice.

**Prompt Pay Requirements.** Starting in 2010, Part D sponsors will be required to pay claims from all pharmacies (other than mail-order and long-term care pharmacies) within 14 days after transmission if submitted electronically or 30 days if submitted otherwise. If claims are not paid according to this schedule, sponsors will be required to pay interest to the pharmacy.

**Coverage of Barbiturates and Benzodiazepines.** Starting in 2013, Part D sponsors must cover barbiturates if used to

treat epilepsy, cancer, or a chronic mental health disorder, and benzodiazepines.

CONCLUSIONS

The year 2009 represents a year of continued refinement to Medicare Part D in terms of the availability of Part D data, the structure of the standard drug benefit, outreach to vulnerable populations, the USP 3-year cycle, the BAE policy, new standards for e-prescribing, and new guidance for MTMPs. The Medicare Improvements for Patients and Providers Act of 2008 legislated additional changes to Medicare Part D for 2009 and beyond. Policy changes may be considered that lead to further improvement of Medicare Part D as more research becomes available on the economic and clinical impact of the benefit, prices paid by sponsors for medications for dual eligibles, and the coverage gap.

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